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IN THE HIGH COURT OF JUDICATURE OF BOMBAY
BENCH AT AURANGABAD

WRIT PETITION NO.2120 OF 2014

Johnson & Johnson Limited PETITIONER
Through its Authorized Representative,
Mr. Ajit Nene,
B-15 / 1, MIDC, Waluj,
Aurangabad – 431 136

VERSUS

1. The State of Maharashtra RESPONDENTS
Through Hon'ble Minister,
Food and Drugs Administration,
Mantralaya, Mumbai – 32

2. Joint Commissioner, Aurangabad Division
Food and Drug Administration, M. S.
Aurangabad, Nath Market,
2nd Floor, Aurangpura
Aurangabad – 431 001

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Mr. P. M. Shah, Senior Advocate I/b Aditya N. Sikchi, Advocate for petitioner

Mr. Y. G. Gujrathi, AGP for respondents - State

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[CORAM : SUNIL P. DESHMUKH AND
S. M. GAVHANE, JJ.]

DATE : 21st DECEMBER, 2018

ORAL JUDGMENT (PER SUNIL P. DESHMUKH, J) :

1. Rule. Rule returnable with consent of learned advocates for the parties and is heard finally.

2. The petitioner is before this court aggrieved by orders passed, by respondent No. 2 – Joint Commissioner, Aurangabad Division, Food and Drugs Administration dated 2nd December, 2013 and by respondent No. 1 – State of Maharashtra, Food and Drugs Administration, Mantralaya, Mumbai dated 25th February 2014 in exercise of powers under Drugs and Cosmetics Act, 1940 (herein after 'D C Act') and Drugs and Cosmetics Rules, 1945 (herein after 'D C Rules'), whereunder, licences issued to the petitioner under Forms No. 25 and 28 of the D C Rules were directed to be suspended for a period of sixty days.

3. Genesis of present writ petition lies in notice issued, to the petitioner by respondent No. 2 – Joint Commissioner, Aurangabad dated 19th June, 2013, to show cause as to why action referred to therein be not taken referring to that report of inspection of the premises of petitioner at Waluj carried out on 14th and 15th June, 2013 draws attention to certain breaches.

4. The first issue raised in the show cause notice was about manufacture on 19th February, 2007 of *Synsyl Violet/undyed (Polyglactin 910) braided absorbable suture,* being without approval from Food and Drugs Administration as 732 packs were processed for sample registration and 50 packs had been sent to China, in the

absence of approval of administration to additional production and without certificate of pharmaceutical product. The administration had given permission for additional production on 3rd May, 2007 for export. Since manufacturing, processing, storing and sale of said products had been done in the premises licenced for other products, there is breach of provisions of sections 18 (c) and 18 (a) (vi) of the D C Act.

5. Second issue refers to absence of estimation of residual ethylene oxide batchwise while *terminal sterilization of ethylene oxide* is carried out in respect of twenty three surgical sutures, observing that the petitioner does not seem to follow norms of international standards – ISO 10993-7 : 2008 (E) Biological Evaluation of Medical Devices – Part – 7 and that while the petitioner carries out requalification of ethylene oxide sterilization once in a year, such an exercise takes place in respect of only one out of twenty three products, according to availability. This would evince that (product specific) process validation of estimation of ethylene oxide residual content does not take place regularly. Thus, the petitioner has committed breach of Schedule-M, Part -I, clause 26.1 read with rule 78 (p) and section 18 (c) of the D C Rules and Act.

6. Third ground in the show cause notice is in respect of point No. 14 of the inspection report alleging that batches of *Prolene* from manufacturing plant of Johnson & Johnson Limited, Baddi, Himachal Pradesh, are regularly being brought to Waluj plant for ethylene oxide sterilization part processing and after the processing, without testing said products are sent back to plant at Baddi. As such, without permission of the licensing authority of concerned region, unauthorizedly processing is carried out on the goods of other States in the licenced premises, contravening sections 18 (c) and 18 (a) (vi) of the D C Act. Baddi in Himachal Pradesh has been declared by the central government as special economic zone and products from said place are being given special concessions and, as such, petitioner has not followed norms of special economic facilities.

