Collector of Central Excise Vs. Wander India Limited

Collector of Central Excise Vs. Wander India Limited

SooperKanoon Citation : sooperkanoon.com/5233

Court : Customs Excise and Service Tax Appellate Tribunal CESTAT Delhi

Decided On : Oct-12-1989

Reported in : (1990)(25)ECC315

Judge : Author: Sadasivam

Appellant : Collector of Central Excise

Respondent : Wander India Limited

Judgement :

On merits of the cases, these appeals relate to a common issue, viz., interpretation of Notification No. 116/69-CE dated 3.5.69, as amended and determination whether the product "Iso Benzacyl Forte" falling under Central Excise Tariff Item 14-E, manufactured by M/s. Wander India Limited and by M/s. Aphali Pharmaceutical Limited on behalf of M/s. Wander India Limited, and the products (i) Reclor capsules, (ii) Resteclin capsules, (iii) Resteclin tablets, (iv) Resteclin I.M.Injection and (v) Steclin I.M. Injection manufactured by M/s. Sarabhai Chemicals were eligible for the benefit of the aforesaid notification, Hence, these four appeals have been heard together and are being disposed of by this common order. There are other legal points which have been raised along with this main issue and the same are also dealt with and disposed of by this order.

2. The facts of the case in Appeal No. ED/SB/1447/83-C are that M/s.

Aphali Pharmaceutical Limited, Ahmedabad manufactured patent or proprietory medicines as loan licencee of M/s.Wander India Limited.

M/s. Aphali Pharmaceutical Limited, manufactured, Inter alia, "Iso Benzacyl Forte" falling under Item 14-E of the Cenual Excise Tariff and availed of the concessional rate of duty of 2.5% ad valorem under Notification No. 116/69-CE dated 3.5.69, as amended by Notification No.106/80-CE dated 19.6.80, on the basis of classification list approved by the Assistant Collector of Central Excise. "Iso Benzacyl Forte" contained, inter alia, Pyridoxine Hydrochloride (Vitamin - B6), an ingredient which was not specified in the above notification.

Consequent to the grant of exemption under the above notification, refund of duty amounting to Rs. 64,972.54 was granted to the respondents in this appeal for the period from 19.6.80 to 31.8.80.

Central excise duty amounting to Rs. 2,62,660.95 for the period from September, 1980 to March, 1981 was also not recovered from the respondents. Subsequently, when it was noticed by the Department that Pyridoxine Hydrochloride (Vitamin - B6) was not included in the Schedule to the notification, it was felt by the Department that exemption under the said Notification was erroneously granted. Therefore, the Superintendent of Central Excise (Technical), Ahmedabad issued a show cause notice No. 14-E(15) 72/R/81 dated 24.10.81 for recovering the amount of Rs.64,972.54 refunded on 12.2.81. Assistant Collector of Central Excise, Ahmedabad also used a show cause notice No. V(14-E) 17.79/VC/80 dated 13.10.81 for denying the exemption under the above notification and another show cause notice No. I/ADM(19)-448-VC/81 dated 10.7.81 calling upon M/s. Aphali Pharmaceutical Limited to show cause as to why the duty amounting to Rs. 2,62,660.95 for the period from September, 1980 to March, 1981 should not be recovered from them.

After considering the replies to the show cause notice and after hearing M/s. Aphali Pharmaceutical Limited, Assistant Collector of Central Excise, Ahmedabad, vide his Order-in-original No.I/ADM(19)448/VC/81 dated 20.8.82/2.9.82, disallowed the benefit of Notification No. 116/69-CE dated 3.5.69 and confirmed the demands under Section 11A of the Central Excises and Salt Act. Aggrieved

with the above order of the Assistant Collector, M/s. Wander India Limited filed an appeal before the Collector of Central Excise (Appeals), Bombay.

Collector (Appeals) observed that Pyridoxine Hydrochloride was a Pharmaceutical necessity and also therapeutically inert and did not interfere with the prophylactic property of other specified ingredients of Iso Benzacyl Forte. By the impugned order, he set aside the Assistant Collector's order and allowed the appeal filed by M/s.Wander India Limited. By the present appeal No. ED/SB/1447/83-C, the Collector of Central Excise, Pune has challenged the impugned order passed by Collector (Appeals).

3. In Appeal No. ED/SB/335/84-C, the facts are that M/s. Wander India Limited (Respondent herein) filed classification lists No. 29/80-81 dated 26.6.80 and No. 114/80-81 dated 29.1.81 in respect of their product "Iso Benzacyl Forte" under Item 14-E of the Central Excise Tariff and claimed exemption and Notification No. 116/69-CE dated 3.5.69, as amended. The classification lists were approved on 28.5.81 allowing the exemption under the aforesaid notification. Subsequently, it was felt by the Department that approval of the classification list was not in order and hence, after consulting the Commissioner, Food and Drugs Administration, Maharastra State and also Deputy Chief Chemist, Customs and Central Excise, the Assistant Collector of Central Excise, Bombay issued a show cause notice No. C.V.CELL/1/R-IX/W/14E/81/7018 dated 21.8.81 asking the respondents herein to show cause as to why the aforesaid two classification lists should not be modified disallowing the exemption under the said notification and why the duty should not be recovered from them. After considering the reply to the show cause notice and after hearing the respondents, the Assistant Collector of Central Excise, Bombay Division-I, vide his order-in-original No.CV-Cell/I/R-IX/W/14E/81/225 dated 7.1.82, held that the product did not merit exemption under Notification No. 116/69-CE and duty at the appropriate rale was to be paid by the respondents on the past clearances, being aggrieved by the order of the Assistant Collector, the respondents filed appeal before the Collector of Central Excise (Appeals), Bombay, who set aside the Assistant Collector's order, vide the impugned order-in-appeal No. E/2127/B 11-411/83 [File No. V-2(14E) 739/82] dated 19.11.83 and held that Pyridoxine Hydrochloride contained in Iso Benzacyl Forte was a

pharmaceutical necessity and also therapeutically inert and did not interfere with the prophylactics activity of the other ingredients in the product. He, therefore, allowed the benefit of exemption under Notification No. 116/69-CE to the respondents. By the present appeal before this Tribunal, The Collector of Central Excise, Bombay has challenged the said order of the Collector of Central Excise (Appeals).

4. In the two appeals filed by M/s. Sarabhai Chemicals, the facts are that they submitted three classification lists dated 25.7.1977, 1.8.1977 and 29.10.1977 respectively in respect of their products mentioned in paragraph 1 of this order and claimed concession rate of duty of 2.5.% ad valorem as against the full rate of 12.5% ad valorem, under Notification No. 116/69-CE dated 3.5.1969, as amended. The Assistant Collector of Central Excise approved all the three classification lists, vide orders dated 20.8.77, 24.10.77 and 8.11.77 allowing the partial exemption of Central Excise duty on all the products under the aforesaid notification. On 12.1.78 the Assistant Collector of Central Excise modified those three approved classification lists by disallowing concessional rate of duty under the aforesaid notification and charged duty at the normal rate of 12.5% ad-valorem. The said orders' dated 12.1.78 of the Assistant Collector were challenged by the appellants before the Collector of Central Excise (Appeals), Bombay who remanded the matters to the Assistant Collector for denovo adjudication, vide his order dated 3.7.80. There after, the Superintendent of Central Excise issued a show cause notice dated 2.5.81 to the appellants asking them to show cause why the classification lists filed by them should not be reviewed on the ground that they contained ingredients which were not specified in the aforesaid notification for concessional rate of duty at 2.5.% ad-valorem. After considering the reply to the show cause notice and giving the appellants the opportunity of personal hearing, the Assistant Collector of Central Excise, vide his Order-in-original dated 12.1.83, allowed the benefit of exemption Notification No. 116/69-CE.The Collector of Central Excise, Baroda,. reviewed the order dated 12.1.83 of the Assistant Collector under Section 35-E(2) of the Central Excises and Salt Act and authorised the Assistant Collector of Central Excise, Division No. III, Vadodara to file an appeal before the Collector of Central Excise (Appeals), Bombay against the Assistant Collector's order dated 12.1.83 in respect of two products, viz resteclin

I.M. Injection and Steclin I.M. injection on the ground that the said two injections contained Lidocaine Hydrochloride which was not specified in the Schedule to the Notification No. 116/69-CE and the said ingredient, being an anaesthetic, could not be considered to be therapeutically inert. The direction of the Collector to file an appeal was communicated to the Assistant Collector of Central Excise, Division III, Vadodara on 9.10.84. Thereafter, an appeal was filed before the Collector (Appeals) in October, 1984 itself in respect of the aforesaid two injections. It was stated in paragraph-4 of the said communication dated 9.10.84 that the appeal would not affect "the decision vide the adjudication order in question regarding the products, viz., Resteclin Capsules, Reclor Capsules and Resteclin tablets indicated in the said order".

On 9.1.85 the Collector of Central Excise, Baroda passed another order under Section 35-E(2) ibid to file an appeal before the Collector of Central Excise (Appeals), Bombay in respect of the products, Resteclin Capsules, Reclor Capsules and resteclin tablets. In pursuance with this order, an appeal was filed before the collector (Appeals) in respect of these products in January, 1985. The Collector (Appeals)passed two orders dated 26.8.85 and 9.9.1985 holding that the appeals were time-barred in view of the amendment of Section 35-E of the Central Excises and Salt Act. Revenue filed an appeal against the two orders of the Collector (Appeals) before this tribunal. The tribunal, vide its order dated 2.7.86, allowed the appeals of the Revenue holding that the Department's appeals before the Collector (Appeals) under Section 35-E were not time-barred and the matters were remanded to the Collector of Central Excise (Appeals), Bombay with direction to decide the appeals on merits. Thereafter, the appeals were considered by the Collector of Central Excise (Appeals) on merits and by the impugned order-in-appeal No. M-1554-1555/80-693-694/86/R dated 3.9.86, set aside the Assistant Collector's order dated 12.1.83 and allowed the appeals of the Revenue.

By the present two appeals, the appellants M/s. Sarabhai Chemicals have challenged the said orders-in-appeal passed by the Collector of Central Excise (Appeals).

5. During the hearing before us Shri A.S. Sunder Rajan argued for the Revenue. Shri V. Lakshmikumarn argued on behalf of M/s. Wander India Limited. S/Shri K.S. Nanavati and Soli J. Sorabjee argued for M/s.

Sarabhai Chemicals.

6. Appeals No. ED/1447/83-C and No. ED/335/84-C were earlier heard by Special Bench 'C consisting of Vice-President (Judicial) and one Technical Member, and orders were reserved. While writing the order, the Bench felt that the judgment of Hon'ble Madras High Court in the case of Hoechst Pharmaceutical Private Limited, Bombay v. Collector of Customs, Madras (O.S. Appeal No. 34 of 1965 and Writ Petition No. 23 to 27 of 1970) was contrary to the view taken by this Tribunal in its decisions in the case of Unique Pharmaceutical Laboratory, Bombay v. Collector of Customs, Bombay and in the case of Piya Pharmaceutical Works v. Collector of Central Excise, Meerut. In view of the judgment of Madras High Court, the view of the Bench which heard these two appeals, was at variance with the earlier decisions of the Tribunal referred to supra.

Bench, therefore, recommended, vide Order No. Misc/55-56/1988-C dated 25.2.1988, that the matter be placed before Five-Member Larger Bench.

Two appeals No. E/2551/86-C and E/2173/86-C filed by M/s. Sarabhai Chemicals were once heard by special Bench 'C consisting of Vice-President (judicial) and one technical Member. Since the main issue in these two appeals in similar to that covered by the case of M/s. Wander India Limited and since the matter relating to the latter had been recommended for placing before Five-Member Bench, the Bench though it prudent and proper that these two appeals of M/s. Sarabhai Chemicals be also heard by the Larger Bench. The Bench recommended accordingly, vide Order No. Misc/53-54/88-C dated 10.3.88.

Consequently, the present Five-Member Bench has been constituted to hear and decide these four appeals.

7. At the beginning of the hearing, Shri Sunder Rajan raised a preliminary objection challenging the jurisdiction of this Five-Member Bench to hear these

appeals. He stated that according to the provisions of Section 129(5) of the Customs Act, 1962, "The Vice-President shall exercise such of the powers and perform such of the functions of the President as may be delegated to him by the President by a general or special order in writing". In exercise of the powers conferred by Section 129(5) of the Act, the President of Customs, Excise and Gold (Control) Appellate Tribunal issued the Customs, Excise and Gold (Control) Appellate Tribunal Order No. 11 of 1982 dated 11.11.1982 to the effect that "In the absence, whether on leave or otherwise of the President, the Senior-most Vice-President, who is available may exercise such of the powers and perform such of the functions of the President as may be necessary for the efficient functioning of the Tribunal". Shri Sunder Rajan argued that such delegated powers and functions could be exercised by the Senior-most Vice-President, when the President was absent, whether on leave or otherwise, and such powers and functions could be exercised by the Senior-most vice-President, as might be necessary for the efficient functioning of the Tribunal. The arguments of Shri Sunder Rajan were that the President of the Tribunal was not in existence on 16.3.88 when this Bench was constituted. The post of the President was lying vacant. It could not, therefore, be said that the President was absent on leave or otherwise. Secondly, the constitution of Larger was not needed for the efficient functioning of the Tribunal. The Roster of the Benches for day-to-day functions was needed for efficient functioning, he argued that the Senior Vice-President could not legally constitute this Five-Member Bench under the delegated powers and function of the President, under CEGAT Order No. 11/82 read with Section 129(5) of the Customs Act, and hence, this Bench had inherent lack of jurisdiction to hear and decide these appeals. On this preliminary objection, Shri Nanavati has argued that the Tribunal's order No. 11/82 dated 11.11.82 is intended to run the Tribunal when the President is not there or is not available. The expression, "absence of President" should not be normally construed to mean that the President is in existence, but is absent. According to him, the constitution of the Bench is an administrative order. This Bench cannot go beyond the order which has constituted it. The Constitution of the Bench cannot be challenged before this Bench itself, and such an objection can be raised before a higher forum only. Shri Lakshmikumaran has argued that Rule 4 of the Customs, Excise and Gold

(Control) Appellate Tribunal (Procedure) Rules, 1982 also empowers the Senior Vice-President to constitute a Larger Bench. The learned Departmental Representative has conceded that Senior Vice-President has power to constitute day-to-day Roster of the Benches. As per roster of the days this Bench has been earmarked to hear these four appeals. He has also argued that although the objection raised by the learned D.R. can be disposed of by this Tribunal itself, propriety demands that this objection should be raised before another competent Forum. The arguments addressed on this preliminary point have been considered by us. We are of the view that this is not the appropriate Forum in which this objection challenging the powers of the Senior Vice-President to constitute this Bench and validity of this Bench constituted under the delegated powers, should be raised by the Revenue. Such an objection could appropriately be raised before the competent Forum. We hold that once the Senior Vice-President has constituted this Bench under his delegated powers, this Bench is obliged to hear the appeals earmarked to it. We have, therefore, overruled this objection raised by the learned Departmental Representative and have proceeded to hear the arguments on merits.

8. Arguing on the merits of the cases on behalf of the Revenue, Shri Sunder Rajan has stated that the Notification No. 116/69-CE, as amended, granted partial exemption from Central Excise duty to patent or proprietory medicines falling under Item 14-E of the Central Excise Tariff if such medicines contained one or more of the ingredients specified in the Schedule annexed to the Notifications. The benefit of this notification was also admissible if such medicines contained any ingredient/ingredients not specified in the said Schedule to the notification if such non-specified ingredients in the medicines were pharmaceutical necessities, such as, diluents, disintegrating agents, moistening agents, lubricants, buffering agents, stabilisers and preservatives; and provided that such pharmaceutical necessities were therapeutically inert and did not interfere with the therapeutic or prophylactic activity of the ingredients specified in the Schedule. In the medicines under dispute, Pyridoxine Hydrochloride (Vitamin- B6) contained in Iso Benzacyl Forte, Ascorbic Acid (Vitamin C) contained in Resteclin Capsules and Tablets as also in Reclor Capsules, and Lidocaine Hydrochloride contained in Intramuscular Injection Steclin and Resteclin were not specified in the Notification No. 116/69-CE.These

non-specified ingredients were not pharmaceutical necessities, such as, diluents, disintegrating agents, moistening agents, lubricants, buffering agents, stablisers and preservatives, not were they therapeutically inert and as such, their inclusion in the medicines under dispute made the medicines ineligible for the benefit of the notification. In support of this proposition, Shri Sunder Rajan has advanced the following arguments:-- (i) The opening paragraph of Chapter-67 of Remigton's Pharmaceutical Sciences, 15th Edition, 1975, describes what is understood by the term "Pharmaceutical necessities". The opening paragraph of this Chapter reads as follows:-- This Chapter describes substances which are of little or no therapeutic value, but which are useful in the manufacture and compounding of various pharmaceutical preparations. Hence, they are referred to as pharmaceutical necessities. The substances described include antioxidants and preservatives; coloring, flavoring and diluting agents; emulsifying and suspending agents, ointment bases; pharmaceutical solvents; and miscellaneous agents. For a more detailed review of the uses of these agents, the interested reader is referred to the various chapter in Part VIII of this book.

Nowhere in this Chapter Vitamin B6 and Lidocaine Hydrochloride have been mentioned, although Ascorbic Acid has been mentioned under the Heading "Antioxidant and Preservatives". Its uses have been described to prevent rancidity, to prevent the browning of cut apples and in the preservation of tinned or frozen food. Ascorbic Acid has not been used in the medicines under dispute as antioxidant or preservative. Isoniazid is an antibiotic ingredient in Iso Benzacyl forte tablet which is a standardized product for the treatment of tuberculosis. The treatment with this medicine over a long period may produce peripheral neuritis and for the treatment of this side effect, Vitamin B6 has been included in the formulation of this T.B. Drug. Lidocaine Hydrochloride is an anaesthetic and it is included in the Intramuscular injections "Steclin" and "Resteclin" to minimise the pain at the time of administering these injections.

Ascorbic Acid is included in the medicines "Reclor Capsules" and "Resteclin Capsules" to counter-act the bad effect of specified ingredients Tetracycline and Chloramphenicol. Therefore, none of the. aforesaid non-specified ingredients falls under any of the categories of pharmaceutical necessities, such as, diluents,

disintegrating agents, moistening agents, lubricants, buffering agents, stabilisers and preservatives as mealioned in the Notification. Only in respect of Resteclin Intramuscular Injection, the appellants declared on the label that Ascorbic Acid was a buffer, but for the other medicines there was no such declaration as buffer.

(ii) The printed literature of the medicine Iso benzacyl Forte does not show that Vitamin B6 (Pyridoxine Hydrochloride) is added as pharmaceutical necessity. Literature says that "Vitamin B6 added specifically to forestall possible INH neurotoxicity". Nobody also prescribes Vitamin B6 as such; it is always prescribed with other medicines, as stated at page 192 of "The Principles and Practice of Medicine" by Sir Stanley Davidson and John Macleod, 10th Edition, Re-print.

(iii) At page 430 of "Pharmacopoeia of India (The Indian Pharmacopoeia)" Volume I, 3rd Edition, dose of Pyridoxine Hydrochloride (Vitamin B6) has been specified. It is stated therein: "Prophylactic, 2 mg daily, therapeutic 10 to 150 mg one to three times daily.

At page 192 of "The Principles and Practice of Medicine" by Sir Stanley Davidson and John Macleod, Chemistry and physiological action of Vitamin B6 and disorders due to Pyridoxine (Vitamin B6) deficiency have been discussed. The relevant extracts are as follows:-- Chemistry and Physiological Action: Vitamin B6 is not a single substance but consists of three closely related chemical compounds with similar physiological actions. The biologically active form of the Vitamin is pyridoxal phosphate, which is the coenzyme for aminotransferases (transaminases) which play a decisive part in the metabolism of amino acids.

Disorders due to Pyridoxine (Vitamin B6) deficiency. Although pyridoxine plays an important role in the metabolism of amino acs, and although a series of pathological changes in the skin, liver, blood vessels, nervous tissue and bone marrow have been produced experimentally in various animals such as the monkey, dog, pig, rat and chicken, neverthless disorders due to deficiency of pyridoxine rarely occur in man, and then very seldom as a result of dietary deficiency.... The peripheral neuritis associated with isoniazid therapy is due to a conditioned pyridoxine deficiency.

The doses prescribed in the Indian Pharmacopoeia at page 430 for Pyridoxine Hydrochloride clearly shows that Vitamin B6 has pharmaceutical as well as therapeutical property. It cannot, therefore, be said that this ingredient is therapeutically inert.

(iv) At page 166 of the "United States dispensatory Physician and Pharmacology", it is stated that "The outstanding characteristic of Ascorbic Acid is its ability to prevent or cure scurvy; exactly how it does so is uncertain. It is known that Ascorbic Acid is necessary for the biosynthesis of intercellular ground substance and collagen. Bone fractures and wounds will not heal in patients with Ascorbic Acid deficiency, possibly because of failure to form collagen. Certain evidence suggests that in serve Ascorbic Acid deficiency the concentration of folic acid in tissues is reduced and the anaemia observed in scorbutic patients is the result of induced tissue folic acid deficiency.

At page 168 of the same technical book, Therapeutic Uses of Ascorbic Acid have been described as follows:-- Therapeutic Uses:- ascorbic Acid is used as a specific curative in scurvy. In many different diseases a deficiency of the vitamin may develop due to anorexia, to fault of a special diet, to failure of absorption as in diarrheal and other disorders, or to increased requirements in hypermetabolism or during the course of infections.

The correction, or better the prevention, of any deficiency of ascorbic acid will benefit such patients.

Ascorbic acid, by virtue of its involvement with the functioning of intercellular substance, has been tired in the treatment of almost all the disorders of mankind. Benefit has been reported in retinal hemorrhage, hematuria, bleeding peptic ulcer, rheumatic fever, tuberculosis, dysentery, fractures, dental caries, and many other conditions. It has also been reported to be of value in reducing the toxic effects of a great variety of medicinal agents and noxious industrial chemicals.

At page 56 of British Pharmaceutical Codex, 1963 Edition, the uses of Ascorbic Acid have been described in the following terms:-- Ascorbic acid is used primarily for the prophylaxis and treatment of scurvy. Although this condition is now seldom

seen, it may occur in the undernourished and in bottle-fed infants. To prevent infantile scurvy, bottle-fed infants should have their feeds supplemented by 2.5. to 5 milligrams of Ascorbic Acid daily. It is advisable that patients who have been placed on restricted diets for therapeutic purposes, as in the treatment of peptic ulcer, should receive supplements of ascorbic acid. Supplements of the vitamin may also be necessary to promote healing of wounds and fractures and in those conditions where vomiting, diarrhoea or diuresis are likely to interfere with its absorption and utilisation. Some obscure types of anemia respond to treatment with ascorbic acid and iron. Large doses of ascorbic acid are often administered therapeutically, but there is little evidence to show that a daily intake of more than 30 to 50 milligrams has any beneficial effect except in the treatment of methaemoglobinaemia, for which 200 milligrams is given thrice daily; in this dosage ascorbic acid has a diuretic action.

At the same page of the book dose has been indicated as "prophylactic, 25 to 75 milligrams daily; therapeutic, 200 to 500 milligrams daily.

At page-2 of Encyclopaedia of Chemical technology by Kirk-Other, Third Edition, volume 24, it has been stated that vitamins are used in the prophylaxis and treatment of various diseases including infectious and neoplastic conditions. At page 8 of the same technical book, it is stated that Ascorbic Acid implies the vitamin's antiscorbutic properties, namely, the prevention and treatment of scurvy. At page 31 of the same book, it is stated that Vitamin C is an essential nutrient for health maintenance. The first uses of the vitamin were to prevent, and treat scurvy. Although the mechanisms are not completely defined, the vitamin does interact with essential nutrients and metabolites, accounting for its biochemical functions. At page 32 of the book, it is stated that The use of ascorbic acid in ameliorating and speeding recovery from the common cold is based on immunostimulation and is recommended by Pauling.

Vitamin C's possible role in cancer prevention, therapy, and management is being studied intensively. It has been related to immunostimulation, collagen encapsulation of tumors, deficiencies in tissue, activity as an antioxidant, and interaction with free radicals.

Ascorbic acid may kill certain tumor cells, increase the effect of some tumor therapeutic agents, and stimulate the host's immune system against residual tumor cells.