7. Fourth is, while licence has been granted to petitioner for *Mersutures, Ethicon*, *plain catgut* by the Food and Drugs Administration, inspection report refers to that raw material of said products from M/s Ovis Biosurgical, Navi Mumbai is directly and regularly sent to Baddi plant of the petitioner for the process of polishing which are regularly being sent from Baddi for further process at Waluj, Aurangabad plant of the petitioner. Thereafter, assembling, sterilizing and testing of finished products takes

place and product is made available for sale. It seems that about such polishing part process at Baddi, in-house record has not been maintained nor approved. Further, this had not been informed to the licensing authority. Part process in other States is being done unauthorizedly without manufacturing in approved premises, in contravention of sections 18 (c) and 18 (b) of D C Act.

8. Fifth is that, it has been found that the petitioner has been using imported raw material, without carrying out all the tests, only on some physical tests and is being released on the certificate of analysis given by supplier for approved production of *Vicryl, Monocryl, PDS II* and *Vircryl Rapid* and as such, there is contravention of rule 74 (c) read with section 18 (c) of the D C Act and Rules.

9. Accordingly, provisions of D C Act and Rules and conditions of licences, bearing No. AD/008 and AD/007 in forms No. 25 and 28 respectively sanctioned for the period from 27th November, 1990 to 31st December, 2016 are not followed and to show cause as to why no action pursuant to subject enactment be taken, directing to submit explanation to the office referring further to that in case of non submission of explanation or if the same is

found to be unsatisfactory, action would be taken without any notice. It was clarified that, if hearing is requested apart from written explanation, such an opportunity would be made available.

10. Petitioner had tendered issue/groundwise explanation to the show cause notice on 26th June, 2013.

11. With respect to the first ground in the show cause notice about manufacturing braided absorbable suture without approval from Food and Drugs Administration and its part export to China, alleging violation of provisions under section 18 (c) and 18 (a) (vi) of the D C Act, respondents have recorded their satisfaction with the explanation, as such, obviating discussion on the same, the petition concerns rest of the issues.

12. As far as second issue/ground under the show cause notice is concerned, it had been explained that petitioner has comprehensive validation process in place, for all types of sterilization used for sutures including ethylene oxide sterilization process, which is in line with globally accepted standards such as ISO 11135-1 involving extensive predefined protocols for critical process and that the protocol was made available during audit of the plant and had also been included

along with explanation and further pointing out that in the absence of specific regulation in D C Act and Rules, ISO 11135-1 and ISO 10993-7 which are international standards are followed and adhered to.

13. It had been explained that industry practice is to have residual testing during initial Ethylene Oxide (EO) sterilization cycle validation demonstrating that product residuals meet acceptable limits prior to their release. Testing is evaluated/repeated when the product or sterilization process is changed. EO residual testing is repeated whenever sterilization process is revalidated. It has also been referred to that for application of ISO 10993-7 standards, frequency of EO residual testing is not defined.

14. It had been clarified that ISO 10993-7 allows group devices of similar design of different sizes and suggests using "*worst case*" product to represent the group of products for estimating residuals as the same process is used for all sutures.

As per ISO requirement, petitioner uses "worst case" suture samples for validation of EO sterilization and residual EO estimation. The process is validated as per ISO 11135-1. Petitioner monitors the process. *Braided Vicryl,* having maximum

surface area and diameter, having probability of retaining the highest amount of residual ethylene oxide, represents worst case suture, is chosen during annual requalification. It has further been referred to that in addition to *Vicryl*, data of other sutures EO residual is maintained. It is submitted that monitoring of each batch for EO residuals is not required. At the end of each sterilization run, parameters for aeration and vacuum are verified by manufacturing and quality assurance personnel and that there is least probability of any batch having higher EO residue as compared to validation runs. Record is maintained and the sample had been annexed. It has further been referred to that validity process has yielded similar acceptable results for worst case suture over the last three decades during annual requalifications as referred to in the following table which had also been given in explanation to show cause notice,

Product Family	Year	Results (ppm)	FDA Requirement (ppm)	Results, mg	ISO10993-7 requirement, mg
Vicryl size 1	2009	60	250	0.02	4
Vicryl size 1	2010	80	250	0.03	4
Vicryl size 1	2011	19.2	250	0.008	4
Vicryl size 1	2012	59.7	250	0.02	4

showing ethylene oxide residual as observed in the annual testing are significantly lower than the specified limit.

15. It has been submitted that there is no specific provision under the D C Act and Rules prescribing any standards and the petitioner, thus, is using ISO standards. The United States Pharmacopeia (USP) does not specify ethylene oxide residual test. Schedule M and ISO 10993-7 do not reflect that every batch should be tested or how frequently reference to ethylene oxide residuals is required. As such, there is no violation of D C Act and Rules so also of Schedule M, Part - I, clause 26.1 or of rule 78 (p) or section 18 (c).

16. With regard to third issue/ground about sterilization of *Prolene* manufactured at Baddi is part processed in the plant at Aurangabad without obtaining permission from licensing authority and that product is being sent back post sterilization without testing, it has been explained that Aurangabad plant has licence since 1991 to manufacture *Prolene* and the process includes sterilization with ethylene oxide. While manufacturing licence for *Prolene* at Baddi plant had been sought, flow chart of process steps to be followed specifically refers to that sterilization of *Prolene* would be conducted at Aurangabad plant. The manufacturer at Baddi and at Aurangabad is a single entity i.e. Johnson & Johnson Limited. This product goes back to Baddi for further processing including cellophane wrapping and tertiary

packing, testing including sterility test etc. Additional testing for the biological indicator verification of sterilization process takes place at both the locations. It had further been informed that manufacturer has valid licence at both the locations. There is no new material/product being processed at Aurangabad and proper documents and records are being maintained giving sufficient indication of that there is no violation of provisions of sections 18 (c) and 18 (a) (vi) of the D C Act by sterilization of *Prolene* at Aurangabad. It had been further clarified that if required, a separate licence would be obtained for carrying out sterilization process on material received from facility at Baddi.

17. In respect of fourth issue/ground *viz.,* that part process (polishing) of the products at Baddi, is in violation of sections 18 (c) and 18 (b) of the D C Act, as no permission or approval for carrying out polishing at Baddi is obtained, it is explained that Aurangabad plant has licence to manufacture *Mersutures, Ethicon, Plain Catgut and chromic catgut*. M/s Ovis Biosurgicals manufactures raw strands from sheep and goat intestines. These strands are components and are not considered as sutures. Polishing of these strands takes place at Baddi. These polished strands are not classified as sutures or semi-finished goods but are the raw material components for manufacture of finished

suture product. Polishing of raw material components is not manufacturing of sutures. The material after polishing comes back to Aurangabad plant as raw material components for manufacture of usable product under licence by carrying out different activities. It is further being referred to that it had been rightly observed so, in the inspection report. Suture products come into existence at Aurangabad plant, through mentioned process and activities and record about manufacturing is available at Aurangabad and excise duty is also paid at Aurangabad. It had been denied that goods are directly sent by M/s Ovis Biosurgicals to Baddi, clarifying that goods are received at Aurangabad and are sent to Baddi for polishing. It is submitted that record of receipts and dispatches are available with the petitioner. As such, it had been submitted that there is no violation of sections 18 (c) and 18 (b) of the D C Act.

18. With regard to ground/point No. 5, about violation of section 18 (c) read with rule 74 (c) of the D C Act and Rules, as only some physical tests of raw material for *Vicryl, Monocryl, PDS II and Vicryl Rapid*, are taken, it had been submitted that provisions do not clarify or provide for extent of testing, and as such, licencee would depend on internal specifications and certificates of testing from supplier for -

i. *Imported raw material is exhaustively tested at other Johnson & Johnson manufacturing sites and the sutures are moisture sensitive and come in air tight cans for preventing degradation of material due to moisture. Hence, to maintain integrity of these materials, they undergo reduced testing (physical verification, vacuum test of pouches, verification of label) before initiation of manufacture process.*

ii. *In absence of monograph for raw material, "in house" or "reduced" testing is used for suture material on the basis of certificate of analysis received from other Johnson & Johnson Companies manufacturing surgical sutures, which are operating under the same quality management system.*

iii. *For the products, tests for raw material and finished products are common and are performed at the end stage (finished goods released). It is also referred to that all necessary tests such as diameter or tensile strength required for sutures are carried out and the same are in compliance of Rule 74-B (3) of the D C Rules and are not in violation of section 18 (c) of the D C Act. It is further submitted that if it is felt that some other or additional tests are to be carried out, the petitioner be informed, so that petitioner may consider implementing the same. Accordingly show cause notice had been answered.*

19. A summary of discussion and submissions had been presented by the petitioner submitting that there is no contravention of any provision under the D C Act and Rules.