It is thought that Vitamin C helps in the prevention and treatment of chronic diseases other than scurvy that are aggravated by adverse external factors, e.g., smoking, alcohol, pollution, drugs, and stress, At pages 574-575 of "Clinical Pharmacology" by D.R. Lawrence, Third Edition, it is stated: Ascorbic acid is a powerful reducing agent and probably plays a part in intra-cellular oxidation-reduction systems. In scurvy there is a general breakdown of collagenous connective tissue, which explains the main symptoms. Ascorbic acid is also needed if conversion of folic acid to biologically active folates, is to be rapid. It is present in high concentration in the adrenal cortex and it may be involved in steroid synthesis.

At page 859 of "The Essential Guide to Prescription Drugs" by James W.Long, it is stated that: By acidifying the urine, Vitamin C (ascorbic acid) creates an environment which is unfavorable to the growth of certain bacteria that commonly infect the urinary tract. This action also enhances the therapeutic effects of some widely used ani-infective drugs.

The above extracts from authentic technical books and literature show that Ascorbic Acid (Vitamin C) has prophylactic and therapeutic value.

It is, therefore, not therapeutically inert. In the result, the medicines which contained Ascorbic Acid as one of the ingredients would not qualify for the exemption under Notification No. 116/69-CE.(v) Tetracycline Hydrochloride and Chloramphenicol have bad effects. At page 109 of the text book "The principles and Practice of Medicine" by Sir Stanley Davidson and John Malceod, Third Edition, dangers of the Tetracycline and Chloramphenicol have been described as follows:-- Many of the normal saprophytes of the alimentary tract are sensitive to the tetracyclines and may be eliminated when these antibiotics are administered. Insensitive organisms are then free to multiply and 'superinfection' may develop which can be very difficult to control. This happens particularly with fungi, such as Candida, which cause stomatitis, glossitis or an anal or vulvar pruritus which can

be very distressing.

The danger of 'Superinfection' following the excessive use of the tetracycline emphasizes the rule that a broad-spectrum antibiotic should not be prescribed if an antibiotic is available which is effective against the specific organism for the illness. This is especially the case in hospital practice where the risk of cross-infection with resistant organisms is always present.

At page-110 of the said book, dangers of Chloramphenicol have been described in the following words:-- As in the case of the tetracylines, chloramphenicol may cause gastrointestinal disturbances and its use in large dosage may be followed by similar super infections. Much more serious, although fortunately rare, are the blood dyscrasia which have been reported following its use. This antibiotic has in its chemical structure a benzene ring of the type known to cause bone marrow aplasia.

Although the risk of the development of aplastic anaemia is remote, its use is justified only in the presence of a serious infection for which there is no alternative therapy.

The bad effects of Tetracycline are also mentioned at page-54 of National Formulary of India, 1979, Third Edition. It is stated that When tetracycline are given over a long period, they destroy the normal bowel flora, giving rise to deficiency of synthesised vitamins especially Vitamin K and group B-Vitamins which may have to be supplemented Regarding Chloramphenicol, it is stated at the same page that in a few persons, it may produce fatal aplastic anemia and so its use is reserved for typhoid fever, and in acute respiratory infections by organisms resistant to other antibiotics. It may also be used in urinary tract infections, due to bacteria, which are sensitive to it.

At page 304 of the said book, under the Heading "ANTIBIOTICS", it is stated, Treatment with vitamin supplements especially the B group and Vitamin K must be administered when broad-spectrum antibiotics are used for more than two weeks.

In the present case, Vitamin B6 neutralists toxic effect of the antibiotics. It is, therefore, a therapeutic necessity and not pharmaceutical necessity in the Iso Benzacyl Forte.

Formulation is made using more than one ingredient so that side effect of one ingredient is neutralized by the other. Thus, it is clear that Vitamin C or Vitamin B6 is not added as a pharmaceutical necessity, but as a therapeutical necessity. Quality control test reports show that Ascorbic Acid of high doses were used in the medicines. These were used as active ingredients. The expression like "Buffering Agents", etc., in the Notification should be restricted to these terms only, and no new expression not similar to these categories is permissible to be imported in the Notification.

At page-14 of the Referring Order No. Misc/55-56/1988-C dated 25.2.88 for constitution of Five-Member Bench, the Tribunal has observed that technically speaking the term "Buffer" is for maintaining PH value.

Buffering agent does not figure in Chapter-67 of Remington's Pharmaceutical Sciences, nor this term has been defined in the Notification. In Taber's Cyclopedic Medical Dictionary, "Buffer" has been defined as a substance to offset the reaction of an agent administered in conjunction with it. In that sense the referring Bench has observed that Vitamin B6 in the Iso-Benzacyl Forte tablet can be considered as buffering agent. the meaning given by the referring Bench to buffering agent is not the intention of the notification, it is also not the purpose of the Notification that medicine should be acceptable to human system.Piya Pharmaceutical Works v. Collector of Central Excise, Meerui that Vitamins are know to be employed in the treatment of deficiency diseases and have a place of their own in the therapy and prophylaxy of humans as well as animals. The Tribunal has held that vitamins have a role to perform which is quite distinct from that of an antibiotic agent like chloramphenicol and the same are not, therefore, therapeutically inert. In its decision in the case of Unique Pharmaceutical Labs., Bombay v. Collector of Customs, Bombay, Tribunal has held that Lignocaine Hydrochloride is local anaesthetic and anti-arrhythmic as per the British Pharmacopoeia and it is not therapeutically inert.

Anaesthetic is not mentioned in the Notification No. 116/69-CE and it is not a category similar to specified categories, such as, diluents, disintegrating agents, etc. In the said case, the Tribunal has held that medicine containing Lignocaine Hydrochloride was not eligible for the benefit under Notification No. 116/69-CE. The present cases of M/s. Wander India Limited and M/s. Sarabhai Chemicals are similar to those two case decided by this tribunal earlier. Those decisions are binding on the tribunal and the same should be followed by this Bench also.

(vii) The tariff which was dealt with by the Madras High Court in the case of M/s. Hoechst Pharmaceuticals Ltd., Bombay (supra) is not pari materia with the tariff involved in the present cases. The facts of the case covered by the judgment of Madras High Court are, therefore, clearly distinguishable from the facts of the present cases. In the circumstances, the said judgment of Madras High Court is not applicable to the facts of the cases before this Bench.

9. On merits of the case, Shri Lakshmikumaran has argued that there are many ingredients which, by themselves, may have therapeutic effects, but when added in medicine along with other ingredients they act as buffering agents or pharmaceutical necessities. Pharmaceutical necessities are those which are added in formulation of medicines so that the medicines can be acceptable to human system. The expression "therapeutically inert" appearing in the second proviso to the notification No. 116/69-CE, means therapeutically inert for the therapy in question. Pyridoxine Hydrochloride LP. 2.5 mg. concurrently administered with specified ingredient "Isoniazid"is not for its therapeutic value. It is used to prevent toxic effect of the medicine.

It is buffering agent as a pharmaceutical necessity. For definition of buffering agent, Shri Lakshmikumaran has cited a few authorities. In Taber's Encyclopedic Medical Dictionary (Page B-65), it has been stated that buffer is a substance tending to offset reaction of an agent administered in conjunction with it. In Dorland's Illustrated Medical Dictionary (Page 195), "Buffer"has been defined as physical or physiological system that tends to maintain constancy. In Butterworths Medical Dictionary (Page 268), it is stated that buffer means anything that slows or inhibits the immediate action of a Chemotherapeutic agent. Pyridoxine

Hydrochloride LP, is added as an ingredient in Iso Benzacyl Forte to prevent Vitamin B6 deficiency after prolonged use of this medicine. He has drawn our attention to pages 273-274 of Clinical Pharmacology, Fifth Edition, in which it has been stated that "Isoniazid" interferes with pyridoxine metabolism, and induces pyridoxine deficiency; pyridoxine output in the urine is increased. The principal effects are peripheral neuropathy, and, more rarely, anaemia, and pellagra (in a malnourished). Other adverse effects include mental disturbances, convulsions, incoordination, encephalopathy, alcohol intolerance, hepatotoxicity and a variety of allergic effect(s).

Drawing out attention to page 1202 of "The Pharmacological Basis of therapeutics", Sixth Edition, 1980 by Godman & Gilman, he has said that it is stated in the said book that Pyridoxine (10 mg per day) should be administered with isoniazid to minimise adverse reactions, especially in malnourished patients and those predisposed to neuropathy (e.g. diabetics and alcoholics)....If pyridoxine is not given concurrently, peripheral neuritis is the most common reaction to isoniazid and occurs in nearly 20% of patients receiving 6 mg/kg of the drug daily.

He has also cited from page 34.48 of 'Text Book of Pharmacology" Second Edition, 1980 by W.C. Bowman and M.J. Rand, which is as follows:-- Side-effects of isoniazid include occasional liver dysfunction. The principal toxic effect is peripheral neuritis which may be prevented by simultaneous administration of pyridoxine.

Shri Lakshmikumaran has also stated that Vitamin B6 in peripheral doses up to 150 mg. prevents adverse effects of Isoniazid. He has cited from page 406 of British Pharmaceutical Codex-1963, which is as follows:-- The onset of peripheral neuritis should be expected with doses of 10 milligrams per kilogram of body weight, and prophylactic doses of 100 milligrams of pyridoxine hydrochloride should be given daily.

He has further stated that in "The Extra Pharmacopoeia"Martindalc, Twenty Seventh Edition (1977) at page 1695, it is mentioned that A daily dose of 150 mg. may be given as a prophylactic against peripheral neuritis in patients on isoniazid therapy, children may be given 25 to 50 mg. daily.

He has also relied on the "Medical Pharmacology - Principles & Conccpts"by Andres Goth, Ninth Edition, 1978, page 619, which says that Pyridoxine Hydrochloride is used to prevent headache and peripheral neuropathy without interference with chemolherapeutic activity. It is also stated therein that pyridoxal phosphate docs not prevent the effect of isoniazid on the tubercle bacillus. Shri Lakshmikumaran has, therefore, argued that Pyrodixine Hydrochloride does not affect the active ingredients and the judgment of Madras High Court is, in the circumstances, directly on the issue involved in the present case.

10. For M/s.Sarabhai Chemicals, S/Shri Soli J.Sorabjce and K.S.Nanavati have argued on different dates. The gists of the arguments of Shri Sorabjee are given below:-- (i) Isoniazid, Para-amino-salicylic Acid and its salts, Chloramphenicol and tetracycline hydrochloride appeared at Serials.

No. 3,4,14 and 25 of the Schedule to the Notification No. 116/69-CE Inclusion of these specified ingredients in the medicines make such medicines eligible for the notification. However, the undermentioned groups of medicines contain certain ingredients which are not specified in the schedule to the notification. These ingredients arc:--Name of medicines Name of the ingredients not specified in the notification(a) Resteclin Capsules and Tablets Ascorbic acid(b) Reclor capsules Ascorbic acid(c) Steclin Injection I.M. Lidocaine Hydrochloride(d) Resteclin Injection I.M.and Ascorbic acid.

According to the notification, non-specified ingredients arc: permissible if they are: (c) Do not interfere with the therapeutic or prophylactic activity of the specified ingredients.

(ii) The aforesaid non-specified ingredients, viz., Ascorbic Acid and Lidocaine, are pharmaceutical necessities. Martindale, the extra Pharmacopoeia, Twenty Eighth Edition by James E.F.Reynolds and Anny B.Prasad, at page 1655, while discussing the uses and functions of Ascorbic Acid (Vitamin C) says that it is used as an antioxidant or buffering agent; it can be used in severe vitamin deficiency. In Chapter 9 of "Text Book of Pharmaceutical Formulation" by B.M.Mithal, Ascorbic Acid is described as stabiliser and antioxidant.

(iii) In his affidavit dated 17.7.86, photo-copy of which is placed at pages 155 to' 157 of the appellants' paper-book Vol. I, Dr.H.P. Tipnis, Principal and Prof, of Pharm-Chcmistry, Bombay College of Pharmacy has said as follows:-- A pharmaceutical formulation is a drug delivery system consisting of active ingredients along with several carefully selected adjuvents.

(Other ingredients) These adjuvents, called pharmaceutical necessities are in a formulation to ensure that the product elicit the intended therapeutic response on administration up to the end of its shelf life. The selection of pharmaceutical necessities added to the products depends on physiochemical properties of drugs included in the product and route of administration. These arc selected in such a way that they should not interfere with therapeutic activity of the main drug. At the same time, the product should be toxicologically safe and acceptable to the patient. These necessities may be grouped into two types-- a. Those required due to pharmaceutical reasons. These include diluents, binders, lubricants, suspending agents, buffering agents, antioxidants, preservatives, complexing agents, ointment bases, etc.

b. Those required for product elegance and patient acceptability.

These include colours, flavours, sweetening agents, taste making agents, local anesthetics, etc.

These ingredients when used as pharmaceutical necessities as described above are considered therapeutically inert, although most of them are occasionally used for their therapeutic value in different circumstances, e.g., Mag. Stearate, and talc used as lubricant in formulations arc also used as dusting powder in treatment of skin diseases. Starch used as binder, disintegrating agent in formulations, is also used for Therapeutic purposes such as starch mucilage is used as emollient and as antidote for Iodine poisoning. Starch 10% and Talc 90% are the ingredients of Talc Dusting powder. Milk Sugar (Lactose) used as diluent in formulations is also used in infant feeding to adjust Carbohydrate and is a laxative also.

Plasdone used as binder in tablets, has also been used as Plasma expander and as an eye drop. Magnesium Chloride used as complexing agent in formulations is

also used in dialysis solution and as a source of Magnesium ion. Ascorbic acid commonly used as antioxidant and buffering agent in formulation is also used as Vitamin in scurvy, for therapcutic purpose. However, none of the above mentioned substances arc used as antimicrobial agent, either alone or in combination.

Several similar examples could be given for different use of a substance. The Food Drug Control administrations of England as well as other official publications have classified these materials as inactive materials to be used in formulations as pharmaceutical necessities." The aforesaid opinion of Dr. Tipnis shows that Ascorbic Acid is used as anti-oxidant and buffering agent in a formulation. It is also described as an inactive agent.

(iv) At page 145 of the appellants' paper-book Vol.1 is a photo-Copy of the list of inactive ingredients prepared by the Food and Drug Administration, published in the New England Journal of Medicines, Vol. 309, 1983. Ascorbic acid is included in the said list. This shows that it is an inactive ingredient. At page 154 of the appellants' paper-book, Vol.1 is a D.O. letter of Dr. O.D. Gulati, Medical Officer, Charutar Arogya Mandal Hospital and Research Centre, Karamsad, Dist. Kheda, Gujarat to the Chief: Medical Division, Sarabhai Chemicals, Baroda, in which it is stated that The term 'inactive' is a relative term. Ascorbic Acid is one of the ingredients which have many diverse functions and uses pharmaceutically. All these agents may act as antimicrobial agents invitro depending on the organism used. However, in medical practice such substances are not used as antimicrobial agents either alone or in combination to be given by oral or parenteral route as antimicrobial agents for the treatment of infections.

To summarise, the term 'inactive' is only relative. These agents are added to pharmaceutical preparations for various pharmaceutical purposes and hence declared as 'inactive'.

This opinion of Dr. Gulati also says that Ascorbic Acid is an inactive ingredient.

(v) At page 217 of the book "Quality Control in Pharmaceutical Industry" by Murray S. Cooper, it is stated that exposure to sunlight causes tetracycline to darken, but this darkening may be retarded by the addition of Ascorbic Acid.

(vi) At page 89 of the appellants' paper-book Vol.1 is a letter dated 25.6.84 from Shri C.N. Patel, Assistant Director, Food and Drugs Control Administration, Baroda to M/s. Sarabhai Chemicals, Baroda. There is another letter dated 30.6.84 from the said Assistant Director to M/s. Sarabhai Chemicals at page 90 of the said paper-book. With these two letters the Assistant Director, Food and Drugs Control Administration, Baroda forwarded serval certificates in which he has stated that Ascorbic Acid contained in the formulations Reclor Capsules 500 mg and 250 mg, Resteclin Capsules 250 mg and 500 mg, Resteclin tables 550 mg, Resteclin and Steclin Injections are therapeutically inert with respect to the diseases claimed to be cured with Chloramphenicol and Tetracycline Hydrochloride. The certificates also say that Ascorbic Acid and Lidocaine Hydrochloride in the Intramuscular Injections Steclin and Resteclin being pharmaceutical necessities are therapeutically inert and do not interfere with the therapeutic or prophylactic activity of the ingredient Tetracycline Hydrochloride.

(vii) In the article titled "Stability of Tetracycline and Riboflavin"by Lewis J. Leeson and Joseph F. Weidenheimer, published in the Journal of Pharmaceutical Sciences, copy of which is placed at pages 49 to 50 of the paper-book Vol.1 of the appellants, it is staled that Ascorbic Acid was selected because it is both a stabiliser in parenteral tetracycline formulations, and a commonly used antioxidant.

(viii) At page 1186 of the technical book The Pharmacological Basis of Therapeutics. Sixth Edition by Godman and Gilman, it is 'stated that because of local irritation and poor absorption, intramuscular administration of tetracycline is generally unsatisfactory and is rarely indicated and that preparations containing a local anaesthetic are better tolerated on intramuscular injection. In his opinion, Dr. Tipnis has also stated that pharmaceutical necessities included local anesthetic which is required for patients' acceptability. Therefore, Lidocaine is a pharmaceutical necessity.

List of pharmaceutical necessities given in the Notification No. 116/69-CE is not exhaustive. It is illustrative because the notification says "such as" and not "namely". Therefore, Lidocaine, being an anaesthetic, is a pharmaceutical necessity although the expression "anaesthetic" is not mentioned specifically in

the notification.

(ix) The foregoing authorities clearly establish that Ascorbic Acid as well as Lidocaine Hydrochloride are pharmaceutical necessities.

Ascorbic Acid is antioxidant and buffering agent, and Lidocaine is an anaesthetic; and these two ingredients are therapeutically inert.

When Ascorbic Acid is used in the Resteclin and reclor groups of medicines, it is not for the cure of Scurvy, or for the cure or treatment of infections and typhoid for which these medicines are used. Similarly, Lidocaine has no nexus with the diseases for the treatment of which the Injections Steclin and Resteclin are administered. It relieves pain and it does not affect the therapeutic effect of the specified ingredients or the drug itself.

In these case of M/s. Hoechst Pharmaceuticals Pvt. Ltd. v. Collector of Customs, Madras in writ Petition Nos. 23 to 27 of 1970 and O.S. Appeal No. 34 of 1965 before the Madras High Court, the issue was the same. In the said case, the issue was whether the presence of Ascorbic Acid took the formulation out of tariff Entry 28(27). If the Ascorbic Acid was a therapeutic ingredient, then the formulation would not fall Within the Tariff Entry 28(27). Madras High Court held that Ascorbic Acid was not used as therapeutic agent in the formulation in that case. This view was held by the High Court irrespective of the fact that Ascorbic Acid has therapeutic effect for treatment of Vitamin B6 deficiency or for the treatment of Scurvy. The judgment of Madras High Court clearly covers the issue involved in the present case and as such the said judgment should be followed, there being no other contrary judgment, of any other High Court or Supreme Court. The Tribunal's decisions in the case of Unique Pharmaceuticals Lab. and in in the case of Piya Pharmaceutical Works did not consider the Madras High Court judgment. In view of this judgment, the reasoning given by the Tribunal for its decisions in those two case is not correct.

(x) The notification says that the non-specified ingredients should not interfere with the therapeutic effect of the ingredients specified in the schedule to the notification. Ascorbic Acid enhances the therapeutic effect of the specified

ingredients and it does not interfere with the therapeutic effect.

(xi) In the circumstances, the medicines under dispute are eligible for the concessional assessment under the Notification No. 116/69-CE, as amended.

11. On merits of the case, Shri Nanavati has argued that Ascorbic Acid is anti-toxic and preservative. He has cited Remington's Pharmaceutical Science, text Book of Pharmaceutical Formulation (Chapter 9) and Pharmaceutic Ingredients, copies of which are at Annexure 'A', 'B' and 'E' respectively of the appellants' paper-book Vol. 11, in this connection. He has also argued that ascorbic Acid is therapeutically inert. The list of inactive ingredients, vide copy at page 145 of the appellants' paper-book Vol. 1, includes this ingredient. The certificates of Dr.H.P. Tipnis and Dr. Gulati also support this view. Ascorbic Acid is used as anti-oxidant or stabiliser in the Pharmaceutical Industry. "Therapeutically inert" is not an absolute term, but is a relative term. If the non-specified ingredient has no therapeutic value in the formulation, then it is therapeutically inert for the purpose of the notification. There is hardly any ingredient which has no therapeutic value as such. If therapeutically inert is meant in absolute term in the Notification No. 116/69-CE, then the second part of the proviso to the notification, viz. "do not interfere with the therapeutic or prophylatic activity of the ingredient or ingredients specified in the Schedule" would not have been in the proviso. The second part of the proviso explains the meaning of 'Therapeutically inter".

If the Department's view is accepted, the, such an interpretation will defect the purpose of the notification. The notification should not be given such an interpretation which will make it redundant, as held in the case of Mrs. Kaushalya Narayan and Ors. v. Dadajee Dhackjee & Co. (Pvt) Ltd., reported in 1980 ELT 102 (Bombay).

Regarding interpretation of notification, he has relied on the decisions - Haldyn Glass Works Pvt.

Ltd. v. ML. Badhwar, and 1982 ELT 885 (Bombay) - Deccan Sales Corporation and Anr. v. R. Parthasarathy and Ors. He has also argued that the appellants' case is covered by the judgment of Madras High Court in the case of M/s. Hoechst

Pharmaceuticals Ltd. v. The Collector of Customs, Madras. The judgment of High Court is binding in the absence of any contrary judgment of any High Court of Supreme Court, as held in the decisions reported in (i) 1978 ELT (J-624) (Bombay) Commissioner of Income tax v. Smt. Godavari Devi Saraf, (ii) - J.K. Synthetics Ltd. v. Collector of Stores Depot v. Collector of Customs, Bombay, (iv) - Amritlal Lalubhai v. Collector of Central Excise, Allahabad and (v) - Indian Plywood Manufacturing Co. Ltd. v. (i) Whether the Assistant Collector of Central Excise had power and jurisdiction to review earlier order on classification: (ii) If he had such power, whether an order revising the classification should operate prospectively or retrospectively; and (iii) Whether the Collector of Central Excise could legally pass a second order of review under Section 35-E of the Central Excises and Salt Act, 1944 on 9.1.85 for filing appeal in respect of the five products of Resteclin and Reclor groups of capsules and tablets.

13. Regarding point No. 1 above, Shri Nanavati has argued that the Assistant Collector has no power to review his own order. The show cause notice issued by him and the subsequent proceeding pursuant to that notice are illegal. On this point, he has relied on the decisions reported in (i) , (ii) 1981 ELT 565 (Madras), (iii) 1977 ELT (J-144) (All), (iv) 1984 ELT 234 (Madras), (v) , (vi) 1987 (13) ECR 907 (Tribunal) and modification of classification list was not applicable here as there was no dispute on rate of duty, the classification list having been already approved. For this, he has relied on the Bombay High Court decision, .

14. On point No. 2, the contention of Shri Nanavati is that the modification of classification list shall take effect from the date of the order. In support of this contention, he has relied on four decisions, viz., those reported . He has stated that there was no change in facts, but was only a change of opinion of the Assistant Collector under the same set of facts. So, the reopening of the classification was not justified. Further, the change could not relate to earlier period when the approved classification list was operative, as held in . He has argued that the show cause notice was for change of classification and not for recovery of short-levy, and the provision of Section 11-A of Central Excises and Salt Act was not invoked.

15. On the third proposition, he has argued that the Collector applied his mind to the entire order of the Assistant Collector of Central Excise and took a decision under Section 35-E(2) of the Central Excise and Slat Act to file appeal in respect of two products only, viz., Steclin Injection I.M. and resteclin Injection I.M. Having exercised his power under that Section once, Collector could not exercise the same power for a second time and give direction to file appeal in respect of the remaining five products.

16. In reply to the argument advanced by the learned advocates, Shri Sunder Rajan has suited that the non-specified ingredients in question are not pharmaceutical necessities. Antioxidant docs not figure in the Notification No. 116/69-CE. As regards limitation he has stated that the show cause notice dated 2.5.81 is not a legal document because the proceedings already started with the Assistant Collector's letter dated 12.1.1978, on which the Collector (Appeals) remanded the case.