20. Petitioner received order dated 2nd December, 2013 under covering letter of even date referring to that licences, Form No. 25 bearing No. AD/008 and Form No. 28 bearing No. AD/2007,

have been suspended for sixty days with effect from 1st March, 2014 to 29th April, 2014 and in case if it is noticed that any manufacture/distribution activity takes place, legal action for contravention of section 18 (c) of the D C Act would be initiated.

21. In the order, it has been referred to that international ISO 10993-7, 2008 (E), provides for -

> (i) 5.0 product release – *" A product is in compliance with the part of ISO 10993 when it meets the requirement for EO"*
> *"For release of batches of EO" sterilized product, one of the two methods in 5.2 and 5.3 respectively shall be use. "*
>
> (ii) Under 4.4.3 product sampling, it is provided *" factors influence not only the initial levels of residuals in device in components but also the rate of dissipation, they shall also be considered when test samples are drawn from the process load and sent to laboratory for analysis "*
>
> (iii) 1.6 sample retrieval provides, *" caution should be exercised when product samples are routinely removed for analysis from the sterilization load soon after the sterilization process is completed "*

22. It had been considered in the order that aforesaid norms of international ISO 10993-7, 2008 (E) had not been followed.

23. It has been observed that licence holder had been doing requalification of ethylene oxide sterilization once in a year and residual ethylene oxide estimation is done in respect of one of the products showing that licencee has not been doing product

specific ethylene oxide sterilization process validation. Estimation of residual content of ethylene oxide is not being regularly done after sterilization. It is also revealed that the licence holder is not checking ethylene oxide residue in each batch. Since suture is used in surgery for sewing injury, it comes directly in contact with blood and internal organs of the body and if ethylene oxide residual remains beyond the permissible limits, the same would be harmful to health and would cause irritation, organ damage, mutagenicity and carcinogenicity in human and animals and reproductive effects in animals and the same is clear from the literature of ISO 10993. It is a serious matter and is harmful to life of patient.

24. Schedule M, Part – III, caption *'Requirements for factory premises for manufacturing medical devices'* of the D C Rules is referred to, to say that product sterilized by ethylene oxide gas should be monitored to assure acceptable levels of residual gas and its degradation products.

25. Thus, it is considered that licencee has contravened Schedule M, Part I, clause 26.1 read with Schedule M, Part III, clause 6, read with rule 78 (p) and section 18 (c) of the D C Act and Rules.

26. It has been observed that while *Prolene* is regularly brought to Aurangabad for ethylene oxide sterilization processing from Baddi and is being sent back after processing, in the licenced manufacturing premises process is carried out on drug produced in the other State without permission of the authority.

27. It is referred to that pursuant to 'Requirements for factory premises for manufacture of medical devices', under Schedule M, part III, clause 6 for sterilization, the licencee shall provide requisite equipments with required controls and recording devices for sterilization of medical devices by ethylene oxide gas in own premises or may make arrangement with some institution approved by the licensing authority for sterilization. The product sterilized by ethylene oxide gas shall be monitored to assure acceptable levels of residual gas and its degradation products. Then it has been considered that the activity is not lawful and licence holder has been reluctant to comply with the conditions in law and, thus, the licence holder has contravened the provisions of D C Act and Rules thereunder, so also, Schedule M, Part III, clause 6.

28. The licence holder has been sanctioned permission for *Mersutures, Ethicon, plain cat gut and chromic catgut*. The licencee obtains

raw material for the same from M/s Ovis Biosurgicals, Navi Mumbai and directly sends it to its Baddi plant for polishing regularly and after polishing, for further process, it is brought to Waluj, Aurangabad plant. The licencee has not been permitted to send licenced product in this State for processing. It does not appear that licence holder has any record or approval for such activity and the same had not been made known to the authorities. Part processing is not carried out in the licenced manufacturing premises and is done in other State and thus, the authorities in the State would not be able to control the process, giving rise to suspicion about quality of product.

29. Contention of the petitioner about material being brought to Aurangabad and sent to Baddi for polishing and is brought back and sutures are manufactured, is not proper and not legal. Schedule M, Part-I, paragraph 10.1 of D C Act requires record to be maintained in respect of raw material used for manufacture and the same is obligatory pursuant to Schedule "U". Material from M/s Ovis Biosurgicals is a raw material and polishing is a manufacturing process. There are provisions to control the processes, however, in violation of the same licencee on its own has changed place of processing without taking permission nor it was informed to the authorities.

30. It is, therefore, considered that there has been contravention of section 18 (c) and 18 (b) of the D C Act and Rules.

31. It is then considered that while it was necessary to carry out tests on raw material, *Vicryl, Monocryl, PDS II and Vicryl Rapid*, are being manufactured without testing raw material by carrying out only physical tests. The petitioner thus, does not comply with the requirement of sample testing. Care has to be taken pursuant to Schedule M, part I paragraph No.10.4 while accepting raw material, with only physical tests products are manufactured using untested raw material. No assurance about its quality can be given. Testing of representative sample of raw material in process and finished product is obligatory for quality production. Representative sample is necessary to be tested of every batch of raw material in order to have quality product, however, without preparing any norms of quality of raw material and without testing conformation to the norms, raw material is being used and thus, possibility of harmful effect on patient's health cannot be ruled out. The petitioner has not taken due care and this is a serious aspect. Thus, the petitioner has contravened rules 74 (c) and 78 (c) (ii) of D C Act and Rules.

32. It is considered that the licence holder has contravened Schedule M, Part I, clause 26.1, Schedule M, Part III, clause 6, rules 78 (p) and 74 (c) and sections 18 (a) (vi), 18 (b) and 18 (c) of the D C Act and Rules and had acted irresponsibly. Respondent No. 2 – authority passed order of suspension of licences of the petitioner from 1st March, 2014 to 29th April, 2014 in exercise of its powers pursuant to provisions of rule 85 (2) of the D C Rules. The matter was, thus, taken in appeal.

33. In the appeal before respondent No. 1 – State of Maharashtra, filed against order passed by respondent No. 2 – Joint Commissioner – licensing authority, it had been submitted that the petitioner is in business of manufacture of sterilized and non sterilized absorbable and non absorbable sutures for decades. It has two manufacturing facilities, one at Aurangabad – Maharashtra and the other at Baddi – Himachal Pradesh. Suture is a medical device, used to hold body tissues after injury or surgery, and generally comprises needle and a natural or synthetic filament. Petitioner has valid manufacturing licences under Forms No. 25 and 28 of the D C Act and Rules thereunder, both at Aurangabad and Baddi.

34. It had been submitted that " ISO 10993-7 Biological evaluation of medical devices part – 7 Ethylene Oxide

Sterilization (EO) residuals ", is neither a standard which is prescribed under the Act or Rules nor is its compliance a condition of the licences under Forms No. 25 and 28. Compliance with ISO 10993-7 is irrelevant and extraneous consideration for the purpose of exercise of power under rule 85 of the D C Rules. Yet, substantive reliance on the same had been placed under the order passed by respondent No. 2, considering it obligatory to carry out testing for EO residual estimation. The case of *"Hukum Chand Shyam Lal V/s Union of India"* reported in *(1976) 2 SCC 128* had been referred to in order to support its submission that an order passed by administrative authority on extraneous consideration is liable to be struck down. Moreover, the petitioner has satisfied the requirements of ISO 10993-7.