Collector (Appeals) did not quash the said proceedings. According to Shri Sunder Rajan, therefore, there was no necessity of issuing the show cause notice dated 2.5.81. He has also argued that the question of limitation was not raised before the lower authorities. They have not dealt with the question of limitation and hence the same could not be raised at this stage. Regarding the Collector's power under Section 35-E Shri Sunder Rajan has argued that this section does not provide that the Collector could not exercise the power of review for the second time against the same order. According to him, the Collector by implication reserved the right to deal with the products Resteclin Capsule and resteclin tablet and reclor Capsule at a later stage. He has, therefore, stated that the second order dated 9.1.1985 of the Collector under Section 35-E was not contrary to the provision of Section 35-E. Collector could exercise his power piecemeal in more than one instalment. Regarding the binding nature of Madras High Court judgment in the case of llocchst Pharmaceutical Ltd. (Supra), Shri Sunder Rajan has stated that High Court judgment is binding if the facts are on all fours. According to him, since the Tariff Item was different in the case before Madras High court, the said judgment is distinguishable and should not be followed by this Tribunal. He has cited this Tribunal's judgment in the case of Collector of Customs v.Shipping Corporation of

India, Regarding the certificates produced by M/s. Sarabhai Chemicals, Shri Sunder Rajan has stated that these are solicited certificates and therefore should not be relied upon. He has also stated that the affidavits dated 26.7.86 of Dr.B.P. Udwadia, Chief, Medical Division of Sarabhai Chemicals, copy of which is at page 153 of the appellants' paper-book, Vol.1 and the D.O. letter dated 15.7.86 of Dr. O.D. Gulati to Dr. B.P.Udwadia, copy of which is at page 154 of the said paper-book, were not before the lower authorities. Hence, no value should be attached to them.

17. Under Notification No. 116/69-CE dated 3.5.69, as amended, the Central Government has exempted patent or proprietary medicines falling under Item 14E of the Central Excise tariff and containing one or more of the ingredients specified in the Schedule annexed to the Notification, from so much of the duty of excise leviable thereon as is in excess of 2 1/2 per cent ad valorem. The Notification says that this exemption shall not apply to any medicine which contains any ingredient not specified in the said Schedule unless the ingredients in the medicine are pharmaceutical necessities such as diluents, disintegrating agents, moistening agents, lubricant, buffering agents, stabilisers and preservatives, provided that such pharmaceutical necessities are therapeutically inert and do not interfere with the therapeutic or prophylactic activity of the ingredient or ingredients specified in the Schedule.

Schedule Annexed To The Notification specified, inter alia, the following ingredients: 18. The disputed medicines contain, inter alia, the following specified and non-specified ingredients:Name of Medicines.

Name of ingre- Name of the ingredients not specified(a) Reclor Capsules Chloramphenicol Ascorbic acid(b) Resteclin Capsules Tetracycline Ascorbic acid & tablets. Hydrochloride(d) Resteclin Injection' Hydrochloride. Hydrochloride I.M.(e) Iso Benzacyl Forte. Isoniazid Pyridoxine Hydrochloride I.P.(vit. B6).

The benefit of the Notification is admissible to those medicines which contain the ingredients specified in the notification. Medicines containing non-specified ingredients are also eligible for the benefit of the notification if such non-specified ingredients are: (iii) Do not interfere with the therapeutic or prophylactic activity of

the specified ingredients.

There is no allegation that the aforesaid non-specified ingredients added in the disputed medicines, as above, interfere with the therapeutic or prophylactic activity of the ingredients specified in the Notification. There is no such allegation in the show cause notice.

There are also no such findings in the orders of the Assistant Collector and the Collector (Appeals). No such contention was raised by the Department in the appeals filled before the Collector (Appeals) against the order dated 12.1.83 of the Assistant Collector of Central Excise. No evidence has also been led by the Revenue to this effect. We are, therefore, to examine whether the non-specified ingredients are pharmaceutical necessities and whether they are therapeutically inert.

19. We shall first examine whether each of the ingredients, viz., Ascorbic(Vitamin C), Lidocaine Hydrochloride, and Pyridoxine Hydrochloride (Vitamin B6) are pharmaceutical necessities. As per the notification, pharmaceutical necessities include inter alia, buffering agents, stabilisers and preservatives. The opening paragraph of chapter 67 of Remington's Pharmaceutical Sciences describes pharmaceutical necessities. In this paragraph, it is stated that pharmaceutical necessities include, amongst other things, antioxidants, preservatives and miscellaneous agents.

Chapter 9 of the "Text Book of Pharmaceutical Formulation" by B.M.Mithal describes "stabilisers". The first paragraph of this Chapter reads as follows:-- The stability of a dosage from may refer to the stability of its physical form, of chemical composition or stability against microbial spoilage. These stability aspects are controlled generally by inclusion of certain materials which have the status of additives. In the popular terminology the matters that ensure stability of chemical composition or which help to prevent microbial growth arc talked of as stabilisers. Such materials will from the subject matter of this Chapter.

Antioxidants are discussed as stabilisers in this Chapter. We extract below the relevant paragraph from this Chapten:-- The chemical molecules present in a

formulation specially the molecules responsible for the therapeutic action, should preserve their chemical entries at all costs. Even very minor changes in their chemical configuration may result in drastic changes in their actions. Amongst the many changes brought about by environmental factors, the oxidative changes are very significant. Many molecules undergo oxidative degradations and as such this is the most severe type of degradation to be reckoned with. Fortunately, this aspect can be taken care of by inclusion of some additives known as antioxidants. The antioxidants have appreciable affinity for oxygen and when they are included in a formulation they compete for it affording protection to other oxygen sensitive compounds.

Some modern antioxidants used in food and pharmaceutical are listed in this chapter. Ascorbic Acid appears at serial No. 1 of this list at page 89 of this Chapter of the Book.

In Remington's Pharmaceutical Sciences, Chapter 67, it is stated that Ascorbic Acid is used as an antioxidant in foods and pharmaceuticals.

It is also used to prevent rancidity.

In "Martingale - The Extra Pharmacopocia', Twenty Eighth Edition by James E. Reynolds and Anne B. Prasad, Page 1655, it has been stated that:- Ascorbic acid has been used as an antioxidant in emulsions of fats and oils, in iron mixtures, in certain injections and eye-drops, and as a browing inhibitor in unprocessed cut fruits, fruit Pulps and juice.

At page 1155 of the United States Dispensatory Physicians and Pharmacology, Twenty seventh Editions, it is stated that Most intravenous dosage form contain ascorbic acid (in a 2 or 3 : 1 ratio with the antibiotic) as an antioxidant and buffer. Even so, solutions should be discarded after 8 hours.

At page 1491 of the United States Pharmacopoeia, Twenty-first Revision, and the National Formulary, Sixteenth Revision, there is a list of pharmaceutic ingredients. Ascorbic Acid appears as an antioxidant in this list.

In the article titled "Stability of Tetracycline and Riboflavin", published in the Journal of Pharmaceutical Sciences(March 1969, Volume 58, Number 3), Page 355, Lewis J. Leeson and Joseph F. Weildenheimer have stated as follows:- The stability of tetracycline solutions in the presence of riboflavin, light, and air was investigated. Although it was found that antibiotic potency loss occurred under these conditions, the addition of ascorbic acid to the system prevented the oxidative tetracycline degradation. There does, however, appear to be minor loss of tetracycline due to the ascorbic acid. This loss is covered by a normal product overage.

In the same article at page 356 of the Journal, while describing the effect of ascorbic acid, it is stated that ascorbic acid is both a solubiliser in parenteral tetracycline formulations and a commonly used antioxidant.

At page 217 of "Quality Control in Pharmaceutical Industry" by Murray S. Cooper it is stated that the darkening of tetracycline due to exposure to sunlight may be retarded by addition of Ascorbic Acid.

In the Hand-Book on Injectable Drugs, Second Edition, by Lawrence A.Trissel, Page 507, it is stated, The ascorbic acid stabiliser has been stated to be inactive when diluted in large-volume parenteral solutions(41) and, therefore, it has been recommended that such solutions be administered immediately after preparation. (41; 232P 944). But, in general, the acidity of the commercial tetracycline HCL preparations is sufficient to bring the PH to below 6.0.

Dr.H.P. Tipnis in his expert opinion (supra) has stated that Ascorbic Acid is commonly used as antioxidant and buffering agent in formulations.

20. The notification does not define the term "pharmaceutical necessities". It, however, specifies, by way of example, a few items as pharmaceutical necessities. Buffering agents, stabilisers and preservatives are specifically mentioned in the notification as pharmaceutical necessities. As already stated in the preceding paragraph, Chapter 67 of Remington's Pharmaceutical Sciences deals with pharmaceutical necessities. Opening paragraph of this chapter says that this Chapter described substances which arc of little or no therapeutic value, but which

are useful in the manufacture and compounding of various pharmaceutical preparations. Hence, they arc referred to as pharmaceutical necessities. It is also stated in the said paragraph that the substances described include antioxidants and preservatives.

The learned Departmental Representative for the Revenue has argued that Pyridoxinc Hydrochloride (Vitamin B6) and Lidocaine Hydrochloride have not been mentioned in Chaptcr-67 (Pharmaceutical necessities) in Remington's Pharmaceutical Sciences. He has also argued that although Ascorbic Acid has been mentioned under the heading "Antioxidants" and "Preservatives" in the said Chapter, it has not been used in the medicines under dispute as antioxidant or preservative. For the reasons stated later, we are unable to accept this argument. Various authorities cited and discussed in the preceding paragraph of our order clearly establish that Ascorbic Acid is an antioxidant, preservative and buffering agent. Page 217 of the Book "Quality Control in Pharmaceutical Industry" by Murray S. Cooper shows that exposure to sunlight causes tetracycline to darken, but this darkening may be retarded by the addition of Ascorbic Acid. This one of the reasons why this acid is added with the ingredients Chloramphenicol and Tetracycline Hydrochloride in the formulations. Ascorbic Acid, being an antioxidant, stabiliser and preservative, is undoubtedly a pharmaceutical necessity.

21. Notification mentions "buffering agents" as one category of pharmaceutical necessities. The term buffering agent has not, however, been defined in the notification. Shri Lakshminkumaran has cited a few authorities to explain what is meant by this term. These authorities have already been discussed in paragraph 9 of this order. Out of the said authorities, the definition given in Taber's Encyclopedia Medical Dictionary is quite relevant here. At page B-65 of the said Dictionary, it has been stated that buffer is a substance tending to offset reaction of an agent administered in conjunction with it.

Tetracycline Hydrochloride and Chloraphenicol have bad effects. Some of these bad effects have been discussed in paragraph 8(v) ante. To counteract the bad effects Pyridoxine Hydrochloride is added to the medicinal formulations. In this

arguments, summarised in paragraph 9 ante, Shri Lakshmikumaran has explained the various bad effects of the ingredient Isoniazid, quoting the authorities.

Pyridoxine Hydrochloride is added in Iso Benzacyl forte as an ingredient to prevent Vitamin B6 deficiency after prolonged use of this medicine. It is stated in Clinical Pharmacology, Fifth Edition, page 273-274 that Isoniazid interferes with pyridoxine metabolism, and induces pyridoxine deficiency. The" principal effects are peripheral neuropathy and sometimes anaemia and pellagra. Other adverse effects are stated to be mental disturbances, convulsions, incoordination, encephalopathy, alcohol intolerance, hepatotoxicity and a variety of allergic effect. In the "Text Book of Pharmacology". Second Edition, 1980 by W.C. Bowman and M.J. Rand, it is stated that Side-effects of Isoniazid include occasional liver dysfunction. The principal toxic effect as per this book is peripheral neuritis which may be prevented by simultaneous administration of Pyridoxine. It is also staged at page 406 of British Pharmaceutical Codex-1963, that the onset of peripheral neuritis on account of Isoniazid should be expected with doses of 10 milligrams per kilogram of body weight and prophylactic doses of 100 milligrams of Pyridoxine Hydrochloride should be given daily. At page 1202 of "The Pharmacological Basis of Therapeutics", Sixth Edition, 1980 by Godman & Gilman, it is mentioned that if Pyridoxine is not given concurrently, peripheral neuritis is the most common reaction to Isoniazid and occurs in nearly 20% of patients receiving 6 mg/kg of the drug daily. Similarly in "The extra Pharmacopoeia" Martindale, Twenty Seventh Edition (1977), page 1695, it is mentioned that a daily dose of 150 mg. may be given as a prophylactic against peripheral ncurilis in patients on Isoniazid therapy, children may be given 25 to 50 mg. daily. To prevent adverse effects of Isoniazid, Pyridoxine Hydrochloride has been added to Isoniazid in the formulation called Iso Benzacyl Forte.

Pyridoxal phosphate does not, however, prevent the effect the Isonia on the tubercle bacillus, as stated at Page 619 of "Medical Pharmacology-Principles & Concepts" by Andres Goth, Ninth Edition, 1978. Pyridoxine Hydrochloride will, therefore, have to be considered as pharmaceutical necessity falling under the category of buffering agents. The definition of buffering agent as found in taber's Medical dictionary (supra) fully covers this ingredient. We have already held that

Ascorbic Acid is an antioxidant, stabiliser and preservation and it clearly falls within the expression "pharmaceutical necessity". In a similar case of "Hoechst Pharmaceuticals Ltd." (supra) the Hon'ble Madras High Court has held that Ascorbic Acid was a buffering agent. In the said case, as in the present one, Ascorbic Acid was added to Tetracycline Hydrochloride.

22. The learned Departmental Representative has argued that quality control test reports showed that Ascorbic acid of high doses were used in the medicines and therefore, according to him, this was used as active ingredient. He has not, however, produced any authority to show that the Ascorbic Acid used in medicinal formulations in high doses along with antibiotics like Tetracycline Hydrochloride and Chloramphenicol cannot be considered as pharmaceutical necessity or that Ascorbic Acid used in high doses along with these two antibiotics should be considered as therapeutic necessity. No material has been placed before us to show that Ascorbic Acid and Pyridoxine Hydrochloride were added as ingredients in the disputed medicines for the treatment of scurvy and pyridoxine deficiency existing in the patients at the beginning of the treatment. From the copies of the operational raw material list of M/s.Sarabhai Chemicals, filed at pages 67 to 71 of the Paper Book submitted during the hearing, we observe that in the Steclin and Resteclin capsules the ratio of Tetracycline Hydrochloride and Ascorbic Acid is 2:1: in Reclor capsules 250 mg, the ratio of Chloramphenicol and Ascrobic Acid is about 1:1; and in Reclor capsules 500 mg. the ratio of these two ingredients is 2:1. The contention of this Company is that the quantum of Ascrobic Acid to be used as an anti-oxidant depends on the type of the pharmaceutical formulation in which it is used. From page 506 of Handbook on Injectable Deugs, 2nd, Edition, by Lawrence A. Trissel we observe that in Tetracycline Hydrochloride(Lederle) intramuscular injection, the proportion of Ascorbic Acid widely varies depending upon the sizes of the vials, as would be seen from the following composition given:- At page 1155 of the United States Dispensatory Physician and Pharmacology it is also mentioned that most intravenous dosage form contain Ascorbic Acid in a 2 or 3 : 1 ratio with antibiotics. These show that the quantum is not the criterion to be a pharmaceutical necessity. It is the purpose of use which is material. We, therefore, find considerable force in the argument of the appellants M/s. Sarabhai Chemicals.

23. Another point argued by Slid Sunder Rajan is that except in the case of Resteclin Intramuscular Injection, in no other medicine the label indicates that Ascorbic Acid was used as a buffer. Rule 96 of the Drugs and Cosmetics Rules, 1945 required such a declaration on the labels. As there is no such declaration, he has argued, it should be concluded that the non-specified ingredients were not pharmaceutical necessities. Shri Nanavati has replied to this argument saying that the Indian Pharmacopoeia, 1985 Edition, page 510 provides that in respect of Tetracycline Injection the label should state the name of the buffering or stabilising agent. In respect of the other medicines there is no such requirement. Hence, on the labels of other medicines the appellants have not indicated the name of the buffering agent on the labels. Shri Sunder Rajan has argued that the Indian Pharmacopoeia is not a statutory book, whereas the Drugs and Cosmetics Act and Rules are statutes and hence, the provisions of the same have to be followed. On this point, we observe that Section 9(b) of the Drugs and Cosmetics Act, 1940 provides that a drug shall be deemed to be misbranded if it is not labelled in the prescribed manner. Rule 96 of the Drugs and Cosmetic rules, 1945 framed under the Drugs and Cosmetics Act, 1940, prescribes the manner of labelling. This rule does not provide that on the labels of the medicines it should be declared which ingredient is used as buffering agent or stabiliser or preservative. The main object of the Drugs and Cosmetics Act, 1940 is to prevent sub-standards in drugs, for maintaining high standards of medical treatment. The first paragraph of the statement of Objects and Reasons of the Amending Act 68 of 1982, which is reproduced below, makes this position clean The Drugs and Cosmetics Act, 1940 regulates import into, manufacture, distribution and sale of drugs and cosmetics in the country. The problems of adulteration of drugs and also of production of spurious and sub-standard drugs are posing serious threat to the health of the community. It is, therefore, considered necessary to amend the Drugs and Cosmetics Act, so as to impose more stringent penalties on the antisocial elements indulging in the manufacture or sale of adulterated or spurious drugs of drugs not of standard quality which are likely to cause death or grievous hurt to the user. This opportunity is also being availed of to incorporate certain other provisions on the other aspects of effective control on the manufacture, distribution, sale of drugs and cosmetics on the basis of experience gained in the

working of the Act.

Section 9(b) of the aforesaid Act provides that the labelling should be done in the prescribed manner. There is no such requirement in the Central Excise Act or Rule or the Tariff. The Notification No.116/69-CE also does not stipulate that labels of the medicines should indicate which ingredients in the medicines have been added as pharmaceutical necessities. In the decision in the case of Glaxo Laboratories (India) Ltd. v.Union of India and Ors., it was held by Bombay High Court that there is nothing in Tariff Entry 28 which suggests that the definition of "drug" under the Drugs and Cosmetics Act, 1940 or under the Drugs (Price Control) Order should be read into it.

24. During the hearing before us, the learned advocate for M/s.

Sarabhai Chemicals submitted specimen copy of labels of the medicines.

The following are declared, inter alia, on the labels of the medicines mentioned below:- Chloramphenicol with Ascorbic acid capsules Each capsule contains:- Chloramphenicol IP 250 mg Ascorbic Acid IP 250 mg.

contains:-Tetracycline Hydrochloride IP 250 mg Ascorbic Acid IP 250 mg.

Tetracycline Hydrochloride B. Vet.C. 50 mg Lidocaine Hydrochloride B.Vet. C.200 mg Magnesium Chloride 235 mg buffered with 1.5.G. Ascorbic Acid B.Vet.C. Tetracycline Hydrochloride USP 100 mg Lidocaine Hydrochloride USP 40 mg Magnesium Chloride 47 mg Ascorbic acid USP as buffer 0.3 gm. Expect Resteclin I.M. injection, which is manufactured according to United States Pharmacopeia, the other medicines as described above are manufactured by the appellants in accordant with the Pharmacopoeia of India (The Indian Pharmacopoeia). Under the Heading "Ascorbic Acid" in the Indian Pharmacopoeia, Third Edition, pages 49-50, there is no indication about the labelling of Ascorbic Acid Tablets and Injections. At page 283 of the said edition of Indian Pharmacopoeia, Lidocaine Hydrochloride has been described. At pages 283-284 of the said book, Lidocaine and Adrenaline Injection has been described. For this injection, there is an indication for labelling, which reads as follows:- There is no direction regarding

labelling in respect of Pyridoxine Hydrochloride which is found to have been discussed at pages 430-431 of the same book. Tetracycline Hydrochloride is discussed at pages 508-511 of the Indian Pharmacopoeia, Volume II, Third Edition. Under Tetracycline Hydrochloride, the following directions are found regarding labelling:- Labelling: The label on the container states(1) the date after which the contents are not intended to be used: (2) the storage conditions; (3) whether or not the contents are intended for parenteral administration.

Under Tetracycline Capsules, at page 509 of the said Volume, the following indication appears regarding labelling:- Labelling: The label on the container states (1) the date after which the capsules are not intended to be used; (2) the storage conditions.

At page 511 of the same book, the following indications are available in respect of Tetracycline tablets:- Labelling: The label on the container states (1) the date after which the tablets are not intended to be used; (2) the storage conditions.

Tetracycline Injection has been discussed at pages 509-51 of the same volume of Indian Pharmacopoeia. The following direction appears under the heading "Tetracycline Injection:- Labelling: The label on the sealed container states (1) the weight of Tetracycline Hydrochloride contained in it; (2) the name of the buffering or stabilising agent; (3) that the contents are to be used for intravenous injection only, in a well-diluted solution; (4) the date after which the contents are not intended to be used; (5) the storage conditions.

At page 781 of "U.S. Pharmacopeia", Twentieth revision, The National Formulary, Fifteenth Edition, Tetracycline Hydrochloride for Injection has been discussed. It is stated therein that Tetracycline Hydrochloride for Injection conforms to the regulations of the Federal Food and Drug Administration concerning antibiotic drugs (446.281) see Antibiotics [1011]. It is a dry mixture of Tetracycline Hydrochloride, one form of which contains Magnesium Chloride or Magnesium ascorbate and one or more suitable buffers, and may contain one or more suitable preservatives, solubilizers, stabilizers, and anesthetic agents, and the other form of which contains one or more suitable stabilizing agents. It contains not less than 90.0 percent and not more than 115.0 percent of the labelled amount of

$C_{22}H_{24}N_2O_8$. HCL.

Regarding labelling, the following indication has been given for Tetracycline Hydrochloride Injection:- Labelling - Label Tetracycline Hydrochloride for injection that contains an anaesthetic agent to indicate that it is intended for intramuscular administration only.

At page 448 of the said Edition of U.S. Pharmacopoeia, the following indication appear under "Lidocaine Hydrochloride Injection":- Labclling-Injections that are of such concentration that they are not intended for direct injection into tissues are labeled to indicate that they are to be diluted prior to administration.

From the above, we observe that only in respect of tetracycline Hydrochloride Injection there is a direction at page 510 of the Indian Pharmacopoeia to the effect that the label should state the name of the buffering or stabilizing agent. M/s. Sarabhai Chemicals have manufactured these medicines according to Indian Pharmacopoeia. Their contention that they have followed the instructions contained in the pharmacopoeia, therefore, appears to be correct. In the absence of any specific provision in the drugs and Cosmetics Act, 1940 and the Rules made thereunder, the appellants cannot be blamed for not declaring the name of the buffering agent or stabilizing agent on the labels of all the medicines.

M/s. Wander India Limited have manufactured Iso Benzacyl Forte according to India Pharmacopoeia. Isoniazid and Pyridoxine Hydrochloride are two ingredients of this medicine. In the Indian Pharmacopoeia, there is no direction about labelling either under Isoniazid or under Pyridoxine Hydrochloride.

25. Buffering agents, stabilisers and Preservatives are specifically mentioned in the Notification itself. Therefore, in the absence of any materials before us to show that Ascorbic Acid and Pyridoxine Hydrochloride have been used in the disputed medicines, not as pharmaceutical necessities, but have been used as therapeutic necessities only, we have to reject the argument of the learned Departmental representative and hold that these ingredients are pharmaceutical necessities. The argument of the learned Departmental Representative that pharmaceutical necessities are such materials which are meant for compounding and manufacture

of medicine but not for treatment of any said effects, has also to be rejected.

26. So far as Lidocaine Hydrochloride is concerned, this is used as an ingredient in he Injections Steclin I.M. and Resteclin I.M. as an anaesthetic. The learned Departmental Representative has argued that anaesthetic is not included in the list of pharmaceutical necessities given in the Notification. According to him, for qualifying as pharmaceutical necessity, the ingredient should be of any of the types mentioned in the Notification. We, however, observe that after the expression "pharmaceutical necessities" and before the names of the substances diluents, disintegrating agents, etc., the words "such as" have been used. The list of pharmaceutical necessities given in the Notification is not, therefore, exhaustive, but it is only illustrative. If the list was exhaustive, then the world "namely" would have been used instead of the words "such as". In the opening paragraph of Chapter 67 of Remington's Pharmaceutical Sciences (supra) a few substances have been described by way of illustrations of the pharmaceutical necessities. The relevant sentence in the said paragraph includes inter alia "Misc. Agents" as pharmaceutical necessities. The expression "Misc. Agents" has not, however, been clarified anywhere in the said Chapter. In his expert opinion, Dr. HP. Tiphis, Principal and Prof. of Pharm-Chemistry, Bombay College of Pharmacy, however, included local anaesthetic as one of the pharmaceutical necessities. The Assistant Director, Food and Drugs Control Administration, Baroda, in his certificates, as referred to in paragraph 10(vi) ante, has stated that Ascorbic acid and Lidocaine Hydrochloride in the intramuscular injections "Steclin" and "Resteclin" are pharmaceutical necessities.

Lidocaine Hydrochloride has been used in these injections to reduce pain at the time of administering these injections. In other words, this ingredient has been added to the injections so that they become easily acceptable to the patient and the injections can be tolerated.

At page 1186 of the technical book "The Pharmacological Basis of Therapeutics", Sixth Edition by Godman and Gilman, it is stated that because of local irritation and poor absorption, intramuscular administration of Tetracycline is generally unsatisfactory and is rarely indicated and that preparations containing a local

anaesthetic are better tolerated on intramuscular injection. At page 1159 of the "United States Dispensatory physician and Pharmacology' Twenty Seventh Edition, copy of which was filed by Shri Nanavati at the time of hearing, states that "intramuscular injection of tetracycline is painful despite the local anaesthetic in some formulations".

It is interesting to note that despite the reported lack of irritation at the injection site, in preparing an intramuscular dosage form, a local anesthetic (Lidocaine) has been added.

At page 781 of the United States Pharmacopoeia, Twentieth Revision and National formulary, Fifteenth Edition, it is stated inter alia that Tetracycline Hydrochloride Injection contains one or more suitable preservatives, stabilizers, solubilizers and anaesthetic agents. It is nobody's case that Lidocaine is used in the injections for curing the disease for which the injections are administered. Although anaesthetic have not been specifically mentioned as one of the pharmaceutical necessities in the Notification, the opening paragraph of Chapter 67 of Remington's Pharmaceutical Sciences includes "Misc. agents" as pharmaceutical necessities. In our view, anaesthetic will fall within the category of "miscellaneous agents" as a pharmaceutical necessity.

In the absence of any material before us to show that Lidocaine Hydrochloride has been added in the injections for the purpose of curing the disease for which the injection is administered, we hold that Lidocaine, being an anaesthetic, is a pharmaceutical necessity.

27. The result of our foregoing discussions is that all the three non-specified ingredients, viz., Ascorbic -Acid, Pyridoxine Hydrochloride and Lidocaine Hydrochloride used by the manufacturers in the disputed medicines are pharmaceutical necessities, the first conditions in the proviso to the Notification, therefore, fulfilled.

28. The next point to be considered by us in whether Ascorbic Acid, Pyridoxine Hydrochloride and Lidocaine Hydrochloride are therapeutically inert. The learned departmental representative has cited many authorities, vide paragraph 8 ante, in

support of his argument that these three non-specified ingredients have got therapeutic effect and hence, these cannot be called therapeutically inert. He has quoted from page 430 of "Pharmacopoeia of India (The Indian Pharmacopoeia), volume I, Third edition, which described doses of Pyridoxine Hydrochloride (Vitamin B6) for Prophylactic purpose 2 mg daily. He has also quoted from page 192 of "The Principles and Practice of Medicine" by Sir Stanley Davidson and John Macleod, in which disorders due to Pyridoxine (Vitamin B6) deficiency have been discussed. The learned Departmental Representative has also cited various authorities to show that Ascorbic Acid is an ingredient for the prevention and cure of scurvy, in addition to its use in the treatment of various other diseases. The authorities relied on by him have been discussed in details in paragraph 8 ante. Regarding Lidocaine Hydrochloride, the case of the Revenue is that it is a local anaesthetic and is used for reducing pain of the injections. The contention of the manufacturers is that the term "therapeutically inert" should not be interpreted as therapeutically inert in absolute term. Their argument is that the non-specified ingredients, even if they are themselves therapeutically active, will qualify for the benefit of the Notification No. 116/69-CE if they are therapeutically inert in the medicines in which they are used. According to them, therapeutically inert is a relative term. In support of this argument, they have relied on the judgment of Madras High Court in the case of Union of India v. M/s. Hoechst Pharmaceuticals Limited in O.S. Appeal No. 34 of 1965 and W.P. Nos. 23 to 27 of 1970. In the said case, the interpretation of Entry 28(27) of the Customs Tariff was under consideration before the Hon'ble High Court. The said Entry reads as follows:- Antibiotics, such as Streptomycin, Gramicidin, Tyrocidine and Tyrothricin and preparations which contain only one antibiotic and are free from other therapeutic ingredients but not including penicillin in bulk, and penicillin and products specified in Items No. 28(26) and 28(26A).

M/s. Hoechst Pharmaceuticals Ltd. manufactured Tetracycline Hydrochloride injections which contained, along with the antibiotic, a percentage of Ascorbic Acid. The question arose as to whether inclusion of Ascorbic Acid in the said injection would by itself take the medicine out of the Tariff Entry 28(27). The findings of the Hon'ble High Court in that case are given below:- Dr. Sanjivi, who gave evidence for the respondent at trial, was definitely of the view that

tetracycline hydrochloride, when administered to a patient has no therapeutic effect on him of Ascorbic Acid. That acid is administered for Vitamin C deficiency, but surely tetracycline hydrochloride cannot be administered for that purpose merely because it contained a percentage of Ascorbic acid. In Entry 28(27), when mention is made of therapeutic ingredients it has reference to its effect rather than the factum of its user as a component of an antibiotic. Dr.Sanjivi, in answer to a question whether Ascorbic Acid was a therapeutic agent or a therapeutic ingredient, stated that in different circumstances it played different roles, and a pure chemical, it may be an ingredient and under certain conditions it may also be a therapeutic agent when it is merely an ingredient, it cannot be therapeutic agent He illustrated his meaning by stating that no Doctor will administer tetracycline Hydrochloride for Vitamin C deficiency. We are of the view that Sadasivam, J., was right in holding that the respondents' drug did fall within the purview of Entry 28(27). As a matter of fact, as already indicated, Ambramycin Achromycin, Steclin, Tetracycline do contain more or less a percentage of Ascorbic Acid.

It has been added as an ingredient of tetracycline Hydrochloride as the evidence discloses, for the purpose of giving a buffer effect, that is to say, to stabilise it when administered in injection. It has not been used as an ingredient for die purpose of therapeutic effect. When we find the expression "therapeutic ingredients" in Entry 28(27), we must have regard to the meaning of each one of those words in the phraseology. It must be an ingredient, at the same time, it must have therapeutic effect In this case, it is clearly demonstrated by the evidence on record that Ascorbic Acid used in the respondents' Tetracycline Hydrochloride is not intended to and does not have any therapeutic effect, but it has been added for its buffer effect. We, therefore, upheld the decree of Sadasivam, J.In the aforesaid case, the Hon'ble High court held that the injection, though containing Ascorbic Acid, fell under tariff Entry 28(27).

Antibiotics, which contained only one antibiotic and were free from other therapeutic ingredients, were covered by that tariff Entry. In spite of the fact that Ascorbic Acid was contained in the injection, the Hon'ble High court held that the antibiotic Tetracycline Hydrochloride injection was covered by that Tariff entry as the Ascorbic Acid was not included therein for the purpose of therapeutic effect In

the present case of the appellants, Ascorbic Acid, Pyridoxine Hydrochloride and Lidocaine Hydrochloride and included in the disputed medicines not for the purpose of therapeutic effect, but as pharmaceutical necessities. These ingredients have no therapeutic effect in the medicine or for the treatment of the diseases for which the disputed medicines are used. Although the three ingredients themselves may have some therapeutic value, the same will not stand in the way of the medicines being eligible for the benefit of the Notification as these ingredients are not used for any therapeutic purpose in the medicines. Pyridoxine Hydrochloride is used in the medicines to counteract the bad effects of the antibiotics, Chloramphenicol and Tetracycline Hydrochloride. Ascorbic Acid was used in the medicines as antioxidant, stabiliser and preservative. These ingredients were not used in the medicines for the treatment of any pre-existing disease. The Lidocaine Hydrochloride is used in the injections Steclin I.M. and Resteclin I.M. as anaesthetic to minimise the pain at the time of administering the injections. It is not used for curing the diseases for which the injections are administered. It has no therapeutic value in the two intramuscular injections under dispute before us. The ratio laid down in the judgment of Madras High Court is squarely applicable to the present case. In his expert opinion, Dr. Tipnis has stated that Ascorbic Acid, Pyridoxine Hydrochloride and Lidocaine Hydrochloride are therapeutically inert and do not interfere with the therapeutic or prophylactic activity of the specified ingredients in the medicines in dispute. The Assistant Director, Food and Drugs Control Administration, Baroda has also given certificate to the same effect In the circumstances, the ratio laid down in the judgment of Madras High Court applies to the present cases.

Following the said judgment, we hold that the three non-specified ingredients in question are therapeutically inert Therefore, me second condition of the proviso to the Notification is also fulfilled. It is neither alleged nor is there any materials to show that the aforesaid non-specified ingredients interfere with die therapeutic or prophylactic activities of the specified ingredients, viz., chloramphenicol and Tetracycline Hydrochloride.

29. In the light of the foregoing discussions, we hold that the medicines in dispute, namely, Resteclin capsules and tablets, Reclor capsules, Steclin Injection I.M.,

Resteclin Injection I.M. and Iso Benzacyl Forte are eligible for the benefit of the Notification No.116/69-CE dated 3.5.1969.

30. Revenue has relied on two earlier decisions of this tribunal which are reported in 1984 (18) ELT 106 and 1985(19) ELT 272. In the first mentioned decision, this tribunal held that Lidocaine Hydrochloride was not therapeutically inert as "Anaesthetic" is not mentioned in the Notification No. 116/69-CE and it is not a category similar to specified categories, such as, diluents, disintegrating agents, etc., and hence, medicine containing Lidocaine Hydrochloride was not eligible for the benefit of the notification. In the second mentioned decision, the Tribunal held that Vitamins were know to be employed in the treatment of deficiency diseases and had a place of their own in the therapy and prophilaxy of humans as well as animals and the vitamins had a role to perform which was quite distinct from that of an antibiotic. The tribunal held that the Ascorbic Acid was not therapeutically inert and hence the benefit of the notification was not available to the medicines containing Ascorbic Acid. The judgment of Madras High Court was not available before the Tribunal when they decided the aforesaid two cases of Unique Pharmaceuticals Lab. and Piya Pharmaceuticals Works respectively. We must follow the judgment of Madras High Court as no contrary judgment of any other High Court of Supreme Court has been brought to our notice. We have, therefore, followed the Madras High Court decision in preference to the two earlier decisions of this Tribunal.

31. In the result, the appeals filed by the Revenue fail and those filed by M/s. Sarabhai Chemicals, Vadodara succeed.

32. Shri Nanavati has argued on legal points, besides merits. The appellants have also raised the question of limitation. Since we are dismissing the appeals of the revenue and allowing the appeals filed by M/s. Sarabhai Chemicals on merits, any findings on the legal points as well as on limitation will be of academic interest only. We do not, therefore, consider it necessary to give any findings on those points.

32. In the result, Orders-in-appeal No. D-570/PN-97/83 dated 10.3.83 and E-2127/B.II-411/83 dated 19.11.83 are upheld and the appeals No.ED/SB/447/83-C

and ED/SB/335/84-C are dismissed. Orders-in-appeal No.M-1554-1555/80-693-694/86/R dated 3.9.86 are set aside and the appeals No. E/2155/86-C and E/2173/86-C are allowed.

33. I have given a careful thought to the order recorded by Brother Shri Mandal and have not been able to persuade myself to agree with his findings in respect of reclor capsules and resteclin capsules and tablets manufactured by M/s. Sarabhai Chemicals. In the two sets of appeal - 2 pertaining to M/s. Wander India Ltd. (Appeal Nos.

ED/SB/1447/83-C and ED/SB/335/84-C) and two appeals pertaining to M/s.

Sarabhai Chemicals (Appeal Nos. E/2177/86-C and E/2155/86-C) the common issue involved is the availability of the benefit of Notification No.116/69 as amended. In terms of this Notification partial exemption from Central excise duty has been granted to patent or proprietary medicines falling under tariff Item 14-E of the Central Excise Tariff, if such medicines contain one or more of the ingredients specified in the Schedule annexed to the Notification. The benefit of this Notification in terms of this Notification could also be extended to such of those medicines which in addition to the ingredients specified in the Schedule as above, also contain any ingredient/ingredients not specified in the said Schedule, if the non-specified ingredients in the medicine were for pharmaceutical necessities, such as diluents, disintegrating agents, moistening agents, lubricants, buffering agents, stabilisers and preservatives; and provided that such pharmaceutical necessities were therapeutically inert and did not interfere with the therapeutic or prophylactic activity of the ingredients specified in the Schedule. In the case of M/s. Wander India Ltd. the product involved is "Iso Benzacyl Forte" having ingredients specified in Notification 116/69 and non-specified ingredient Pyridoxine Hydrochloride (Vitamin B6) and the question that was posed was whether the addition of Vitamin B6 will disentitle this product from the benefit of Notification 116/69. The issue in this context was also considered by a 2-Member Bench of this tribunal and the issue was considered at length as to whether the Vitamin B6 could be considered as pharmaceutical necessity for the purpose of the benefit of this Notification in respect of the tablets in question and the other requirements of

this Notification were satisfied by this ingredient. In the order recorded by me and by which the matter was referred to the 5-Member Bench as the view taken in the order was at variance with the earlier view taken in another order, the matter was examined in the context of the parameters of the Notification for the purpose of the exemption under the Notification 116/69 in respect of the following as to whether Vitamin B6 added could (1) qualify as a pharmaceutical necessity as a diluent, buffering agent, stabiliser, preservative, etc.

(2) if it qualified as a pharmaceutical necessity as in (1) above whether it was therapeutically inert; and (3) whether it interfered with the therapeutic or prophylactic activity of the other ingredients in the said tablets. The view held in the said order by the 2-Member Bench has been accepted in the order recorded by Brother Shri Mandal and it has been held that the addition of Vitamin B6 in the Iso Benzacyl Forte tablets satisfied the requirement of the Notification.

The findings recorded in the said order for convenience of reference in regard to the above are as under:- So far as the third criterion is concerned it is accepted by both the sides that Vitamin B6 in the said tablets does not interfere in any way with the activity of the other ingredients in these tablets.

Their claim in this regard is based on the definition of buffering agent as given in the Taber's Cyclopedia Medical Dictionary. The definition of buffer given is as under: 1. A substance esp. a salt of the blood tending to preserve original hydrogen ion concentration in the solution upon adding an acid or a lease.

2. A substance tending to offset reaction of an agent administered in conjunction with it.' They have claimed and cited evidence in this regard from printed literature that long term isoniazid therapy in some cases results in peripheral neuritis and if pyridoxine is not given concurrently peripheral neuritis is the most common reaction to this therapy in nearly 20% of the patients received 6 mg/kg of the drug (the recommended dosage) daily. He pleaded that the therapy caused some liver dysfunction resulting in the vitamin B6 deficiency and on account of which the said side effect occurred. The Revenue has, however, pleaded that buffering agent mentioned in the notification should be taken to mean only such materials as are for compounding and manufacture of the medicine but not for treatment of any

side effects. The learned JDR for the Department relied for this purpose on the scope of the term buffering agents as mentioned in The Condensed Chemical dictionary, 10th Edition by Gessner G. Hawley. He pleaded that the buffering agent has added to maintain PH value and was in the nature of a stabiliser and that stabiliser in this Dictionary has been described as under Any substance which tends to keep a compound mixture or solution from changing its form or chemical nature. The stabilisers may retard a reaction rate, preserve a chemical equilibrium, act as antioxidants, keep pigments and other components in emulsion form or prevent the particles in a colloidal suspension from precipitating.

The learned JDR pleaded that following the principle of ejusdem generis the words buffering agent should take its meaning from other pharmaceutical necessities mentioned in the notification. His plea is that the buffering agent has to be such as corresponds in properties to the other items mentioned and could only be the one which was intended for manufacture of the medicine or its compounding purposes. Vitamin B6, he pleaded, was not meant for manufacturing and compounding need of the specified scheduled medicines in the notification. The plea is that the word buffering agent used should be taken to mean only an agent which helps in the formulation of the drug and should functionally be of the same type as other items mentioned before and after the words "buffering agent" in the notification.

We observe the word "buffering agent" is specifically mentioned in the notification. The principle of ejusdem generis will only apply when the scope of word which follow the enumerated things constitute a genre and general words which follows these have to be interpreted. In the instant case buffering agent has been mentioned specifically and therefore what it stands for has to be understood as such. What is relevant is as to how the buffering agent is known in the pharmaceutical industry and the medical field. In this context we notice that Buffer as defined in the Butterworths Medical Dictionary: Second Edition is as under: 1. A combination of substances present in solution which tends to control the concentration of hydrogen ions in that solution and maintain it at a level in spite of the addition of comparatively large amounts of acid or alkali; a shock absorber against change in PH value, usually a mixture of a weak base and its salt with a strong acid, or a weak acid and its salt with a strong base.

2. Anything that slows or inhibits the immediate action of a chemotherapeutic agent. Buffer action. The neutralizing of acids or alkalis without affecting the PH value of the solution. Buffer capacity. The measure of buffer action expressed in hydrogen ions neutralized. Buffer index. Buffer value (See below) Buffer pair. A weak acid and its salt or a weak base and its salt, which act together as a buffer system. Buffer salt A salt of a low dissociation acid, such as a carbonate, acetate or phosphate, which acts as a buffer. Buffer solution. A solution of buffers which maintains a desired PH value; a specially prepared buffer solution to produce required PH values. Buffer system. A mixture of buffers designed to produce a determined buffer action. Buffer value. The buffer action of a solution measured in terms of the standard acid or alkali necessary to effect a change in the PH value of the solution (ME buffet.) 34. We observe that technically speaking the term (''Buffer'') is for maintaining PH value. We find that buffering agent as such does not figure in the Chapter on Pharmaceutical necessities cited supra nor the term has been defined in the notification. It has been shown by the respondents that at least in one medical dictionary the buffer is a substance to offset the reaction of an agent administered in conjunction with this. In that sense vitamin B6 in the said tablets can be considered as a buffering agent.

We observe that the pharmaceutical products marketed for treatment of various diseases and medical conditions both as prophylactic and therapeutic agents, the various steps for preparation of a medicine for a desired end-use essentially comprise compounding of the medicine with additional ingredients, if necessary, so that (1) it has a reasonable shelf life; (2) it is in a form that it can be administered/made usable for treatment; (3) it can be absorbed in the human system; (4) it is acceptable to the human system.

The additives added for achieving the objectives at (1) to (3) are in the nature of diluents, stabilisers, etc. All these additives for various purposes will be in the nature of pharmaceutical necessity.

After medicine has been administered in the human/animal system it has to be such as is acceptable to the system and can be tolerated in it.

This would mean'the medicine has to be in such a formulation along with some other additions that the adverse side effects are taken care of as otherwise in case the medicine produces adverse effects it cannot be recommended for treatment if some other alternate medicines are available. In fact it is a well known fact that whenever a new drug is discovered before it is approved for general use by the concerned authorities, be it in India or abroad, one factor taken into reckoning for the purpose of this recommendation is side effects that the medicine would produce. In this context therefore if a particular drug causes side effects the addition of another drug to counteract the side effect(s) will have to be considered as a pharmaceutical necessity as otherwise particular drug cannot be administered for treatment purposes because of the side effects that it may create. In the present case it has been show through authentic literature that isoniazid therapy over a long period produces peripheral neuritis. The addition of vitamin B6 to counteract this side effect has therefore to be considered pharmaceutical necessity and vitamin B6 added has to be considered buffering agent. In this context we observe that in the Taber's Dictionary cited the buffering agent has been defined as a substance to offset reaction of an agent administered in conjunction with this. The Revenue have cited the Chapter on Pharmaceutical Necessity in Remington's book in this regard. We observe that while certain range of pharmaceutical necessities have been discussed therein, no specific discussion is there of the buffering agent in that Chapter. In view of what we have stated above, we hold that Vitamin B6 added qualifies for consideration of buffering agent and therefore satisfies the first criterion as indicated above by us so far as the exemption notification is concerned." I have reproduced in entirety the findings in the said Miscellaneous Order as based on this rationale I am holding the view different from what has been held in Brother Shri Mandal's order in respect of the two products as mentioned in the opening paragraph of the order above.

35. After hearing the arguments in the present case, I continued to subscribe to the view cited supra and I hold that addition of vitamin B6 in Iso Benzacyl Forte tablets is a pharmaceutical necessity and I find that Brother Shri Mandal's finding in this regard also more or less follow the same rationale. In regard to the satisfaction of the second parameter in the case of Iso Benzacyl Forte tablets that whether Vitamin B6 in the said tablets could be considered as therapeutically inert,

following the ratio of the judgment of the Hon'ble High Court of Madras in the case of Hoechst Pharmaceutical Private Ltd., Bombay v.Collector of Customs, Madras, (O.S. Appeal No. 34 of 1965 and Writ Petition No. 23 to 27 of 1970) given in the context of addition of Ascorbic Acid in Tetracycline injections and the findings recorded in our Miscellaneous Order extracts of the same reproduced above, I hold that Vitamin B6 can be considered as therapeutically inert and our findings in this regard are as under: We observe that ingredient in a medical formulation can be considered as therapeutic agent only when its administration will have a therapeutic effect in the context of the therapy for which medicine is given. This would mean that there should be a pre-existing condition which the ingredient will help to cure. The quantum of such ingredient should also be such that it would take care of the condition for which the ingredient is recommended as therapeutic agent. We observe that it is not the case of the Revenue that the quantum of Vitamin B6 present in the tablets is such that it is recommended for the treatment of Pellagra or other conditions created by Vitamin B6 deficiency. The quantum of Vitamin B6 in the tablet is 2.5 mg and from the literature produced before us it is seen that the addition of this quantity is to minimise the toxic effect of the long term Isoniazid therapy. All that the vitamin B6 dose is that it prevents the peripheral neuropathy which may result due to Isoniazid therapy. From the evidence produced it appears that Isoniazid interferes with the system in such a manner that a deficiency of Vitamin B6 results in some case and administration of Vitamin B6 makes up for that deficiency. In fact, Vitamin B6, as such, treats no condition but is given to counterbalance the effect of Isoniazid on the system. In this view of the matter, therefore, addition of Vitamin B6 can be taken to be not for therapeutic purposes and is, therefore, inert so far as the patients who are being administered Isoniazid therapy by administration of Iso Benzacyl Forte tablets. In our view whether an ingredient is therapeutically active or inert has to be seen with reference to the therapy in question and the effect on the system it creates.

I observe that in the order recorded by Brother Shri Mandal essentially the same rationale as above has been followed while giving the findings in regard to the availability of the Notification 116/69 and holding that the non-specified ingredients satisfied 3 parameters discussed above for the purpose of the availability of the benefit of the Notification for the said tablets. As mentioned in the opening

paragraph of this order, I agree that in the case of Iso Benzacyl Forte tablets the addition of Vitamin B6 satisfies all the requirements of the Notification in question for the reasons set out in the paragraph above in respect of the other products manufactured by Messrs. Sarabhai Chemicals dealt with in the other two sets of appeals my views and findings based on the rationale as set out above are as under.

36. The products involved and the declared ingredients on the labels in respect of the same are the following:- Chloramphenicol with Ascorbic Acid capsules Each capsule contains:-Chloramphenicol IP 250 mg. Ascorbic Acid IP 250 mg.

Tetracycline with Vitamin C capsules. Each capsule contains:-Tetracycline Hydrochloride IP 500 mg. Ascorbic Acid IP 250 mg.

Tetracycline with Vitamin C. Each tablet contains:- Tetracycline Hydrochloride IP 500 mg. Ascorbic Acid IP 250 mg.

Tetracycline Hydrochloride B.Vet.C.500 mg. The vial contains : Tetracycline Hydrochloride B. Vet.C.500 mg. Lidocaine Hydrochloride B.Vet.C. 200 mg. Magnesium Chloride 235 mg. buffered with 1.5. G. Ascorbic Acid B.Ve LC. Tetracycline Hydrochloride USP 100 mg. Lidocaine Hydrochloride USP 40 mg. Magnesium Chloride 47 mg.

Ascorbic Acid USP as buffer 0.3 gm. The specified ingredients as set out in the Schedule to Notification 116/69 in respect of the above products are chloramphenicol at Sl.No. (i) Tetracycline in respect of product at Sl. Nos. (ii) to (v) and the ingredients added to the product which are non-specified in the Notification are Ascorbic Acid in respect of products at Sl. Nos. (i),(ii),(iii) and Ascorbic Acid and Lidocaine Hydrochloride and Magnesium Chloride in respect of products at Sl. Nos. (iv) & (v). The issue in respect of these products is whether the addition of Ascorbic Acid and Lidocaine Hydrochloride can be taken to be permissible for the purpose of the exemption Notification in these products. The point to be decided is whether the Ascorbic Acid and the Lidocaine Hydrochloride have been added as pharmaceutical necessities in terms of the Notification and, if so, whether these could be taken to be therapeutically inert So far as the addition

of Lidocaine Hydrochloride in products at Sl. Nos. (iv)&(v) above is concerned, the averment based on United States Dispensatory Physician and Pharmacology, 27th Edition, page 1159, is that "intramuscular injections of Tetracycline is painful despite the local anaesthetic in some formulations".