35. It had been submitted that the order passed by respondent No. 2 does not disclose reasons for rejecting explanation tendered by the petitioner nor does it disclose exact nature of alleged violation. Case of *"Siemens Engg. And Manufacturing Co of India V.s Union of India" (1976) 2 SCC 981*, had been relied on to emphasise that it is imperative, in exercise of *quasi* judicial function, to record reasons in support of order. Case of *"Union of India V/s Mohan Lal Kapoor" 1974 (1) SCR 797* has also been referred to, to underscore importance of reasons, which would show application

of mind to subject matter for a decision, since reasons are link between material on which conclusions are reached and actual conclusions. The case of *"Mst. Saleha Khatun Bewa V/s The State of Assam and Others" AIR 1977 Gauhati. 18* particularly, paragraph No. 20 from the same has been referred to, to further emphasise that quasi judicial authorities should give reasons for rejecting submissions of the subject. Certain portions were also quoted from said decision. It was submitted, order passed by respondent No. 2 would show that no reasons are given to reject explanation of the petitioner and the order simply repeats allegations in show cause notice purporting to be grounds in the order. The order is deficient to depict nexus between facts considered and conclusions reached. It was, thus, contended that the order passed by respondent No. 2 suffers from arbitrariness, non application of mind and non observance of principles of natural justice.

36. Respondent No. 2 had committed error in relying on inapplicable provisions at various places. While the show cause notice does not refer to violation of Schedule M, Part -III of the D C Rules, the same has been extensively referred to by respondent No. 2 to consider that there was an obligation on the petitioner to carry out batchwise tests of EO residual estimation.

It is purported to be pointed out that for alleged inadequate testing of raw material of certain products under Form No. 28 of licence of the petitioner, rule 74 (c) of the D C Rules has been invoked, which provides for conditions applicable to products covered under Form No. 25 licence.

37. It had further been submitted that while violation of ISO 10993-7 had been alleged, reference to several other provisions have been made *viz.,* 5.0, 5.2, 5.3, 4.4.3 and D 1.6. Those provisions had not been referred to in the show cause notice and consequently the petitioner had been deprived of opportunity to respond to these contentions.

38. The petitioner has complied with Schedule M, Part-III, Clause 6 in relation to products received at the Aurangabad facility from the Baddi facility for part processing of EO sterilization.

39. It was submitted without letting opportunity to respond to considerations it had been concluded that petitioner had violated Schedule M, Part III and consequently, violated conditions of Form No. 28 of the licence. It had further been claimed that principles of natural justice have been contravened at many places denying opportunity of being heard to petitioner, since the

department went on improving upon its own case. Petitioner did not have opportunity to make submissions in relation to weighed considerations.

40. While receipt and processing of product from Baddi with EO sterilization at Aurangabad is not claimed to be violating Schedule M, Part – III, however, the same had been relied on to allege violation of section 18 (c) and 18 (a) (vi) of the D C Act.

41. So is the case in respect of testing raw materials while show cause notice did not allege any violation of rules 78 (c) (ii) of the D C Rules, however, said provision has been relied on in the order by respondent No. 2 to hold petitioner guilty of violation of conditions of licence in Form No. 28. It had thus submitted that the order by respondent No. 2 is arbitrary and depicts non application of mind and non observance of principles of natural justice.

42. The tests carried out on raw materials for *Vicryl, Monocryl, PDS II, Vicryl Rapide* are sufficient to satisfy the requirements under rule 78 (c) (ii).

43. It had been pointed out that show cause notice and order by respondent No. 2 would have no reference to products falling

under Form 25 of licence, for Form 25 products are non sterile and allegations with regard to EO treatment are not applicable to them. Allegations about EO sterilization of *Prolene* have no bearing on Form 25 licence as *Prolene* is not covered under Form 25. The allegations concerning polishing of raw material are with respect to such items which have no concern with Form No. 25. So is the case in respect of allegations about testing of imported raw material, which do not relate to Form No 25 and is not covered under the same, yet, the order passed by respondent No. 2 covers suspension of petitioner's Form No. 25 licence as well.

44. In this respect, a judgment of Gauhati High Court in the case of *"Mst. Saleha Khatun Bewa V/s State of Assam and Others" AIR 1977 Gau 18*, had been referred to, and attention has been sought to paragraph No. 17 thereof to impress upon that if drug is not covered by a licence in particular form, question of cancellation of said licence would not arise. It was thus submitted and claimed that authorities had no power to suspend Form No. 25 licence of the petitioner and the show cause notice does not relate to products under Form No. 25 licence.