At the same page it is stated "it is interesting to note that despite the reported lack of irritation at the injection site, in preparing an intramuscular dosage form, a local anaesthetic (Lidocaine) has been added." Further, at page 781 of the Unites States Pharmacopoeia, Twentieth Revision and National Formulary, Fifteenth Edition, it is stated inter alia that Tetracycline Hydrochloride Injection contains one or more suitable preservatives, stabilizers, solubilisers and anaesthetic agents. It is seen that Lidocaine has been added to relieve the pain caused by the administration of Tetracycline Hydrochloride at the injection site. The question to be considered is whether the use of Lidocaine in this context could be taken to be pharmaceutical necessity. As in the case of addition of Vitamin B6 in the case of Iso Benzacyl Forte tablets, as mentioned earlier, Lidocaine is not added to treat any pre-existing condition of pain at the injection site before the administration of the medicine but it is added to relieve side effect created by the administration of Tetracycline Hydrochloride. I have held in the context of addition of Vitamin B6 that when an ingredient has been added to take away the side effect of the administration of a medicine the same would qualify as a buffering agent based on the definition of "buffering agent" as given in Medical Dictionary cited supra in the extract of the Miscellaneous Order.

Lidocaine added, therefore, in the injections can be considered as a pharmaceutical necessity as addition of buffering agents is permissible in terms of the Notification 116/69. Brother Shri Mandal has held the addition of Lidocaine as permissible in terms of the Notification holding the same to be as a miscellaneous agent, which category figures as pharmaceutical necessity in the Remington's Pharmaceutical Sciences referred to in his order and cited by the Revenue. I, therefore, hold that the addition of Lidocaine Hydrochloride in the products at Sl.

Nos. (iv) & (v) viz., Steclin and Resteclin manufactured by Sarabhai Chemicals is permissible for the purpose of Notification 116/69 as a pharmaceutical necessity

holding it as a buffering agent The next point for consideration in this context is whether Lidocaine Hydrochloride could be considered as the therapeutically inert and whether it can be taken to interfere with the therapeutic or prophylactic property of Tetracycline Hydrochloride. It is nobody's case that Lidocaine Hydrochloride interferes with the therapeutic or prophylactic properties of the specified ingredients viz., Tetracycline Hydrochloride. The point, therefore, that remains to be considered is whether the Lidocaine can be taken to be therapeutically inert. This point has been discussed at length in the context of vitamin B6 in Iso Benzacyl Forte tablets in the Miscellaneous Order No. Misc/55-56/88-C dated 25.2.88 referred to supra and extracts of which have been produced, the rationale of which I have adopted for the purpose of this order. From the discussion above it is seen that Lidocaine Hydrochloride has been added to make the Tetracycline Hydrochloride more acceptable to the system by taking away the pain the injection of the same caused at the injection site and that it is not administered to take care of any pre-existing condition of pain. No doubt, Lidocaine Hydrochloride has the therapeutic property of taking away the pain when administered in certain required doses to relieve the condition from which somebody is suffering from pain by having anaesthetic effect but that by itself is not enough reason to hold the addition of Lidocaine in the Tetracycline injection as therapeutic agent in the above formulation for the reasons given in the context of addition of Vitamin B6 in Iso Benzacyl Forte Tablets. We have held as under in the context of addition of Vitamin B6 in the Iso Benzacyl Forte tablets:- That ingredient in a medical formulation can be considered as therapeutic agent only when its administration will have a therapeutic effect in the context of the therapy for which medicine is given. This would mean that there should be a pre-existing condition which the ingredient will help to cure. The quantum of such ingredient should also be such that it would take care of the condition for which the ingredient is recommended as therapeutic agent.

In the present case it is not the case of the Revenue that the quantum of Lidocaine Hydrochloride is equivalent to a recommended dose for taking care of pain which was pre-existing before the administration of the injection. In this view of the matter, therefore, Lidocaine added has to be considered as therapeutically inert. In view of the above, I hold that addition of Lidocaine Hydrochloride is permissible for

the purpose of benefit of Notification 116/69 as it satisfies all the parameters for addition of non-specified ingredients as set out in this Notification.

37. The next point for consideration is whether the addition of Ascorbic Acid in all the five formulations above could be taken to be permissible for the purpose of the exemption Notification. The use of Ascorbic Acid as a pharmaceutical necessity has to be considered in the context of its being either a stabilising or a buffering agent and it is in this context that Brother Shri Mandal has examined the issue in the order recorded by him.

38. The Ascorbic Acid has various uses and one of its use is as an anti-oxidant. This has also therapeutic properties and is used both as a therapeutic agent and also as a prophylactic agent. It is used to treat scurvy, etc., and also helps in healing of the wounds as it is necessary for the biosynthesis of intercellular substance and collagen.

In the book "United States Dispensatory Physician and Pharmacology", at page 166, the above uses have been set out. Further at page 168 of the same technical book, Therapeutic uses of Ascorbic Acid has been described as follows:- Therapeutic Uses:- Ascorbic Acid is used as a specific curative in scurvy. In many different diseases a deficiency of the vitamin may develop due to anorexia, fault of a special diet, to failure of absorption as in diarrheal and other disorders, or to increased requirements in hypermetabolism or during the course of infections.

The correction, or better the prevention, if any deficiency of Ascorbic Acid will benefit such patients.

Ascorbic acid, by virtue of its involvement with the functioning of intercellular substance, has been tried in the treatment of almost all the disorders of mankind. Benefit has been reported in retinal hemorrhage, hematuria, bleeding peptic ulcer, rheumatic fever, tuberculosis, dysentery, fractures, dental caries, and many other conditions. It has also been reported to be of value in reducing the toxic effects of a great variety of medicinal agents and noxious industrial chemicals.

At page 34 of Encyclopaedia of Chemical Technology by Krik Othmer IIIrd Edition Vol. 24 it has been stated.

It is thought that vitamin 'C' helps in the prevention and treatment of chronic diseases that are aggravated by adverse external factors, for example, smoking, pollution, drugs and stress.

The use of Ascorbic acid as an antioxidant is well recognised in case of Tetracycline used for parenteral purpose, i.e., Tetracycline injections as seen from an article titled "Stability of Tetracycline and Riboflavin" by Lewis J. Leeson and Joseph F. Weidenheimer, published in the journal of Pharmaceutical Sciences. The Hon'ble High Court of Madras in the case of M/s. Hoechst Pharmaceuticals Pvt. Ltd. v. Collector of Customs, in O.S. Appeal No. 34 of 1965 and Writ Petitions Nos. 23 to 27 of 1970 have, after taking into consideration the evidence placed before them have held that Ascorbic Acid used in Tetracycline injections is a stabilizing agent which is in the nature of Pharmaceutical Necessity. The use of Ascorbic Acid as an antioxidant is thus well recognised and accepted so and in the Tetracycline injections it is precisely for this use that the same is added.

The Honb'le High Court of Madras in the case of Hoechst Pharmaceuticals Pvt. Ltd., referred to supra, have held as under:- As a matter of fact, as already indicated, Ambramycin, Achromycin, Steclein, Tetracycline do contain more or less a percentage of Ascorbic Acid. It has been added as an ingredient of Tetracycline Hydrochloride as the evidence discloses for the purpose of giving a buffer effect, that is to say, to stabilise it when administered in injection. It has not been used as an ingredient for the purpose of therapeutic effect. When we find the expression 'therapeutic ingredients' in Entry 28(27), we must have regard to the meaning of each one of those words in the phraseology. It must be an ingredient, at the same time, it must have therapeutic effect In this case, it is clearly demonstrated by the evidence on record that Ascorbic Acid used in the respondent's Tetracycline Hydrochloride is not intended to and does not have any therapeutic effect, but has been added for its buffer effect.

The Hon'ble High Court has clearly held that Ascorbic Acid added in the Tetracycline injections has only a stabilising effect and has no therapeutic effect In

this context the matter so far as the Tetracycline Hydrochloride injections are concerned stands concluded that Ascorbic Acid added is a pharmaceutical necessity and that it has to be considered as therapeutically inert. Following, therefore, the judgment of the Hon'ble High Court and in the absence of any contrary judgment of any other High Court, the benefit of Notification 116/69 is available in respect of Steclin and Resteclin capsules at Sl. Nos. (iv) & (v) notwithstanding the addition of non-specified ingredients in Tetracycline Hydrochloride.

39. So far as the addition of Ascorbic Acid to Chloramphenicol and Rector Capsules at Sl. No. (i) and to Tetracycline in Resteclin 250 mg.

capsules and Resteclin 500 mg. in tablet form at Sl. Nos. (ii) & (iii) is concerned, the position is not at par with that in the case of addition of the same in Tetracycline injections discussed above. As held in the judgment of the Hon'ble High Court and also as seen from the technical literature cited in Brother Shri Mandal's order and referred to by both the sides, Tetracycline in solution form is not stable and the addition of Ascorbic Acid is as a stabilising agent in parenteral Tetracycline formulations. In this context the position is set out in the article titled "Stability of Tetracycline and Riboflavin" by Lewis J. Leeson and Joseph F. Weidenheimer, (page 32, para (vii) of Shri Mandal's order), published in the Journal of Pharmaceutical Sciences, a copy of which has been placed at pages 49 to 50 of the paper-book, Vol. I of the appellants. The need for the addition of Ascorbic Acid in Tetracycline formulations in injectible form is, therefore, well-established and accepted as a pharmaceutical necessity. However, there is no such use indicated for administration of Tetracycline in capsule or in tablet form. It may be pointed that use of the ascorbic acid in Tetracycline or Chloramphenicol for the purpose of the notification can only held to be permissible in case it can be shown that the addition of the same as an ingredient is required as a pharmaceutical necessity. The use of Ascorbic Acid in the formulations can be considered only in the context of its being either as a stabiliser or a buffering agent, as there is no submission from either side that its use could be considered in any other context in terms of the Notification. Therefore, it will have to be seen whether in the said three brands of capsules Ascorbic Acid is required to be used

as a stabiliser or as a buffering agent As discussed in the earlier paragraph, stabiliser would be required to be added in case there is likelihood of any degradation of the specified ingredients which would take place in the absence of the stabilising ingredient or in other words that the products, viz., Chloramphenicol and Tetracycline in the present case are unstable. The technical literature on the two products, however, states to the contrary. Regarding the stability of Tetracycline the following is set out in the book "Goodman and Gilman's, The Pharmacological Basis of Therapeutics", Sixth Edition Editors Alfred Goodman Oilman, Louis S. Goodman and Alfred Gilman, published by Macmillan Publishing Co., New York, at page 1181:- The crystalline bases are faintly yellow, odorless, slightly bitter compounds. They are only slightly soluble in water at pH 7(0.25 to 0.5 mg/ml), but they form soluble sodium salts and hydrochlorides, are quite stable as dry powders, most of these agents lose activity relatively rapidly when in solution.

In the same book at page 1191 following is set out regarding the stability of Chloramphenicol:- The antibiotic is unique among natural compounds in that it contains a nitrobenzene moiety and is a derivative of dichloroacetic acid.

The biologically active form is levorotatory. It is only slightly soluble in water (1:400). The antibiotic is extremely stable.

Chloramphenicol is inactivated by enzymes present in filtrates of certain bacteria, which reduce the nitro group and hydrolyze the amide linkage; it is also acetylated.

It is seen that Tetracycline is quite stable as dry powder and Chloramphenicol is extremely stable. No literature or authority has been cited to show that the addition of Ascorbic Acid in these two in the dry powder or tablet form is recommended or is required to be done to ensure the stability of the product for the purpose of storage or marketing. In the case of Tetracycline it is clearly set out that the salts of Tetracycline loses activity relatively rapidly when in solution and it is only when the same is required to be administered in a solution or injection form that the stabilising agent like Ascorbic Acid has to be added. What is true in the case of solution of Tetracycline is not true in the case of the product when in powder or tablet form. It is clearly set out and there is no averment to the contrary that

Tetracycline in the powder form or tablet form is in any way unstable or it will lose its activity in case Ascorbic Acid was not added to the same. In the case of Chloramphenicol it is clearly set out that the same is extremely stable and nothing has been brought on record to show that there is any need to add any stabilising agent in the same. It is observed that when the appellants are claiming the benefit of notification, and it is well settled principle of law, it is for the appellants to establish their claim to the benefit of the Notification. I may mention that there is no discussion regarding the need for the addition of Ascorbic Acid as a stabilising agent in the order recorded by Brother Shri Mandal when the Tetracycline and Chloramphenicol are in the tablet or capsule form for the reason that these will lose their activity in case Ascorbic Acid is not added.

As I have pointed out above, the position is rather to the contrary in the two products, since both are quite stable in the powder form. The question of need for addition of Ascorbic Acid, therefore, for this reason is not all there and nor it has been shown to be there by the appellants.

40. The next point for consideration is whether Ascorbic Acid is required to be added as a buffering agent in the context that it will counteract some of the ill-effects of Tetracycline or Chloramphenicol as in the case of Iso Benzacyl Forte tablets referred to supra where the need for addition of B6 vitamin. It is observed that both Tetracycline and Chloramphenicol produce untoward effects. Tetracycline may be toxic in nature because of gastrointestinal irritation on oral administration, which may cause vomiting and diarrhea or some skin effects or toxicity of the liver or kidneys etc. Brother Shri Mandal has also recorded the ill-effects of the same in para 8(iv) of his order above. Likewise, Chloramphenicol also may produce untoward effects like Hypersensitivity reactions, Hematological Toxicity and other effects like vomiting, diarrhea and irritation. Brother Shri Mandal has also set out the details of the side-effects in his order.

There is no averment from the appellants that Ascorbic Acid has been added to the capsules and tablets in question to take care of any specific ill-effect that may be created by Tetracycline and Chloramphenicol. There is no specific finding also in this regard by Brother Shri Mandal excepting for general discussion that ill-

effects are produced by the two drugs. There is no pleanor any authority cited that both the drugs interfere with the mechanism of Vitamin C or Ascorbic Acid absorption or metabolising of the same in the human system warranting the addition of Ascorbic Acid in these medicines as in the case of Iso Benzacyl Forte tablets where Vitamin B6 was required to be added. No evidence has also been produced from any medical authority in this regard. Ascorbic Acid has various properties, one of its chemical properties is that it acts as an antioxidant and, therefore, acts as a preservative or stabliser in Tetracycline injections. It has various therapeutic properties and is used both as a therapeutic agent and also as a prophylactic agent. It is used to treat scurvy, etc., and also helps in healing of the wounds as it is necessary for the biosynthesis of intercellular substance and collagen.

In the Book "United States Dispensatory Physician and Pharmacology" at page 166, the above uses have been set out. Further, at page 168 of the same technical book, Therapeutic uses of Ascorbic Acid has been described as follows:- Therapeutic Uses:- Ascorbic Acid is used as a specific curative in scurvy. In many different diseases a deficiency of the vitamin may develop due to anorexia, fault of a special diet, to failure of absorption as in diarrheal and other disorders, or to increased requirements in hypermetabolism or during the course of infections.

The correction, or better the prevention, of any deficiency of ascorbic acid will benefit such patients.

Ascorbic acid, by virtue of its involvement with the functioning of intercellular substance, has been tried in the treatment of almost all the disorders of mankind. Benefit has been reported in retinal hemorrhage, hematuria, bleeding peptic ulcer, rheumatic fever, tuberculosis, dysentery, fractures, dental caries, and many other conditions. It has also been reported to be of value in reducing the toxic effects of a great variety of medicinal agents and noxious industrial chemicals.

At page 34 of Encyclopaedia of Chemical Technology by Krik Othmer IIIrd Edition Vol.24 it has been stated It is thought that vitamin 'C' helps in the prevention and treatement of chronic diseases that are aggravated by adverse external factors, for example, smoking, pollution, drugs and stress.

It is seen from the above that Vitamin C is administered for treatment of various disorders and also for the increased requirement of the same during the course of infections and even to reduce the toxic effect of great variety of medicinal agents and noxious industrial chemicals. In view of the fact as discussed in the earlier paragraphs that there is no requirement for the reason of the chemical properties to Ascorbic Acid a preservative or a buffering agent to counteract any ill-effects of the Tetracycline and Chloramphenicol drugs as a buffering agent, it has to be held that the administration of Vitamin C along with these drugs is only to meet the increased requirements of the same when a person is suffering from the infection and the administration of the same with Chloramphenicol and Tetracycline is only to fight the infections for which the other two drugs are given as an other agent for counteracting the infections. The addition, therefore, of Ascorbic Acid in the above mentioned drugs has been done at the option of the manufacturers not for the reason of its pharmaceutical necessity but for the therapeutic and prophylactic effect that this has when given in the conditions of infection for which Tetracycline and Chloramphenicol are administered. The assessees have made a feeble plea in support of their plea that Ascorbic Acid addition in the case of Chloramphenicol capsules (Reclor) is a pharmaceutical necessity and have cited the MARTINDALE the Extra Pharmacopoeia, Twenty-eighth Edition, and have pointed out that Ascorbic Acid has been shown therein as having anti-microbial action and that it has been stated therein that Ascorbic Acid enhanced anti-bacterial activity in vitro of ampicillin, erythromycin, chloramphenicol. However, they have not produced any evidence nor shown any authority that this has the same effect in vitro nor does even MARTINDALE say so. Question of, addition of Ascorbic Acid in Reclor capsules for this reason, therefore, docs arise nor it stands established. The appellants were specifically asked whether they have any evidence to show that Ascorbic Acid was added for this reason and they have stated that there was no such evidence to back up their plea.

A mention was also made that in the case of Tetracycline exposure to sunlight as mentioned at page 217 of the Book "Quality Control in Pharmaceutical Industry" by Murray S. Cooper, darkens and that this darkening can be retarded by addition of Ascorbic Acid. It may be pointed out that Tetracycline in capsules does not get exposed to sunlight and, therefore, there is no question of the same getting

darkened and hence there is no need as such for the addition of Ascorbic Acid as a pharmaceutical necessity to counteract the darkening. So far as Tetracycline tablets are concerned, the samples of the same have not been produced before us and in case the same are coated or are packed in bottles or strips, there would be no exposure of the same to sunlight and there would be no question of getting darkened. In any case no factual data has been provided nor a plea has been made before us that in the case of capsules and tablets manufactured by the appellants that the position is such that Tetracycline would darken in the form of which these are manufactured and marketed indicating that there is some degradation of the Tetracycline in case Ascorbic Acid is not present. As mentioned earlier, since the appellants are claiming the benefit of notification, it is for them to establish with facts that the addition of Ascorbic Acid as a pharmaceutical necessity as set out in the notification 116/69 is there. This, as discussed above, has not been done and the facts placed before us do not lead to the conclusion that the addition of Ascorbic Acid is as a pharmaceutical necessity and the addition of the same has to be held as for the therapeutic and prophylactic effect of the same in the capsules and tablets for combating the conditions of infection for which Tetracycline and Chloramphenicol are administered.

41. When I started recording the order I came across a publication tided "MIMS INDIA Monthly Index of Medical Specialities" a well recognised publication of medical journal, which gives information regarding the different products marketed by different companies, the composition of the same and also the dosage and side effects of the various drugs. In July, 1985, Volume 5 Number 7, issue M/s. Sarabhai's capsules "Reclor" and "Resticlin" are listed therein and are set out as under at page 84 7A under the heading "Antibiotic" under the categories "Infections and Infestations":- Chloramphenicol 250 mg. 500 mg. caps. Typhoid, paratyphoid, chloramphenicol sensitive infections.

250 mg. 12 Rs.5.79; 500 mg.: 6 Rs.5.18 1.5-3g daily in divided doses.

S/P: Adequate blood studies must be made periodically in prolonged or repeated therapy.

It is seen that the contents of the capsules and dosage of the same and the contract indication and side effect are given. It is observed that the appellants themselves are manufacturing these capsules without the addition of Ascorbic Acid. When this is the position, it clearly goes to establish that the addition of Ascorbic Acid to Tetracycline and Chloramphenicol is not required as a pharmaceutical necessity. There cannot be a better proof than the combination in which the appellants themselves manufacture and market their products. If addition of Ascorbic Acid was required as a pharmaceutical necessity, the question of their marketing the drugs without the addition of Ascorbic Acid would not have arisen. The appellants obviously have not placed the true facts on record. Inasmuch as, however, this fact came to my notice and was not before the other Members of the Bench nor the fact of appellants having marketed the products Tetracycline and Chloramphenicol without the addition of Ascorbic Acid was put across by the assessees, I felt that it was necessary that the assesses should be given an opportunity to make their averment in regard to the same before any inference could be drawn in regard to that. I had recorded the note order for circulation for this purpose for consideration of the other Members. I, however, find that the other members do not agree with this proposition and are of the view that the hearing need not be reopened for the reason that it is not the function of the Tribunal to collect evidence to the detriment of the other party in that to reopen the case for hearing and that since proceedings before the Central Excise authorities are quasi-judicial in character they can be supported only on findings in the impugned orders and not by any other ground as held in the case of Cibatul Ltd. v. Union of India, 1979 ELT 407. I have, therefore, no choice but to record my order drawing the inference from the published authoritative literature, viz., "MIMS INDIA", which I have come across and which is well accepted in the medical circles and the information contained therein having a direct bearing on the issue before us. I will not like to record any detailed reasons in support of my understanding that any authoritative literature which is available and which was not before the Bench could be made use of and that the appellate Tribunals have the necessary authority to do so as held by the Hon'ble Supreme Court in the case of McMillan and followed by the Hon'ble High Court of Madras (Full Bench) in the case of State of Tamil Nadu v. Arulmurugan and Co. [1982] 51 STC 381

(FB)(Mad). The observations of the Hon'ble High Court are as under: decided by the Supreme Court. But this case is not to be regarded either as an isolated phenomenon or as a decision turns peculiarly on the construction of a special provision in the Indian Income tax Act, 1922, namely, Section 13. The Supreme Court's decision, as we earlier said reiterated a principle of wide application in tax law.

An appellate authority under the taxing enactments sits in appeal, only in a manner of speaking. What it does, functionally, is only to adjust the assessment of the appellant in accordance with the facts on the record and in accordance with the law laid down by the legislature. An appeal is a continuation of the process of assessment and an assessment is but another name for adjustment of the tax liability to with the taxable event in the particular tax-payer's case. There can be no analogy or parallel between a tax appeal and an appeal, say, in civil cases civil appeal, like a law suit in the court of first instance out of which it arises is really and truly an adversary proceeding, that is to say, a controversy tussle over mutual rights and obligations between contesting litigants ranged against each other as opponents. A tax appeal is quite different. Even as the assessing authority is not the tax-payer's "opponent", in the strictly procedural sense of the term, so too the appellate authority sitting in appeal over the assessing authority's order of assessment is not strictly an arbitral tribunal deciding a contested issue between two litigants ranged on opposite sides.In a tax appeal, the appellate authority is very much committed to the assessment process. The appellate authority can itself enter the arena of assessment either by pursuing further investigation or causing further investigation to be done. It can do so on its own initiative, without being prodded by any of the parties.(Emphasis applied by me). It can enhance the assessment, taking advantage of the opportunity afforded by the tax-payer's appeal, even though the appeal itself has been moved only with a view to a reduction in the assessment. These are specially exceptional attributes of the jurisdiction of a tax appellate authority. These attributes underline the truth that the appellate authority is no different functionally and substantially, from the assessing authority itself. This position has been well brought out in more than one decision of the Supreme Court. In McMillan's case , which we earlier referred to, may be regarded as highlighting only one aspect of the wide range and peculiar slant in

the appellate power in fiscal matters.

42. In view of the above I hold that the additional information relied upon by me, as above, has necessarily to be taken note of more so since the information is in respect of M/s. Sarabhai's own product. In case the hearing had been reopened, we would have had the opportunity of seeing the samples of the products as marketed by the appellants and the appellants would have also had the opportunity of putting forth their plea as to why the appellants were marketing their Tetracycline and Chloramphenicol capsules and tablets without the addition of Ascorbic Acid. In any case, going by the authoritative information available, I hold for the reasons set out above and also in view of the fact that the appellants themselves are marketing the products with the addition of Ascorbic Acid, the Ascorbic Acid cannot be considered as a pharmaceutical necessity for the purpose of benefit of the Notification 116/69 in the case of Reclor and Resteclin capsules and tablets and, therefore, dismiss their appeal in regard to the same, on merits.

43. M/s. Sarabhai Chemicals have also challenged the legality of the impugned order on various grounds. The thrust of their argument is that classification in respect of their product had acquired finality as approved by the Asstt. Collector allowing them the benefit of Notification No. 116/69 and that there was no warrant in law for the modification of the same denying them the benefit of the Notification, it is observed that in respect of the five products the appellants had filed 3 separate classification lists on 25.7.77, 11.8.77 and 29.10.77 and the products covered in each of these three classifications respectively are: Reclor capsules 500 mg. Resteclin cap. Resteclin 500 mg. Resteclin IM These classification lists as seen from record were approved on 28.8.77, 24.10.77 and 8.11.77. However, by two separate letters dt.

12.1.78, the Asst. Collector reclassified the aforesaid products as not eligible for the benefit of the exemption. Apparently, this decision was taken without issuing any show cause notice and on appeal by appellants the Asstt. Collector was directed by Collector (Appeals) to adjudicate to the matter de novo and a show cause notice in this regard was issued on 2.5.81.

The Asstt. Collector by his order dt. 12.1.83 held that the products in question were eligible for the benefit of the Notification 116/69.

44. This order of the Asstt Collector was taken up before the Collector of Central Excise (Appeals) on directions issued by the Collector of Central Excise under Section 35-E of the Central Excise Rules and Salt Act 1944 by two separate orders issued by him. He first ordered the matter to be taken up in appeal under Section 35-A in respect of Resteclin IM and Steclin IM and second direction was given in respect of the remaining products separately. These proceedings ultimately culminated in the impugned order before us. The legal pleas taken by M/s. Sarabhai are: 1. The Asstt. Collector could not review his own order or order of his predecessor reclassifying the goods and the only remedy was under Section 35-A. 2. The Collector having passed one order under Section 35-E in respect of the two products first could not have passed another order in respect of the remaining products, as having passed the first order he had exhausted his powers under Section 35-E. 3. In any case the demand could not be raised prior to the date when the fresh order of re-classification and that in as much as the order on the re-classification were passed on 12.1.83 the demand could not be raised for the period before that.

45. The revenue however, pleaded that the Asstt. Collector had necessary powers to review the classification list and to reclassify the goods and that there was no infirmity in the orders of the collector issued under Section 35-E of the Central Excise and Salt Act.

It is observed that the process of modification of the earlier approved classification lists commenced by the issue of the orders of the Asstt.

Collector on 12.1.78. However, theses proceedings were not held to be maintainable and the order of the reclassification was passed after the issue of show cause notice on 2.5.81 by the issue of the order of the Asstt. Collector on 12.1.83 in favour of the assessees. So far as the authority of the Asstt. Collector to initiate the proceedings for reclassification of the goods is concerned it may be mentioned that there is a built-in-provision for the same as it is under Section 11-A and earlier under the Rules under which a demand for short levy could be raised.

The Hon'ble Supreme Court has upheld the authority of the revenue for doing the same. Further, as cited by the revenue the Hon'ble Karnataka High Court in have also held that classification list can be re-opened/reassessed under Section 11-A of the Act. That the reclassification can be done has also been upheld by Madhya Pradesh High Court by Hon'ble High Court of Karnataka in ; by Hon'ble Calcutta High Court and by this Tribunal in the judgment in the case of Naik Associates 1985(5) ECR 1981 (para 21). There is no legal bar to the reclassification. As it is under Rule 173-B(5) of the Central Excise Rules the proper officer has the authority to make a modification in respect of the rate of duty in case of the approved classification list and the said rule for convenience of reference is reproduced below.

When the dispute about the rate of duty has been finalised or for any other reasons affecting rate or rates of duty, a modification of the rate or rates of duty is necessitated, the proper officer shall make such modification and inform the assessee accordingly.

In the present case, the Asstt. Collector modified the rate of duty after issuing a show cause notice. Although the decision taken by him was in favour of the assessee, the proceedings therefore initiated for the reclassification were drawn in accordance with the law and no fault can be found in respect of the same. The Collector, however, took the matter under Section 35-E and directed the Asstt. Collector to file an appeal before the Collector (Appeals) for determination of the points that the Collector spelt out in the direction issued under Section 35-E of Central Excise and Salt Act, 1944.

46. The Collector of Central Excise as mentioned earlier issued two, separate orders under Section 35-E and directed the Asstt. Collector to file appeal against the order of the Asstt. Collector dt.12.1.83. In the first order dt.18.10.84, the direction was only for Resteclin IM Steclin IM and the second order was issued on 9.1.85 and this relates to the products in question and which have been held to be not eligible for the benefit of the notification by the above. The Collector of Central Excise (Appeals) dismissed the department''s appeals as time-barred. However, this Tribunal by their order dt.2.7.86 held the appeals to be within time and the

matter was remanded to Collector (Appeal) who passed the impugned order. That the appeals were filed by the Jurisdictional authorities in pursuance to the direction given under Section 35-E in time, therefore, stands concluded and the grievance of the appellants in this regard before us therefore, docs not merit consideration at this stage. The plea that survives for consideration now is in regard to the period for which the demand can be raised against the appellants. It is observed that the order of the Asstt. Collector dt. 12.1.83 stands merged with the order of Collector (Appeal) and it has to be held that the goods stood reclassified with effect from this date as the Collector(Appeals) has held that the goods were not eligible for the benefit of the Notification and which finding in respect of Reclor capsules and Resteclin capsules and Tabs has been upheld by me in the order above. The learned Collector (Appeal) has given his findings on merits but has not gone into the question of the period for which the demand could be raised. It is not clear from the record nor there is any material in this regard on the file to show as to whether after the appellants were issued a letter by the Asstt.

Collector on 12.1.78 that their products stood reclassified without the benefit of the notification, the assessment in the case of appellants were done on a provisional basis or whether the appellants made clearance after paying duty under protest or whether any demands were raised by the authorities. Also there is no information on record to show as to the nature of assessment done on the RT12 returns filed before the authorities. The question of limitations for the purpose of the demand against the appellant has to be considered in the facts of this case and the same cannot be dealt with in the absence of information as shown. In the absence of the facts on records the matter has, therefore to be remanded for de novo examination in regard to this aspect by the lower authority. The Asstt. collector is, therefore, directed to re-examine the matter in regard to the quantum of demand in the light of the above findings after giving the appellants an opportunity of hearing. It is clarified that so far as the re-classification of goods is concerned the relevant date for the same as mentioned above is to be taken as 12.1.83.

47. In the result appeals No. ED/SB/447/83-C and No. ED/SB/335/840 filed by the Department in the case of M/S. Wander India Ltd. are dismissed and appeals No. E/2155/86-C and No. E/2173/86-C of M/S.Sarabhai Chemicals, Vadodara are

partially allowed in the above terms.

48. Inasmuch as, however, since the majority view has emerged and the order on the appeals as set out in para. 32 of the order recorded by Brother Shri Mandal has the concurrence of other two Members, the appeals stand decided in terms of the said order notwithstanding my order on the appeals above.

49. I have had the advantage of reading the erudite judgment prepared by my learned Brother Shri D.C. Mandal and agreed to by the Hon'ble Sr.Vice-President and the Judicial Member Shri Harish Chander and also the judgment prepared separately by my learned Brother Shri V.P.Gulati, Technical Member.

50. After reading and re-reading the majority judgment and the judgment prepared separately my learned Brother Shri V.P.Gulati I agree with the majority view recorded in para.32 of the order and also with the view expressed by my learned Brother Shri V.P. Gulati in his judgment prepared separately, whereby he has allowed the appeal No. E/2155/86-C pertaining to the appellants M/s. Sarabhai Chemicals, Baroda and which relates to the grant of benefit of Notification 116/69 as amended in respect of Resteclin IM and Steclin(VET) IM. However, I feel unable to agree with my learned Brother Shri V.P. Gulati that the appellants M/s.

Sarabhai Chemicals (Appeal No. E/2173/86-C) were not entitled for concessional rate of duty with respect to their products namely Reclor Capsules, Resteclin Capsules and Resteclin Tablets in terms of the said exemption Notification No. 116/69-CE as amended and since I am dis-agreeing with my learned Brother Shri V.P.Gulati on this point I feel it expedient to express myself to emphasise that in my opinion also the view taken by the majority is alone sufficient.

51. With respect to these aforesaid Capsules and Tablets the majority as aforesaid has held that the appellants are entitled for concessional rate of duty in terms of the said Notification and therefore allowed Appeal No. E/2173/86-C pertaining to M/s. Sarabhai Chemicals also.

While holding so the majority had held that the addition of the Ascorbic Acid (Vit-C) in the said Capsules and Tablets was a Pharmaceutical necessity and it was

Therapeutically inert and since it was never the case of the department that the addition of Ascorbic Acid interferes with the Therapeutic or Prophylactic activity of the specified ingredients the majority did not examine this aspect. Whereas my learned Brother Shri V.P. Gulati in his separate judgment has disallowed the claim of the appellants M/s. Sarabhai Chemicals for concessional rate of duty in terms of the said exemption Notification No. 116/69-CE with respect to the aforesaid Capsules and Tablets only on the ground that the addition of Ascorbic Acid (Vit. C) to the Tetracycline Hydrochloride in the Resteclin Capsules and Tablets and Chloramphenicol in the Reclor Capsules is not a pharmaceutical necessity as envisaged in the said Notification No. 116/69-CE for the crystalline bases of Tetracyclines form soluble Sodium Salts and Hydrochlorides are quite stable as dry powders and for this purpose by learned Brother has relied upon the following passage appearing at page 1181 of the Book "Goodman and Oilman's the Pharmacological Basis of Therapeutics, 6th Edition which runs thus- The crystalline bases are faintly yellow, odorless, slightly bitter compounds. They are only slightly soluble in water at PH 7 (0.25 to 0.5 mg/ml), but they form soluble sodium salts and hydrochlorides.

While the bases and the hydrochlorides are quite stable as dry powders, most of these agents lose activity relatively rapidly when in solution.

52. Likewise my learned Brother Shri V.P. Gulati has disallowed the claim of the appellants with respect to the Reclor Capsules on the ground that Chloramphenicol is highly stable and for this purpose has placed reliance on the passage appearing at page 1191 of the said Book of Goodman and Gilman's. The said passage runs thus- The antibiotic is unique among natural compounds in that it contains a nitrobenzene moiety and is a derivative of dichloroacetic acid.

The biologically active form is levorotatory. It is only slightly soluble in water (1:400). The antibiotic is extremely stable.

Chloramphenicol is inactivated by enzymes present in filtrates of certain bacteria, which reduce the nitro group and hydrolyze the amide linkage; it is also acetylated.

53. However, my learned Brother Shri V.P. Gulau' has accepted that the use of Ascorbic Acid as an antioxidant is well recognised and accepted so in the Pharmaceutical science but rejected the claim of the appellants that the addition of Ascorbic Acid in the chloramphenicol and Tetracycline in powder form in Capsules or Tablets was necessary to prevent it from the degradation holding that the Tetracycline in Capsules does not get exposed to sunlight and therefore, there is no question of the same getting darkened and hence there is no need as such for the addition of Ascorbic Acid as a Pharmaceutical necessity with a view to stabilise the Tetracycline contents in the Capsules.

Likewise Resteclin Tablets if coated, the question of the same getting darkened would not also arise as coating of the Resteclin Tablets would prevent exposure of Tetracycline contents to the sunlight.

54. Thus in a nutshell my learned Brother has disallowed the claim of the appellants for concessional rate of duty in terms of Notification No. 116/69-CE on the ground that the addition of Ascorbic Acid in the Chloramphenicol and Tetracycline Hydrochloride in the Reclor Capsules and Resteclin Capsules and Tablets could not be considered as Pharmaceutical necessity as envisaged in the said Notification.

However, he has not expressed any contrary view in his separate judgment regarding the findings of the majority that the addition of Ascorbic Acid in the said Capsules and Tablets was Therapeutically inert.

55. At the outset I may say that it was never the case of the department that the addition of Ascorbic Acid to the Chloramphenicol and Tetracycline in the Reclor Capsules and Resteclin Capsules and Tablets was not a Pharmaceutical necessity. In other words,it was never disputed nor controverted by the department that the addition of the Ascorbic Acid was not a Pharmaceutical necessity as would appear from the chequered history of the case and from the various orders passed by the authorities concerned from time to time and also from the impugned order passed by the Collector (Appeals) against the appellants and what was contended was that Ascorbic Acid added to the Chloramphenicol and Tetracycline Hydrochloride in the Capsules and Tablets was not

"Therapeutically inert" as required under the proviso to the said Notification. To begin with- (1) The appellant company as narrated in the majority judgment is engaged in the business of manufacturing, inter alia, patent and proprietary medicines, Pharmaceuticals, bulk drugs. etc, and submitted their three Classification Lists dated 25.7.77, 1.8.77 and 29.10.77 to the authorities concerned for approval claiming benefit of the said Notification No. 116/69. The Assistant Collector of Central Excise approved the said Classification Lists vide his three separate orders dated 20.8.77, 24.10.77 and 8.11.77 giving benefit of the said Notification. However, on 12.1.78 the Assistant Collector of Central Excise issued three different orders suo motu without giving any opportunity of hearing to the appellants revising the earlier Classification Lists and re-classifying them withdrawing the benefit of the said Notification No. 116/69 given earlier. Since these three orders all dated 12.1.78 were passed without hearing the appellants, the Collector of Central Excise (Appeals), Bombay on appeal by the appellants remanded the matter to the Assistant Collector of Central Excise for de novo adjudication vide his Order dated 3.7.80. On remand the Supdt. of Central Excise vide his letter No. I/MP/SC/CL/80/361 dated 17.3.81 asked the appellants to submit the details of the active and inactive ingredients inter alia of their products in question namely, Reclor Capsules, Resteclin Capsules and Tablets, etc. In compliance the appellants vide their letter dated 20.4.81 submitted the details of the active and other ingredients of their said products, inter alia, submitting as follows- Product-reclor capsules. Chloramphenicol-is a broad-spectrum antibiotic. It is prone to oxidative degradation, hence, in order to protect it from the said degradation, Ascorbic Acid has been included in the formulation as an Stabilizer. Ascorbic Acid is one of the safest and most effective anti-oxidant. Therefore, is a pharmaceutical necessity for this product.

Tetracycline Hydrochloride is a broad-spectrum antibiotic classified as a life saving drug. It is suspectible to oxidating degradation and darkness in colour and the degradation products are not only therapeutically inactive, are quite toxic also. The degradation is retartcd by addition of ascorbic Acid (Ref. Quality control in Pharmaceutical Industry-Volume-2 by M.S. Cooper Page-No. 217).

Although, other stabilizers may also be used, however Ascorbic Acid has been selected as it is safer than other anti-oxidants.

Tetracycline Hcl is reported to be compatible with Ascorbic Acid (Ref. Journal of American Pharmaceutical Association Volume 25, Page 694, 1954, edition by Frank H. Buck Walter. Ascorbic Acid being a potent anti-oxidant has been included in this formulation as a stabilizer. It stabilizes the Tetracycline Hcl. and thereby insures clinical safety and efficacy of the product throughout the shelf life. Thus it is a pharmaceutical necessity incorporated in the product for the purpose of stability and safety only".

Tetracycline Hydrochloride is a broad spectrum antibiotic classified as a life saving drug. It is susceptible to oxidating degradation and darkness in colour and the degradation products are not only therapeutically inactive, are quite toxic also. The degradation is retarted by addition of Ascorbic Acid (Ref. Quality Control in Pharmaceutical industry Vol. 2 by M.S. Cooper Page No. 217).

Although other stabilizers may also be used, however, Ascorbic Acid has been selected as it is safer than other anti-oxidant.

Tetracycline Hcl. is reported to be compatible with Ascorbic Acid.

(Ref. Journal of American Pharmaceutical Ascorbic Volume 25, page-694, 1954 edition by Frank H. Buck Walter). Ascorbic Acid being a potent anti-oxidant has been included in this formulation as a stabilizer. It stabilizes the Tetracycline Hcl. and thereby insures clinical safety and efficacy of the product throughout the shelf life. Thus it is a pharmaceutical necessity incorporated in the product of stability and safety only.

56. It appears that on receipt of the said details of the active and inactive agents the department received the report dated 15.4.81 from the Assistant Chemical Examiner to the effect that the product in question namely, Reclor Capsules, Resteclin Capsules and Tablets may not be deemed to be covered by the said Notification No. 116/69.

Thereafter, the Supdt. of Central Excise issued a show cause notice dated 2.5.81 to the appellants to show cause as to why the benefit of concessional rate of duty in terms of the said Notification No. 116/69 be not withdrawn as the products in question contains ingredients which are not specified for concessional rate of duty in terms of the said Notification and for this purpose in the show cause notice reliance was placed on the said report of the Assistant Chemical Examiner of "Central Excise Divisional Laboratory, Baroda (wrongly quoted as Chemical Examiners report in the show cause notice) under his No.14-E/PPM/80-81/2714 to 2718. The said report reads thus-Sub:- Samples of Reclor-250 mg. Resteclin-500 mg. Resteclin 250 mg. from Sarabhai Chemicals.

Please refer to the correspondence resting with your letter No.I/MP/CL/SC/80 dated 12/2/1980 pertaining to the tables of P. or P.Medicines listed below:- The P. or P. Medicines for which above information have been furnished may not be deemed to be covered by notification No. 116/69 dt. 3/5/69 as amended and read with Central Excise Baroda Collectorate's letter No. V/14D(8) 1/76 MP dated 30/8/76. Labels retained.

57. In answer the appellants submitted their reply dated 12.6.81 contending, inter alia, that "in case of other three products namely Resteclin Capsules; Resteclin Tablets and Reclor Capsules Ascorbic Acid is added along with active ingredients tetracycline Hcl. (Resteclin Capsules & Tablets) and Chloramphent (in case of Reclor Ca.) in order to ....

(a) Protect the drug against oxidation as ascorbic acid is an excellent antioxidant and both these drugs are susceptible to oxidative degradation.

(b) Ascorbic acid is one of the vitamins required by human body for normal functioning thus it is absolutely safe and it does not interfere with the normal activity of the antibiotics. Additions of ascorbic acid makes these products 'more stable' and safer without affecting their therapeutic value any way.

58. The appellants also during the adjudication proceedings submitted certain certificates and the technical notes of their products in question and the gist of personal hearing to the adjudicating authority. The adjudicating authority after the

usual adjudication proceedings agreed with the appellants that the addition of Ascorbic Acid to the Chloramphenicol and Tetracycline Hydrochloride in the Rector Capsules and Resteclin Capsules and Tablets was a Pharmaceutical necessity as the Ascorbic Acid has been used as stabiliser as it is one of the safest and most effective anti-oxidant. As regards the other requirements of the Notification that such Pharmaceutical necessities should be the therapeutically inert and do not interfere with the therapeutic or prophylactic activity of the ingredient or ingredients specified in the Schedule he also agreed with the appellants.

Consequently he passed his adjudication Order-in-Original dated 12.1.83 giving benefit of concessional rate of duty under the said Notification No. 116/69 dated 3.5.69, as amended.

59. Thereafter it appears that the Collector of Central Excise took up the matter for the purpose of satisfying himself as to the legality of the said adjudication order dated 12.1.83 passed by the Assistant Collector under Sub-section (2) of Section 35-E of the Central Excises &Salt Act, 1944 and after examining the record of the case he directed the Assistant Collector of Central Excise and Customs, Baroda to file the appeal to the Collector of Central Excise (Appeals), Bombay against that part of the adjudication order dated 12.1.83 which relates to the products "Resteclin IM" and "Steclin Im" vide his order dated 9.10.84.

Accordingly, the appeal was filed by the Assistant Collector before the Collector of Central Excise (Appeals), Bombay. It further appears that the Collector of Central Excise again vide his order dated 9.1.85 directed the Assistant Collector to file the appeal against that part of the adjudication order dated 12.1.83 which relates to the grant of concessional rate of duty under Notification No. 116/69 with respect to the Rector Capsules and Resteclin Capsules and Tablets opining that the Ascorbic Acid is not "Therapeutically inert" and to support his view he cited a few lines appearing at page 1655 of the Book entitled "Martindale. The Extra Pharmacopocia" 28th Edition. The said opinion is reproduced below for ready reference- In the manufacture of all the medicines indicated above, Ascorbic Acid has been used as other ingredient amongst others. For availing of the said

exemption, the condition stipulated in the notification that the other ingredient or ingredients should be therapeutically inert and do not interfere with therapeutic or activity of the ingredient or ingredients specified in the schedule to the notification is required to be satisfied. Ascorbic Acid is not therapeutically inert The use and antibiotic action of Ascorbic Acid has been indicated at Page No. 1655 of the book entitled. "Martindale. The Extra Pharmacopocia" 28th edition are as under:- Ascorbic acid is essential for the synthesis of collagen and intercellular material. It is involved in the conversion of folic acid to folinic acid in electron transport processes and in the healing of wounds and is believed to be involved in the metabolism of tyrosine. Ascorbic acid enhances the antibacterial activity in vitro of ampicillin, erythromycin, chloramphenicol colistin.(Emphasis supplied).

60. While opining as aforesaid he discarded the opinion of the Assistant Director of Foods and Drugs, Central Administration, Baroda which was submitted by the appellants observing as follows- The opinion of the Assistant Director Foods and Drugs, Central Administration, Baroda received in this connection is with reference to the disease and not with reference to the active ingredients. The certificate of Assistant Director Food and Drug ADMN, Baroda do not bear dates and one of them is not signed. Therefore these certificates that Ascorbic Acid contained in the formulations was theraputically inert with respect of the disease claimed to be cured with active ingredients viz., Tetracycline chloramphenicol. This indicated that ascorbic acid is not therapeutically inert in respect of other medicines. Notification No. 116/69 does not provide any restricted sense in respect of inerteness. As such ascorbic acid used as other ingredient in all the medicines in question are not therapeutically inert. The certificate also do not give any opinion about the other ingredient like mangensium starate, milk sugar starch etc. which can also not be considered as inert ingredient.(Emphasis supplied) 61. Thus from the above it is clear that the Collector of Central Excise in exercise of his powers conferred upon him under Sub-section (2) of Section 35-E of the Act (which specially provides that the Collector of Central Excise may after examining the record of any proceeding in which an adjudication order is passed by any authority subordinate to him, by order direct the authorised authority to apply to the Collector (Appeals) for the determination of such points arising out of the such order as may be specified by him) directed the Assistant Collector to file the appeal to the Collector (Appeals)

for determination of the only point as to whether the Ascorbic Acid used by the appellants in the manufacture of Reclor Capsules and Resteclin Capsules and Tablets could be considered as "Therapeutically inert".

Accordingly the appeal was filed by the Assistant Collector with respect to the products in question namely Reclor Capsules and Resteclin Capsules and Tablets. The same was allowed by the Collector (Appeals) vide his common impugned order dated 3.9.86. From this impugned order so passed it is also clear that the only issue which was involved in the appeal with respect to the disputed products namely, Reclor Capsules and Resteclin Capsules and Tablets was as to whether the ascorbic acid used by the appellants in the manufacture of the said products could be considered as Therapeutically inert or not and he (Collector (Appeals)) while dealing with this question agreed with the view expressed in the authorisation letter issued by the Collector to the Assistant Collector to file appeals. The said discussion of the Collector (Appeals) in the impugned order runs as follows- As regards the remaining products viz., Reclor Capsules, Resteclin Capsules, and (iii) Resteclin Tablets, the grounds for filing E.A.2 application as mentioned in the authorisation letter issued by the Collector are that in the manufacture of these products ascorbic acid has been used as other ingredients amongst others, and for availing of the exemption under notification No. 116/69 dt.3/5/69, the condition stipulated that the other ingredient or ingredients should be therapeutically inert and do not interfere with therapeutic or prophylactic activity of the ingredient or ingredients specified in the Schedule to the notification is required to be satisfied.

Theascorbic acid is not tliereapeutically inert. The use and antibiotic action of ascorbic acid has been indicated at page No. 1655 of the book entitled 'Martindale-the extra Pharmacopoeia' 28th Edition. Further the opinion of the Asstt. Director Foods and Drugs Control Adm. Baroda is with reference to disease and not with reference to the active ingredient, and the certificates do not bear dates and none of the certificates is not signed, and therefore these certificates cannot be considered as authentic. It is also stated in the said authorisation letter that notification No. 116/69 docs not provide any restricted sensein respect of inertness as such ascorbic acid used as other ingredient in all the medicines in

question are not therapeutically inert, and the certificates also does not give any opinion about the other ingredients which also cannot be considered as insert ingredients, and that the Deputy Chief Chemist has categorically stated that these products will not be covered by exemption notification No. 116/69 and therefore these medicines are not eligible for exemption. I agree with the view expressed in the authorisation letter (Emphasis supplied).