45. One more aspect was highlighted i.e. about no reference to any product under Form No. 25 was made even in inspection report or during the hearing. As such, it was submitted that the impugned order passed by respondent No. 2 is without jurisdiction, it is arbitrary and without application of mind.

46. It was contended that while Form No. 28 licence relates to ninety five different products, there are twenty nine products from the same, which are not at all related to allegations in show cause notice and yet, the order by respondent No. 2 covers said twenty nine products unconcerned with show cause notice. The case of *"Universal Drug House Pvt. Ltd., V/s State of Bihar and Others", AIR 2004 Patna 86*, has been cited to lay stress on that suspension of unrelated and unconcerned products under impugned order passed by respondent No. 2 is unsustainable and exercise of powers shall be with due caution and not mechanical or arbitrary, pointing out that in the cited judgment, the court had quashed impugned order in relation to the unrelated products. It was contended that exercise of power to suspend licence had been arbitrary and without due caution. Food and Drugs Administration does not have unguided discretion to pass such orders giving clear indication of non application of mind to the facts of the matter.

47. The case of *"Tolaram Reluman and Another V/s State of Bombay" [(1955) 1 SCR 158 : AIR 1954 SC 496 : 1954 Cri. L. J. 1333]* has been referred to, to consider that if two constructions of a provision are possible, the court must lean towards that construction which exempts the subject from penalty rather than the one which imposes.

48. It was submitted that products, under licence Forms No. 25 and 28, manufactured by the petitioner do not pose any safety risk upon use by public. The products are critical components of wound treatment and surgeries. Petitioner has been manufacturing sutures in India since decades contributing significantly in the arena of patient care. Any interruption in licence would affect supply of products and consequently would adversely impact public health.

49. Respondent No. 1, Food and Drugs Administration, Maharashtra State, in its order dated 25th February, 2014, has purportedly referred to the reasons for licence suspension and to defence points by the petitioner on five items and has observed that after hearing the petitioner represented by the persons referred to and taking into consideration written submissions by petitioner and documents and written submissions made by

respondents and considering all the aspects, it had been noticed that Joint Commissioner, Food and Drugs Administration, Aurangabad – respondent No.2 had given show cause notice to the petitioner and opportunity of personal hearing had been given.

50. Respondent No. 1 observes that manufacturer has said that frequency of residual content of EO is not clearly mentioned in law or ISO and petitioner does said test on worst possible case and hence on one product once in a year. It is violation of provisions of D C Act and hence submissions by the manufacturer are unsatisfactory.

51. It is further observed that manufacturer was doing EO sterilization at Aurangabad for product *Prolene* being manufactured at its Baddi facility, without permission from Aurangabad authority and manufacturer has submitted that no permission is required and flow sheet with the licensing authority at Baddi refers to the same, but has not produced permission letter from concerned authority or any related evidence. It has further been considered that only submission by the manufacturer cannot be considered as valid. It has been referred to under D C Act such processing is part of manufacturing and

licence is required and explanation given by manufacturer that since both the facilities are owned by the manufacturer is not a valid explanation, as both the facilities have independent licences from independent licensing authorities.

52. With respect to polishing of strands purchased from M/s Ovis Biosurgicals to manufacture sutures, it had been considered that since entry of material from M/s Ovis Biosurgicals is taken in the books at Aurangabad, it would be clear that material coming from Mumbai is raw material and hence submissions by the manufacturer are unsatisfactory.

53. It has further been observed that imported raw material used by manufacture for products *Vicryl, Monocryl, PDS II and Vicryl rapid* is not tested by manufacturer and only in house visual (external) and some physical tests are carried out instead of all tests. Releasing raw material on the basis of certificate of analysis provided by the supplier is not expected under law.

54. Impugned order in appeal goes on to observe that manufacturer submits that there is no violation of any provisions of Act in relation to Form No. 25 licence and thus suspension of licence is not correct, however, it is clear that order by licensing authority as per provisions of rule 85 of the D C Rules, is correct.