62. Thus from a resume of the facts narrated above it is clear that the Assistant Collector who adjudicated the case vide his order dated 12.1.83 allowed the claim of the appellants to the concessional rate of duty in terms of Notification No. 116/69 with respect to the Reclor Capsules, Resteclin Capsules and Tablets after agreeing with the appellants that the addition of Ascorbic Acid in the manufacture of the aforesaid Capsules and Tablets was a Pharmaceutical necessity and the Ascorbic Acid is therapeutically inert and does not interfere with the therapeutic or prophylactic activity of the main ingredients and that the Collector of Central Excise in terms of Sub-section (2) of Section 35-E of the Act directed the Assistant Collector to file appeal to the Collector (Appeals) for determination of the only point as to whether the ascorbic acid used in the manufacture of Capsules and Tablets in question is therapeutically inert or not as in his opinion the use of Ascorbic Acid was not therapeutically inert and this issue (point) on appeal was decided in favour of the department.

62. It deserves to be mentioned here that the department has not filed any Cross-Appeal or Cross-Objections before us on the question that the addition of Ascorbic Acid in Reclor Capsules, Resteclin Capsules and Tablets was not a pharmaceutical necessity and obviously because the matter ended when the Collector of Central Excise (Appeals) did not refer this question for determination in his Order passed under Sub-section (2) of Section 35-E of the act directing the assistant collector to file the appeal. Likewise, the Collector (Appeals) also acted in accordance with law while passing the impugned order confining himself only to the ground taken up in the authorisation ofUhe Collector and in my opinion rightly so because the appeal had to be confined to the ground(s) specified by the Collector in his authorisation. See the case of Collector of Central Excise v. Oswal Vanaspati & Allied Industries, authorisation of the collector was confined to only

one ground but the Assistant Collector in his appeal before the Tribunal had taken among other grounds including those on merits and on an objection by the respondent therein that it was not permissible for the Assistant Collector to go beyond the authorisation, the Tribunal while sustaining the objection held that "appeal has to be confined to Only one ground of principles of natural justice taken by the Collector in his authorisation".

64. Thus in the teeth of these indisputable facts the question that the addition of Ascorbic Acid in the manufacture of Reclor Capsules, Resteclin Capsules and Tablets was a Pharmaceutical necessity is a concluded question in favour of the appellants and neither the department has a right to raise the said concluded question nor the Tribunal is required to reexamine the said question afresh in the absence of any challenge. In this background I am of the considered view that it was neither necessary for the majority nor for my learned Brother Shri V.P.Gulati to examine the said concluded question in this appeal and since the only issue which arose for our consideration in the instant appeal No. E/2173/86-C filed by M/s. Sarabhai Chemicals is that as to whether the addition of Ascorbic Acid in the manufacture of Reclor Capsules, Resteclin Capsules and Tablets was Therapeutically inert stands concluded by the majority with which I fully agree in favour of the appellants, and since my learned Brother Shri V.P. Gulati has not recorded any contrary opinion on this issue the said appeal No.E/2173/86-C also deserves to be allowed.

65. Assuming but not admitting in view of my findings above that we are called upon to decide the question as to whether the addition of ascorbic Acid in the manufacture of Reclor Capsules, Resteclin Capsules and Tablets was a Pharmaceutical necessity, I agree with the majority view and would like to add as under to emphasise that the view taken by the majority in the instant case is alone sufficient.

66. The majority as aforesaid has held that addition of Ascorbic Acid in Reclor Capsules and Resteclin Capsules and Tablets was a pharmaceutical necessity whereas the dissent view is that it is not. In order to appreciate the question in hand it would be useful to recall the provisions of Notification No. 116/69 which is

the subject matter of interpretation before us. The same in so far as relevant are as follows- ....Nothing contained in Paragraph 1 shall apply in (sic)medicines which contain any ingredients not specified in the said Schedule unless the ingredients in the medicine are pharmaceutical necessities such as diluents, disintegrating agents, moistening agents, lubricants,buffering agents, stabilizers and preservatives.

67. The expression "Pharmaceutical necessity" has not been defined in the said Notification. On the other hand it uses the expression "Pharmaceutical necessities such as diluents buffering agents, stabilizers and preservatives." From the use of the words 'such as' it is clear that the enumeration which follows the expression 'such as' is not exhaustive and it merely illustrates "Pharmaceutical necessities" For this interpretation I am supported by the judgment of the Gujarat High Court rendered in the case of Jalal Plastic Industries v. Union of India, 1981 ELT 653. To this interpretation my learned Brother Shri V.P. Gulati also agrees (see his referring order) and therefore, he has agreed with the majority that the claim of the other appellants M/s.

Wanders Limited, Bombay that the addition of Vit. B6 chemically described as Pyridoxine Hydrochloride and not specially mentioned in the Notification as Pharmaceutical necessity, in Isobenzacyl Forte Tablets is a Pharmaceutical necessity is correct.

68. "Stabilizers" and "buffering agents" are mentioned as "Pharmaceutical necessities" in the said Notification expressly but my learned Brother Shri V.P. Gulati has rejected the claim of the appellants M/s. Sadrabhai Chemicals that Ascorbic Acid was added to the Chloramphenicol Capsules and Tetracycline Capsules and Tablets as Stabilizer or buffering agent.

69. In Butterworths' Medical Dictionary, 2nd Edition the term 'Stabilizer' has been defined as follows- 1. In a chemical action, any substance employed to maintain an equilibrium or moderate the velocity.

70. From the above it is clear that "any compound which improves the stability of another compound is stabiliser". In other words if any compound is used in another

compound to make it more stable Or to improve its stability it comes within the definition of stabilizer. In the instant case with respect to the Resteclin IM and Steclin IM it was the case of the appellants that Magnesium Chloride is added to the active ingredient tetracycline HCL to stabilize the drug which is otherwise unstable see internal page 6 - Paper Book page 57 reply to the show cause notice dated 12.6.81 submitted to the assistant Collector. The same is reproduced below- Resteclin I.M. and Steclin I.M. has tetracycline HGL LP. as active ingredients which is broad spectrum antibiotic. Here Magnesium Chloride is added to stabilize the drug which is otherwise unstable....

71. But with respect to the resteclin Capsules, Resteclin Tablets and Reclor capsules the case of the appellants was that Ascorbic Acid is added alongwith active ingredients Tetracycline HCL and Chloramphent in order to make these products "more stable" and "safer" without affecting their therapeutic value anyway. see reply to the show cause notice - internal page 8 Paper Book page 59. The same is reproduced below for ready reference- ...In case of other three products namely Resteclin Capsules; Resteclin Tablets and Reclor Capsules Ascorbic Acid is added along with active ingredients Tetracycline Hcl. Resteclin Capsules & Tablets) and Chloramphent (in case of Reclor Ca.) in order to....

(a)Protect the drug against oxidation as ascorbic acid is an excellent antioxidant and both these drugs are susceptible to oxidative degradation.

(b) Ascorbic acid is one of the vitamins required by human body for normal functioning thus it is absolutely safe and it does not interfere with the normal activity of the antibiotics. Additions of ascorbic acid makes these products 'more stable' and'safer''without affecting their therapeutic value any way".

72. Now my learned Brother Shri Gulati after holding that the use of Ascorbic Acid as an anti-oxidant is well recognised and accepted so and that Ascorbic Acid in Tetracycline Inj. and Vit. B6 in Iso benzacyl Forte Tablets is a stabilizing agent which is in the nature of pharmaceutical necessity rejected the claim of the appellants holding that Tetracycline and Chloramphenicol are quite stable in view of the two passages appearing at page 1181 and 1191 in the Book 'Goodman & Gilman's. The Pharmacological Basis of Therapeutics. He without citing any

authority has further opined that Tetracycline in capsules does not get exposed to sunlight and therefore, there is no question of the same getting darkened and hence there is no need as such for the addition of the ascorbic acid as a pharmaceutical necessity with a view to stabilize the tetracycline contents in the Capsules and likewise the Tablets, if coated to prevent exposure of tetracycline to the sunlight the question of the same, therefore, getting darkened would not also arise. From this it is clear that he has not examined the claim of the appellants that the Ascorbic Acid is a pharmaceutical necessity because the addition of Ascorbic Acid makes these products more stable and safer and had negatived the contention of the appellants only on the ground that since according to the two passages appearing at pages 1181 and 1191 in the Book of Goodman and Gilman's The Pharmacological Basis of Therapeutics, Sixth Edition, the crystalline bases and the hydrochlorides of Tetracyclines are quite stable as dry powders and the Chloramphenicol, antibiotic is extremely stable the question of adding the ascorbic acid in the manufacture of the disputed capsules and tablets does not arise. If in my considered opinion the said contention of the appellants that the addition of ascorbic acid in the manufacture of the disputed capsules and tablets was a pharmaceutical necessity to make these products more stable is examined in the right perspective on the basis of the evidence and the technical literature on the record, it would be clear that the appellants have not only proved their case but it remained unrebutted by the department. In MC. Graw-Hill Dictionary of Scientific and Technical Terms, Second Edition the term "stability" has been defined as chemical durability, resistance to weathering. Any compound which improves the stability of another compound is a stabilizer as defined in the Butterworth's Medical Dictionary referred to above. The Notification in hand permits the use of such stabilizer as pharmaceutical necessities as stated above. It appears to me that the instant Notification No. 116/69 is drafted on the lines of General Notices contained in the pharmacopoeia of India and U.S. Pharmacopoeia. In Pharmacopeia of India Third Edition at page 3 under the General Notices it is stated that " an official drug substance, as distinguished from a dosage form, contains no added substances except where specifically permitted in the individual monograph. Where such addition is permitted, the label indicates the name(s) and amount(s) of any added substance(s). Unless otherwise specified in the individual monograph, or

elsewhere in the General Notices, suitable substances, such as bases, carriers, coatings, preservatives, stabilisers, vehicles and other Pharmaceutical aids may be added to a Pharmacopoeial dosage form or finished device to enhance its stability, usefulness or elegance, or to facilitate its preparation. Such substances shall be harmless in the amounts used, shall not exceed the minimum quantity required to provide their intended effect, shall not impair the therapeutic efficacy of the dosage form, and shall not interfere with the tests and assays prescribed for determining compliance with the official standards".

Likewise in U.S. Pharmacopoeia Twentieth Revision (1980) under the heading General Notices at page 4 it is stated that "unless otherwise specified in the individual monograph, or elsewhere in the General Notices, suitable substances such as bases, carriers, coatings, colors, flavors, preservatives,stabilizers, and vehicles may be added to a Pharmacopeial dosage form or finished device to enhance its stability, usefulness, or elegance, or to facilitate its preparation". From these General Notices it is clear that suitable substances such as preservatives, stabilizers, etc.,may be added to a Pharmacopeial dosage form or finished device to enhance its stability.

73. In his book 'Text Book of Pharmaceutical Formulation", Shri B.M, Mittal had described "stabilizers" as follows- The stability of a dosage form may refer to the stability of its physical form, of chemical composition or stability against microbial spoilage. These stability aspects are controlled generally by inclusion of certain materials which have the status of additives. In the popular terminology the matters that ensure stability of chemical composition or which help to prevent microbial growth are talked of as stabilizers. Such materials will form the subject-matter of this Chapter 74. Right from the stage of reply to the show cause notice it was the case of the appellants with respect to the disputed capsules and Tablets that the Ascorbic Acid is added in these Capsules and Tablets to protect the drug against oxidation and these drugs are susceptible to oxidative degradation and further that additions of ascorbic acid makes these products more staple and safer without affecting their therapeutic value any way and also produced the technical literature.

After examining the said literature and the contentions of the appellants the Assistant Collector agreed with these contentions of the appellants and therefore, dropped the show cause notice vide his order dated 12.1.83. This finding of the Assistant Collector that the addition of ascorbic acid makes these products more stable and safer was never disputed by the Collector in his authorisation, whereby he directed the Assistant Collector to file the appeal before the Collector (Appeals) nor the Collector (Appeals) had recorded any contrary finding on this issue against the appellants in his impugned order. Thus, in the teeth of these admitted facts and circumstances on record I hold that the appellants have succeeded in proving their case that the addition of ascorbic acid in the manufacture of the disputed capsules and tablets was a pharmaceutical necessity because it was added as a stablizer to make these products more stable and if I may say so the case of the appellants has gone undebutted by the department.

75. That apart the whole thrust in the dissent recorded by learned Brother Shri V.P. Gulati was that since according to the aforesaid two passages appearing in the said Book of Goodman and Gilman's, the crystalline bases and the hydrochlorides of Tetracyclines are quite stable as dry powders the claim of the appellants that the ascorbic acid was added as a stablizer in the disputed capsules and tablets cannot be accepted. I with respect do not agree firstly because I do not find such description in Pharmacopoeia of India 3rd edition or in British Pharmacopoeia, 1980 or U.S. Pharmacopoeia. I am stating all these facts because all through it was the case of the appellants that they had been manufacturing the disputed capsules and tablets in accordance with Pharmacopoeia of India and it may be noted here that the Goodman and Gilman's in their preface to the First Edition to the said book have stated that "the emphasis throughout the book, as indicated in its title, has been clinical". They have further stated that "in many instances these new interpretations necessitate radical departures from accepted but outworn concepts of the actions of drugs." Likewise in their Preface to the Fifth Edition the same Authors had stated that "An authoritative textbook in such a diverse and active discipline could no longer be written by the two authors; however, as editors, they could devote their efforts to fulfill their original objectives". From the 6th edition of the said book we find that the said authors have included in their said book an article/paper written by Merle

A. Sande and Geralad L. Mandell on the topic Tetracyclines and Chloramphenicol, Chapter 52 pages 1181 and 1191. On the other hand in the article titled "Stability of Tetracycline and Riboflavin", published in the Journal of Pharmaceutical Sciences (March 1969, Volume 58, Number 3), Page 355, Lewis J. Leeson and Joseph F. Weildenheimer have stated as follows- The stability of tetracycline solutions in the presence of riboflavin, light, and air was investigated. Although it was found that antibiotic potency loss occurred under these conditions, the addition of ascorbic acid to the system prevented the oxidative tetracycline degradation. There does, however, appear to be minor loss of tetracycline due to the ascorbic acid. This loss is covered by a normal product overage.

And secondly because if I read the said-passage appearing at page 1181 I do not find such a absolute statement. On the point of repetition the said passage is reproduced below- The crystalline bases are faintly yelow,odorless, slightly biter compounds. They are only slightly soluble in water at pH 7 (0.25 to 0.5 mg/ml), but they form soluble sodium salts and hydrochlorides.

While the bases and the hydrochlorides are quite stable as dry powders, most of these agents lose activity relatively rapidly when in solution.

76. From the language of the said passage it would be clear that what the authors have said is that the bases and the hydrochlorides are quite stable as dry powders, if one compares the stability of the bases and the hydrochlorides when they are in solution and that is why the authors have used the words "most of these agents lose activity relatively rapidly". The use of the words "relatively rapidly" are significant. Had it been intended by the authors that the bases and the hydrochlorides are quite stable as dry powders, they would have not used the further words in the said sentence "relatively rapidly" after the words "most of these agents lose activity" and before the words "when in solution". In other words the authors could have stated that "most of these agents lose activity when in solution" and on such omission the entire sentence would have read as "while the bases and the hydrochlorides are quite stable as dry powders, most of these agents lose activity when in solution." To be more precise on the point I am of the view that the said passage does not suggest that in no case the bases and

hydrochlorides as dry powders require any stabilizer and had it been so, no question of describing the storage condition of these powders either in the capsule form or in the tablet form would have been prescribed under Indian, British and U.S. Pharmacopoeia. The very prescription of the storage condition in the said Pharmacopoeia by itself suggests that these bases and hydrochlorides as dry powders when in the capsules form and tablets form do lose their activity during their shelf life and becomes useless/harmful on the expiry date.

Needless to say that India is a tropical country where the temperature throughout the year remains more than prescribed for storing the capsules and tablets and more particularly being a poor country, refrigerating facilities are not available to the majority of the citizens. If this is accepted, then the whole edifice of the dissent order falls. In the dissent it is observed that there was no averment to the contrary by the appellants that the Tetracycline in the powder form or tablet form is in any way unstable or it will lose its activity in case ascorbic acid was not added to the same or that nothing has been brought on record to show that there was any need to add any stabilizing agent in the Chloramphenicol. In my considered opinion to say so would be unfair to the appellants as could be seen from the reply submitted by the appellants to the show cause notice, the written submissions made before the Assistant Collector and the Collector (Appeals) and technical literature produced at the time of hearing.

Besides, during the course of the arguments Shri Soli Sorabji and Shri Nanavati, learned Counsels for the appellants while submitting that the question of addition of ascorbic acid in the manufacture of disputed capsules and tablets was a pharmaceutical necessity being stabiliser also produced number of authorities and technical literature of which reference has been made by my learned Brother Shri D.C. Mandal in paragraph 19 onwards. At one stage my learned Brother Shri V.P. Gulati has also stated in this connection that when the appellants are claiming the benefit of Notification, and it is well settled principle of law, it is for the appellants to establish their claim to the benefit of the Notification. In this connection 1 would like to say that this broad proposition of burden of proof was the subject-matter of consideration before the Hon'ble Supreme Court in the case of Tata Oil Mills Co. Ltd., v. Collector of Central Excise, .

While accepting the proposition that an assessee claiming relief under an exemption provision in a taxing statute has to show that he comes within the language of the exemption, their Lordships added that "But, in trying to understand the language used by an exemption Notification, one should keep in mind two important aspects. (a) the object and purposes of the exemption, and (b) the nature of the actual process involved in the manufacture of the commodity in relation to which the exemption is granted". So far as the object and purposes of the exemption Notification No. 116/69 in hand is concerned, the object is very clear. The object of the Notification is to grant a concession to the manufacturer of patent or proprietary medicines so that ultimately the benefit may be extended to the poor section of the society who are struggling for their life by making these life saving drugs available to them at the cheapest rate. On this point, law is very clear. In the case Suhrid Geigy Limited v. UOI, 1980 ELT 759, a Division Bench of the Gujarat High Court while discerning the object of an exemption Notification under Rule 8 of the Central Excise Rules, 1944 with respect to the manufacturer of patent or proprietary medicines (in our case also we are concerned with the exemption notification No. 116/69 issued with respect to the manufacture of patent or proprietary medicines) held that the primary object of such exemption notification is to serve the patients and the ailing humanity, its secondary object is to encourage trade and business therein. Thus, if the primary object of the exemption notification with which I am concerned is to render service to the patients by enabling the manufacturers to make it available at the cheapest rate, can it be said that such object will be better served by carving out a imaginary thin line that since the Tetracycline HCL and Chloramphenicol are stable as dry powders and therefore, the appellants who are the manufacturers of the patent and proprietary medicines namely Reclor Capsules, Resteclin Capsules and Resteclin Tablets cannot add the ascorbic acid in the manufacture of their said product as a stabilizer when the stabilizers are specifically named as pharmaceutical necessity in the said notification itself. In other words can the benefit of the concessional rate of duty be snatched away which is ultimately to be enjoyed by the patients and ailing humanity on the interpretation that since the Tetracycline HCL and Chloramphenicol are stable the appellants cannot be allowed to make it more stable by adding the ascorbic acid in their said products,

when it is said in law that the exemption notification should be construed liberally so that the assessee may not be deprived of the advantage of the concession. See Haldyan Glass Works Pvt. Ltd. v. ML. Badhwar, 1980 ELT 291-Bom wherein case of Commissioner of Income Tax Chugandas & Co.

was relied upon.

77. Needless to say that I am not prepared to run the judicial risk of staking of the whole verdict on the said observations made in the aforesaid book of Goodman and Gilman's The Pharmacological Basis of Therapeutics that the Tetracycline bases and the hydrochlorides are quite stable as dry powders, most of these agents lose activity relatively rapidly when in solution and that the antibiotic Chloramphenicol is extremely stable and, therefrom, to argue that there was no. necessity of adding the ascorbic acid in the disputed capsules and tablets as a stabilizer is to misread the whole Science of Pharmacology particularly when it is a dynamic industry where new technology, research and knowledge are constantly emerging to meet the needs of changing drug patterns, lifestyles and environment, if I keep in mind the caution given by their Lordship of the Hon'ble Supreme Court in the case of Shivaji v. State of Mahaiashtra that Court must not abandon a scientific attitude to medical science (digestive processes in that case as quoted by Modi in his Medical Jurisprudence), if it is not to be guilty of judicial superstition.

78. Now look at the evidence led by the parties. As stated above the Classification List claiming confessional rate of duty under the said Notification No. 116/69 dated 3.5.69, inter alia, with respect to the Reclor Capsules and Resteclin Capsules and Tablets containing respectively Chloramphenicol and Tetracycline Hydrochloride in admixture with Ascorbic Acid (Vit. C) were approved by the Assistant Collector of Central Excise by his three Orders of 1977. However, the Assistant Collector of Central Excise vide his order dated 12.1.78 revised the said approved Classification Lists withdrawing the benefit of the said Notification. On appeal by the appellants the case was remanded by the Collector (Appeals) for de novo adjudication vide his Order dated 3.7.80. On remand a show cause notice dated 2.5.81 was issued to the appellants to show cause as to why the benefit of concessional rate of duty given under the said Notification No. 116/69 be not

withdrawn and the only evidence relied upon in the show cause notice was the report of the Chemical Examiner of Central Excise, Baroda given under his No. CE/14E/PPM/80-81/2714 to 2718. The said report with respect to the disputed capsules and tablets insofar as relevant is reproduced below for ready reference- The P. Or P. Medicines for which above information have been furnished have been furnished may not be deemed to be covered by notification No. 116/69 dt.3/5/69 as amended and read with Central Excise Baroda Collectorate's letter No. V/14D(8) 1/76 MP dated 30/8/76. Labels retained.

79. From the above it is clear that after having approved the earlier classification list in 1977, the Assistant Collector of Central Excise decided to revise the approved Classification List withdrawing the benefit of the said Notification. In this premises the burden was on the department to justify the re-classification and to discharge this burden the Assistant Collector in his show cause notice dated 2.5.81 only relied upon the said report of the Assistant Chemical Examiner, Central Excise Baroda (wrongly describing it as a report of the Chemical Examiner). From the said report as extracted above it is clear that irrespective of the fact that the report was bereft of particulars/details, the Assistant Chemical Examiner himself recorded his negative opinion by stating that the said medicines "may not be deemed to be covered by notification No. 116/69 dated 3.5.69". In other words he did not mention in his opinion as to whether the addition of ascorbic acid was not a pharmaceutical necessity or that it was not therepeutically inert or that it interferes with the therapeutic or prophylactic activity of the main ingredients. It is settled law that the probative value to be attached to the certificate must depend upon a variety of circumstances, such as the data available to the Examiner, the method of analysis adopted by him, the fulness of his conclusions and speaking generally, the vulnerability to which his premise is subject. In order that a certificate may inspire confidence in the mind of the Court, it is not sufficient that the Chemical Examiner merely records his negative opinion. To permit the department to rely upon a mere negative opinion without making available to the assessee the grounds on which that opinion is based is a procedure which runs counter to the well established restrictions subject to which alone opinion evidence can be accepted. In this view of the matter I am supported by the observations made by a Division Bench of the Bombay High Court in the

case of State v. Bhausa . However, the matter does not rest here. In reply to the show cause notice the appellants by way of abundant precautions submitted that their product satisfies all the requirements of the said exemption notification, i.e., to say the addition of ascorbic acid was a pharmaceutical necessity, that it was therapeutically inert and that it does not interfere with the therapeutic or prophylactic activity of the main ingredients and also submitted the various literature and the Technical notes of each product. This entire evidence was duly considered by the Assistant Collector in his Order-in-Original dated 12.1.83 and after considering so he agreed with the appellants that the addition of ascorbic acid was a pharmaceutical necessity. For ready reference his findings insofar as relevant are extracted below- I have gone through the case records, the submissions in reply to the SC.N, and their deposition at the time of personal hearing.

(1) In respect of Reclor capsules active ingredients is chloramphenicol to prevent oxidating degradation. Ascorbic acid has been used as stabilizer as it is one of the safest and most effective antioxidants. Even though it is not inert in absolute term it does not interfere with antibiotic activity of the product chloramphenicol.

(2) In respect of Resteclin Capsules Tetracycline Hydrochloride is the active ingredient. It is susceptible to oxidative degradation and darkness in colour. To retard degradation, Ascorbic acid is used in support. They cited reference to quality control in Pharmaceutical Industry volume-2 by M/s. Cooper page 217. Ascorbic Acid is safer than other antioxides and as per journal of Amercial Pharmaceutical Assn. Vo. 25 page 694, 1954 Edition by Frank Buck Walker, Ascorbic Acid ensures clinical safety and efficacy of the product.

(3) In respect of Resteclin Tablets active ingredient is Tetracycline Hydrochloride. Some arguments put forth as in case of Resteclin Capsules .

In view of the Drug Control Administration Certificate in respect of the products in question and information quoted from various authorities it is considered that other ingredients are inert and they do not interfere with therapeutic or prophylactic activities of main ingredients of the respective medicines in chloramphenicol and Tetracycline Hcl contained in Reclor capsules and Resteclin Capsules. Resteclin

Tablets, Resteclin I.M. and Steclin as discussed above. The above-referred medicines are correctly classifiable under 2-5% Adv. duty under Notification No. 116/69 dated 3-5-69 as amended.

80. As stated above the Collector (Appeals) also while exercising the powers of review agreed that the addition of Ascorbic acid in the manufacture of disputed products in question, i.e., to say, Reclor Capsules, Resteclin Capsules and Resteclin Tablets was a pharmaceutical necessity and therefore, he obtained the report from the Deputy Chief Chemist only on the limited issue as to whether the Ascorbic Acid and Lidocaine Hydrochloride-(Synonymous with Lignocaine Hydrochloride) a local anaesthetic are therapeutically inert. The said report of the Deputy Chief Chemist is dated 7.1.85 and is on record. In its said report he has expressly stated that The point of issue appears to be whether Ascorbic Acid and Lidocaine Hydrochloride-(Synonymous with Lignocaine Hydrochloride) are therapeutically inert.

He without examining the said issue in right perspective with reference to the various authoritative books available on the subject confined himself only to a passage appearing in the book entitled Martindale.

The Extra Pharmacopoeia 28th edition p. 1655 and reiying upon it concluded that the said produce will not be covered under the said notification No. 116/69. After the receipt of the said report of the Deputy Chief Chemist, the Collector of Central Excise in his authorization order dated 9.1.85 also while relying upon the said passage appearing in the said Book of Martindale directed the Assistant Collector that the Ascorbic Acid is not therapeutically inert and therefore, the view of the Assistant Collector that the addition of Ascorbic acid was therapeutically inert be referred to the Tribunal by way of appeal to the Tribunal. From this it is clear that there is absolutely no evidence from the department to prove or to rebut that the addition of ascorbic acid in the manufacture of the disputed Capsules and tablets was not a pharmaceutical necessity or that the contention of the appellants that the ascorbic acid was added in the disputed Capsules and Tablets was not for making them more stable and safer as contended by them. In this view of the matter the question as to whether the addition of ascorbic acid in the manufacture

of the disputed Capsules and Tablets was a pharmaceutical necessity stands concluded in favour of the appellants and we cannot make a new case for the department at this stage to hold that the addition of Ascorbic acid was not a pharmaceutical necessity as it was not stabilizer as envisaged in the said Notification. In this premises to say that the appellants have not adduced any evidence to show that the addition of ascorbic acid in the manufacture of the disputed Capsules and Tablets was a pharmaceutical necessity would in my considered opinion be not correct and therefore, I with respect disagree with the observations made by my learned Brother Shri V.P. Gulati that the question of need for addition of ascorbic acid, therefore, for this reason is not at all there and nor it has been shown by the appellants. To say so in my considered opinion would be quite unfair to the appellants. On the other hand the appellants in their memorandum of appeal has taken up in a ground that there was no dispute that the non-specified ingredients including Lidocaine Hydrochloride and ascorbic acid in various formulations were used as pharmaceutical necessities. The said ground is reproduced below for ready reference- 19.18. The Collector of Central Excise (Appeals) ought to have held that from the report of the Deputy Chief Chemist (Note of Deputy Chief Chemist, Vadodara Dated 7-1-1985) on the basis of which orders for filing appeals under Section 35E were passed, it was clear that there was no dispute that the non-specified ingredients including Lidocaine Hydrochloride and ascorbic acid in various formulations were used as pharmaceutical necessities.

81. Even at the time of hearing of the appeal the learned Counsel for the appellants drew our attention to their reply submitted in answer to the show cause notice dated 2.5.81 and also to the written submissions made before the Adjudicating Authority. In particular, he drew our attention to internal page 8 of their reply to the show cause notice - Paper Book page-59 to emphasise inter alia that ascorbic acid was added in the manufacture of disputed capsules and tablets to make these products more stable and safer without affecting their therapeutic value any way and also to support his contention he cited the various authorities as referred to by my learned Brother Shri D.C. Mandal in his order. Further emphasising on the point it was also contended that the developments of pharmaceutical science is a general phenomenon and the pharmaceutical

formulations have advanced during the last 20 years to a very great extent from early days of mixtures and powders, etc., to present day formulations like capsules, tablets, etc., and that earlier medicines were compounded by the Doctors which could maintain its therapeutic value for not more than 7 to 10 days and continued, that these days medicines are manufactured on a very large scale till the end of their shelf-life which is normally more than a year and that the nature and amount of pharmaceutical necessities required has changed accordingly and will keep on changing depending upon furture development. It was also argued by the learned Counsel for the appellants that the addition of the ascorbic acid in the manufacture of the disputed capsules and tablets was a pharmaceutical necessity being buffering agent to ensure the stability of the product for the purpose of storage and marketing. In reply the main thrust of the arguments of Shri A.S. Sunder Rajan, learned SDR was that the ascorbic acid is itself an active ingredient and therefore, the question of addition of the same for pharmaceutical necessity does not arise. Stretching his submission further he submitted that the ascorbic acid is a well-recognised medicine for the treatment of scurvy and cited various authorities to show that ascorbic acid is prescribed for the treatment of scurvy. He has not however produced any authority to show that the ascorbic acid used in medicinal formulations in high doses alongwith antibiotics like Tetracycline Hydrochloride and Chloramphenicol cannot be considered as pharmaceutical necessity. No material was placed before us to show that ascorbic acid was added as ingredients in the disputed medicines for the treatment of scurvy. Even not a single stance was quoted before us to show that the disputed capsules and tablets were ever prescribed by the Doctors for the treatment of scurvy. It may be stated that even no argument by way of counter was submitted by the learned JDR to show that the addition of the ascorbic acid in the Tetracycline Hydrochloride and Chloramphenicol was not added to make them more stable and safer. In other words it was never argued before us that Tetracycline Hydrochloride and Chloramphenicol are quite stable as dry powder and therefore, there was no necessity to make them more stable by adding ascorbic acid. In (act not even a faint suggestion by way of reply was ever made nor any literature was produced to show that addition of ascorbic acid to make the disputed products more stable and safer was not needed whereas numerous authorities were cited by the learned

Counsel for the appellants.

82. My learned Brother Shri V.P. Gulati after extracting a few lines from the Book of Goodman and Gilman's The Pharmacological Basis of Therapeutics, Sixth Edition (Page 1181 and 1191) that Tetracycline form soluble sodium salts and the bases and the hydrochlorides are quite stable as dry powders and the antibiotic Chloramphenicol is extremely stable had observed that It is clearly set out and there is no averment to the contrary that Tetracycline in the powder form or tablet form is in any way unstable or it will lose its activity in case Ascorbic Acid was not added to the same. In the case of Chloramphenicol it is clearly set out that the same is extremely stable and nothing has been brought on record to show that there is any need to add any stabilising agent in the same.

With due respect I disagree with him, when I look to the averments made by the appellants in their reply to the show cause notice and at the time of personal hearing etc. Likewise he has observed that Mention was also made that in the case of exposure to sunlight as mentioned at page 217 of the Book 'Quality Control in Pharmaceutical Industry' by Murray S. Cooper, Tetracycline darkens and that this darkening can be retarded by addition of Ascorbic Acid. It may be pointed out that Tetracycline in capsules does not get exposed to sunlight and, therefore, there is no question of the same getting darkened and hence there is no need as such for the addition of Ascorbic Acid as a pharmaceutical necessity to counteract the darkening. So far as Tetracycline tablets are concerned, the samples of the same have not been produced before us and in case the same are coated or are packed in bottles or strips, there would be no exposure of the same to sunlight and there would be no question of getting darkened. In any case no factual data has been provided nor plea has been made before us that in the case of capsules and tablets manufactured by the appellants that the position is such that Tetracycline would darken in the form in which these are manufactured and marketed indicating that there is some degradation of the Tetracycline in case Ascorbic Acid is not present.

With respect I do not agree with him. I cannot subscribe to such sweeping observations made by my learned Brother Shri V.P. Gulati that capsules do not get

exposed to sunlight and that the tablets if coated or packed in bottles or strips there would be no exposure of the same to sunlight and therefore, no question of getting darkened. The research conducted and the result reported in the Journal of Pharmaceutical Sciences - a publication of the American Pharmaceutical Association - May 1971 issue Volume 60 Number 5 is the complete answer to the said observations made by him. In that journal it is reported under the heading "Degradation Products of Chloramphenicol" as follows- Abstract - Incubated aqueous solutions of chloramphenicol at various pH's (1-14) yielded detectable amounts of p-nitrobenzaldehyde (an oxidation product) and arylamine (a reduction product). Identical degradation products were also found in certain dosage forms (creams and capsules) although they were not found in ophthalmic ointment.

83. However, I would like to delve on the point further. In "The United States Dispensatory", 27th Edition page 1155 while dealing with the stability of the dry state of the tetracyclines it is observed that- Stability. - In the dry state the tetracyclines, both as the free compounds and as the hydrochlorides, are quite stable when stored in proper containers with a tight seal and protected from light and moisture. At room temperature, losses of potency are small over periods of 1 to 2 years or more. At 50C. they may lose up to 5 percent, of their potency in 4 to 6 months.But all tetracycline Salts tend to darken when exposed to strong direct sunlight and probably also if exposed to lesser intensity of light for a longer period of time.

Loss of potency and or of 'pharmaceutical elegance' is not the only factor to be considered. Some degradation products of tetracyclines, e.g., anhydrotetracyclines and or epianhydrotetracyclines, display a fair degree of antibacterial activity but are toxic (see below, under Untoward Effects).

84. While describing the storage conditions of Tetracyclines Capsules, Tetracyclines hydrochlorides and Chloramphenicol all authorities are unanimous in their views that these should be preserved in a seal closed container and protected from the light. In Pharmacopoeia of India Volume-I Third Edition 'Capsules' have been defined as solid dosage forms in which the drug or mixture of drugs is enclosed in a hard or a soft, soluble,"shell" of gelatin or any other

suitable material, and under the general requirements of storage it is laid down that Capsules should be stored in tightly closed containers at temperatures not exceedings 30. In the same Volume, at page 500 "Tablets" have been defined as solid dosage forms, each containing a unit dose of one or more medicaments and "Coated tablets" are defined as tablets covered with one or more layers of mixtures of various substances. It is further stated therein that the vast majority of all tablets manufactured are made by compression of uniform volumes of powders or granules by applying high pressure and utilising steel punches and dies. The particles to be compressed consist of one or more medicaments, with or without added substances such as diluents, binders, disintegrating agents, lubricants, and substances capable of modifying the behaviour of the medicaments in the digestive tract, and under the "General Requirements" of its storage it is laid down that tablets should be stored in containers which afford protection against breakage or crushing, access of moisture, contamination and to the extent possible deterioration. In the "United States Dispensatory", 27th Edition at pages 1155 and 1156 while describing the stability of Tetracycline Capsules packed in original container it is stated that once the pharmacist opens an original container (of say 1000 capsules), the original conditions of storage no longer prevail, either for the remaining stock or for the capsules dispensed ... it is the obligation of the pharmacist and the physician to impress upon the patient the importance of protecting the medication from direct strong light and of discarding unused portions of tetracyclines remaining after termination of treatment.

It is significant to note that the lest for such disgradation product was not prescribed in the 2nd Edition of the Indian Pharmacopoeia and its supplement published in 1966 and 1977 respectively but the same has now been prescribed in Indian Pharmacopoeia, Third Edition, 1985 under the heading "Related substances" (page 507). This itself is a proof that quality of Tetracycline available earlier was suspectable to disgradation and required addition of pharmaceutical necessity like ascorbic acid to prevent disgradation. In these circumstances I am unable to agree with my learned Brother Shri V.P. Gulati that Tetracycline capsules does not get exposed to sunlight and therefore, there was no question of the same getting darkened and hence there is no need as such for the addition of ascorbic acid as a pharmaceutical necessity to counteract the darkening. As

regards the Tetracycline tablets he has further observed that "the samples of the same have not been produced before us and in case the same are coated or are packed in bottles or strips there will be no exposure of the same to the sunlight and there would be no question of getting darkened, but he has not cited any authority in support of his said observations.

To say that the samples of the Tetracycline tablets were not produced and therefore it cannot be said as to whether the disputed tablets were coated or were packed in bottles or strips would be unfair to the appellants as though the samples were not produced before us the requisite details are available on the record. From the approved Classification List (Page 41-42 of the paper book) it is clear that the appellants have given the description of the disputed capsules and tablets as follows- 85. From the above description it is clear that the Reclor capsules were packed in bottles and Resteclin Capsules and Resteclin Tablets were packed in vials. From the storage conditions laid down in the Indian Pharmacopoeia as stated above and the observations made in the United States Dispensatory, 27th Edition regarding stability of the Tetracycline capsules, it is clear that even though the capsules and tablets are packed in a container (of say 1000 capsules), the original conditions of the storage no longer prevail, either for the remaining stock or for the capsules dispensed and the patient are required to protect the medication from direct storage light. It is significant to note that in the Book of Goodman and Gilman's The Pharmacological Basis of Therapeutics, sixth edition the Writer of the article by Merle A.Sande and Gerald L. Mandell while describing the stability of Tetracyclines had no doubt stated that the Tetracycline and Chloramphenicol are quite stable as dry powders but there is no further discussion on the point. Whereas Murray S. Cooper in their Book Quality Control in Pharmaceutical Industry at page 217 has discussed this aspect in detail and stated that Tetracycline occurs as an yellow, odorless, crystalline powder which is stable in air. Exposure to sunlight causes it to darken, but this darkening may be retarded by addition of sodium metabisulfite or ascorbic acid. Thus, I agree with the majority and hold that the addition of ascorbic acid in the manufacture of disputed capsules and tablets was a Pharmaceutical necessity.

86. As regards the contention raised by the learned Counsel for the appellants that Ascorbic acid was required to be added as a buffering agent in the manufacture of the disputed capsules and tablets to counteract ill-effects of Tetracycline or Chloramphenicol, my learned Brother Shri V.P. Gulati has rejected the said contention of the appellants observing that "there is no averment from the appellants that Ascorbic Acid has been added to the capsules and tablets in question to take care of any specific ill-effect that may be created by Tetracycline and Chloramphenicol. There is no plea nor any authority cited that the both drugs interfere with the mechanism of Vitamin C or Ascorbic Acid absorption or metabolising of the same in the human system warranting the addition of Ascorbic Acid in these medicines as in the case of Iso Benzacyl Forte.... No evidence has also been produced from any medical authority in this regard", though he has admitted that both Tetracycline and Chloramphenicol produce untoward effects, Tetracycline may be toxic in nature because of gastrointestinal irritation on oral administration, which may cause vomiting and diarrhoea or some skin effects or toxicity of the liver or kidney etc. as recorded by Shri D.C. Mandal in para 8 (iv) of his Order and that Chloramphenicol also produce untoward effects like Hypersensitivity reactions, Hematological Toxicity and other effects like vomiting, diarrhoea and irritation. With due respect if I am permitted to say it would be unfair to the appellants to say that there is no averment or plea from the appellants on this point To complete the record I may say that right from the beginning it was the case of the appellants that Ascorbic Acid added in Chloramphenicol is one of the safest and most effective anti-oxidant and that chloramphenicol becomes more safe in the presence of Ascorbic Acid See page 65 of the Paper Book and that the addition of ascorbic acid in Tetracycline Hydrochloride insures clinical safety and efficacy of the product throughout the shelf-life and is incorporated in the product for the purpose of stability and safety only. See page 66 of the Paper Book.

They also produced the Technical Literature along with their reply to the show cause notice and also various authorities at the time of hearing before the Adjudicating Authority as well as before us. In their reply to the show cause notice see page 56 of the Paper Book they have very specifically stated that a Pharmaceutical formulation is a drug delivery system consisting of active ingredients along with several very carefully selected adjuvents and that at the

same time the product should be toxicologically safe and acceptable to the patient.

Nature of Pharmaceutical necessities added to a product depends on physicochemical properties of drug included in the product and the route of administration and therefore, the addition of ascorbic acid in their products has to be considered in these backgrounds and further that ascorbic acid is one of the vitamins required by human body for normal functioning and thus it is absolutely safe and addition of ascorbic acid makes the disputed capsules and tablets more stable and safer. Before us also the learned Counsel for the appellants argued about the necessity of addition of ascorbic acid in the manufacture of the disputed capsules and tablets and cited the various authorities as discussed by my learned Brother Shri D.C. Mandal in his order. From the various authorities cited by the learned Counsel for the appellants and the arguments made as already discussed by my learned Brother Shri D.C.Mandal, I hold that the addition of Ascorbic Acid in the manufacture of disputed capsules and tablets was required to be added to take care of toxic effect that may be created by Tetracycline and Chloramphenicol and I with respect do riot agree with the inference drawn by my learned Brother Shri V.P. Gulati that addition of ascorbic acid in the manufacture of disputed capsules and tablets was only to meet the increased requirements of the same when a person is suffering from infection and the administration of the same with Chloramphenicol and Tetracycline is only to fight the infection for which the other two drugs are given as another agent for countering the infections.

87. In the passing it may be mentioned that my learned Brother Shri V.P. Gulati has also relied upon a negative circumstance against the appellants observing that when he started recording his separate order, he came across a publication titled "MIMS India Monthly Index of Medical Specialities" (Jul 1985 Vol 5 No. 7) wherein the Reclor Capsules, Resteclin Capsules and Resteclin Tablets manufactured by the appellants are listed and from the contents of the capsules and doses listed therein it was observed that the appellants are manufacturing these capsules without addition of Ascorbic acid and when this is the position, it clearly goes to establish that the addition of Ascorbic Acid to Tetracycline and Chloramphenicol was not a pharmaceutical necessity. After coming across of the said publication he has blamed the appellants by stating that they "obviously have not placed the true

facts on record" and also went further to state that in these circumstances he felt it necessary that the appellants should be given an opportunity to make their averment in regard to the same before any inference could be drawn in regard to that and therefore, he had recorded a note order for circulation for this purpose for consideration of the other Members of the Bench, but the other Members did not agree for the re-opening of the case observing that since the proceedings before the Central Excise Authorities are quasi-judicial in character, they can be supported only on the findings in the impugned order and not by any other ground as held in the case of Cibatul Ltd. v. Union of India, 1979 ELT 407 and therefore he has no choice but to draw an adverse inference against the appellants from the said literature of MIMS India and after drawing the adverse inference against the appellants as aforesaid he had also thought it proper to state that in case the hearing had been re-opened, we would have had the opportunity of seeing the samples of the product as marketed by the appellants and the appellants would have also had the opportunity of putting forth their plea as to why the appellants were marketing the Tetracycline and Chloramphenicol capsules and tablets without the addition of ascorbic acid.

Regarding these observations I would content myself by saying only that the said information was available before the authorities below and before us also at the time of hearing of the appeals (See Annexure 'F' page 86 of the Paper Book) wherein the appellants had stated that they have changed the formulation of the disputed capsules and tablets from November and December, 1982 and had stopped adding ascorbic acid in the manufacture of the said products. This information was very much available before the Collector of Central Excise when he authorised the Assistant Collector to file the present appeal through his authorisation letter dated 9/10-1-85, but this circumstance was never relied upon by the Collector of Central Excise in his authorisation letter nor it was argued by the learned JDR at the time of hearing before us nor any question was put by the Bench particularly by my learned Brother regarding the said negative circumstance. In these circumstances no adverse inference can be drawn against the appellants.

Besides, this negative circumstance is in my considered opinion is also not incriminating circumstance against the appellants, if we look to the facts and circumstances of the case. In the instant case we are concerned with Classification List relating to the year 1977 which were earlier approved, but subsequently proposed to be revised by the show cause notice of the year 1981. It is not in dispute that development of pharmaceutical science is a general phenomenon and enormous change in the content, stature and function of the Pharmacology; its role in the biomedical sciences; and its impact on the clinical sciences and rational therapeutics has been witnessed during the last 10 years. It is to be remembered that preparing, compounding and dispensing of medicines at one time lay within the province of the physician but this work is now delegated almost completely to the Pharmacist Thus, we have to examine the issue in hand keeping in view the pharmaceutical sciences available at that time. If at that time ascorbic acid was thought to be a pharmaceutical necessity in manufacturing the disputed capsules and tablets, it cannot be said by any stretch of imagination that at present, i.e., after a lapse of about 6" years on account of a subsequent development in a Pharmaceutical Science, it was not used as such and therefore, it was not a pharmaceutical necessity earlier also.

Apart from that there may be various reasons for not adding the Ascorbic Acid in the manufacture of the disputed capsules in 1982 onwards. It is on record that after the approval of Classification List granting benefit of the said exemption notification, the Assistant Collector in Jan 1978 suo motu arbitrarily revised the earlier Classification List withdrawing the benefit of the said Notification and therefore, the appellants have to take up the matter in appeal and accepting the appeal the Collector (Appeals) remanded the matter by his order dated 3.7.1980 for de novo adjudication and on remand a show cause notice was issued in May 1981 proposing to withdraw the benefit of the said Exemption Notification. Thus, if after the issue of the show cause notice in May 1981 the appellants deleted the ascorbic acid from the formulation of the disputed capsules and tablets to put an end to the controversy raised by the department, does it follow that the addition of ascorbic acid was not a pharmaceutical necessity in 1977.

In other words what is relevant is as to how the addition of ascorbic acid in the manufacture of the disputed capsules and tablets was known in the pharmaceutical industry and the medical field at the relevant time when it was used as such. It is on record that the appellants were manufacturing the disputed capsules and tablets in accordance with the Pharmacopoeia of India (The Indian Pharmacopoeia). Under the heading Chloramphenicol and Tetracycline in the Indian Pharmacopoeia there is no indications as aforesaid about the stability of these antibiotics unlike in the Book of Goodman and Gilman's The Pharmacological Basis of Therapeutics, Sixth Edition. In this view of the matter I with due respect disagree with my learned Brother Shri V.P. Gulati that since the appellants themselves are now marketing the disputed products without the addition of ascorbic acid, die addition of the ascorbic acid in the manufacture of the disputed capsules and tablets in 1977 cannot be considered as a pharmaceutical necessity for the purpose of benefit of the said Notification No. 116/69 now.

88. Before I part I would like to mention that in his order my learned Brother Shri V.P. Gulati has stated that there is no discussion regarding the need for the addition of ascorbic acid as a stabilizing agent in the order recorded by my learned Brother Shri D.C. Mandal when Tetracycline and Chloramphenicol are in the tablet and capsule form for the reason that this will lose the activity in case ascorbic acid is not added.

With respect I do not agree with these observations if we read the order recorded by Shri D.C. Mandal as a whole and in any case there was no necessity for it for, it is common knowledge and also supported by technical literature as discussed by me above that the bases of these products do lose their activity in capsules/tablets. Likewise I do not agree with the observations made by learned Brother Shri V.P. Gulati that there is no specific finding also in this regard, i.e., to say ascorbic acid has been added to the disputed capsules and tablets to take care of any specific ill-effect that may be created by Tetracycline and Chloramphenicol except for general discussion that ill-effect was produced by two drugs if we read the said order as a whole. In paragraph 25 of the order recorded by my learned Brother Shri D.C. Mandal, he after considering the arguments

advanced by both the parties and the literature available on record concluded that Buffering agents, stabilisers and preservatives are specifically mentioned in the Notification itself. Therefore, in the absence of any material before us to show that ascorbic acid and pyridoxine hydrochloride had been used in the disputed medicine, not as pharmaceutical necessities, but have been used as therapeutic necessities only, we have to reject the argument of the learned Departmental Representative that the pharmaceutical necessities are such material which are meant for compounding and manufacturing of medicines but not for treatment of side effects, has also to be rejected.

89. In the result, as ordered by the Majority and also concurred by Brother V.P. Gulati, I also dismiss the two appeals No. ED/SB/447/83-C and No. ED/SB/335/84-C filed by the department and allow the appeal No.2155/86-C pertaining to the appellants M/s. Sarabhai Chemicals and which relates to the exemption of Resteclin I.M and Steclin I.M.(Vet).

I also agreeing with the Majority and concurred by my learned Brother Shri V.P. Gulati also notwithstanding his order on the said appeal as ordered by him in paragraph 48 of his separate order, allow the other appeal No. E/2173/86-C filed by the appellants M/s. Sarabhai Chemicals and which relates to the exemption of Reclor Capsules, Resteclin Capsules and Resteclin Tablets.