55. The order further goes on to observe that taking into consideration violations by the manufacturer, all these violations relate to all the products including in Form No. 28 licence and it is lawful to suspend form No. 28 licence. It is then considered that judicial decisions relied upon on behalf of the manufacturer at the time of hearing do not apply to the matter. Manufacturer has mentioned many other points in the written submissions and all these points have been considered. Observing that manufacturer has violated D C Act and rule 78 (p) read with Schedule M, Part I and clause 26.1 particularly, sections 18 (c), 18 (a) (vi), 18 (b), rules 74 (c), 78 (c) (ii) and ISO 10993-7, 2008 (E) and purportedly taking into consideration all aspects and powers conferred on it under rule 85(3) of the D C Act and Rules, upholding order passed by the licensing authority dated 2nd December, 2013, expecting that manufacturer would remove all the deficiencies found in the show cause notice, rejected the appeal, making concerned order effective from 15th March, 2014.

56. The petitioner has assailed, the orders dated 2nd December, 2013 passed by respondent No. 2 and 25th February, 2014 passed by respondent No. 1, in the writ petition.

57. Learned senior advocate Mr. P. M. Shah, appearing for the petitioner purports to passionately emphasize that it would not be a case at all wherein it can be said that there has been contravention of any statutory and legal provision. The show cause notice is non specific and vague. It does not show that there has been infringement of any rule or statutory provision. Allegations have been far too general in nature and are besides the factual position.

58. On the legal side, he has been categorical on that it is impermissible to go beyond the scope of show cause notice. He contends that the Food and Drugs Administration has went on improving its case at each stage of proceeding and many considerations have flown in, in the order passed by respondent No. 2 from far beyond reach of show cause notice. The case is further sought to be improved in the affidavit filed and during submissions in the court.

59. He then purports to reiterate the position as explained in the reply to the show cause notice and memorandum of appeal as well as written submissions.

60. Mr. Shah submits that, basically, in the present matter neither the show cause notice nor the orders by respondents No.

2 and 1, show that any particular provision of the D C Act and Rules has been contravened by the petitioner.

61. He purports to quite elaborately deal with the aspect involved that the proceedings ought not to have travelled beyond the show cause notice, yet, in good faith the petitioner has addressed the issues demonstrating that there is no violation of any provision of D C Act and Rules.

62. He submits that so far as issue No. 1 with regard to EO residue estimation is concerned, show cause notice is in respect of ISO 10993-7, 2008 (E), section 18 (c), rule 78 (p), Schedule M, part 1, point 26.1. Whereas, order by respondent No. 2 goes beyond the same and holds non compliance of Schedule M, Part III, clause 6, however, at the appellate stage said ground has been dropped. While show cause notice does not refer to the United States Pharmacopoeia (USP), the same has been referred to directly in the affidavit and during hearing rule 78 (c) (ii) read with Schedule U had been argued. He submits that it is not permissible, as referred to above, to go beyond the show cause notice. It would have to be considered that the Aurangabad manufacturing facility has been carrying out EO sterilization and testing since 1991 in the same manner. The provisions referred

to in the show cause notice, in the order of respondent No. 2 or for that matter in the affidavit in reply, do not provide for frequency of testing of EO residue. He submits that section 18 (c) requires compliance of the conditions of licence and rule 78 (p) requires the petitioner to comply with Good Manufacturing Practices (GMP) (i.e. schedule M). He points out note to Schedule M stating that a licencee has to evolve appropriate methodology, systems and procedures, which have to be documented and maintained for inspection and reference and that premises shall be used exclusively for production of drugs and no other manufacturing activity shall be undertaken. He submits that this gives an indication of that a licencee is to develop its own protocols in compliance with Schedule M. Clause 26.1 provides for validation studies as essential part of Good Manufacturing Practices, to be carried out as per pre-defined protocols for EO sterilization for testing of EO residuals. The issue sought to be raised is about frequency of EO residue testing. He submits that none of the provisions specify frequency of such testing. He submits that the petitioner has voluntarily complied with international standards ISO 10993-7 *(Biological evaluation of medical devices part 7, Ethylene oxide sterilization residuals)* and ISO 11135-1 *(sterilization of health care products – Ethylene Oxide – part 1 requirements for development, validation and*

routine control of a sterilization process for medical devices). He submits that besides said standards, comprehensive process validation for sterilization used for sutures is already in existence. He refers to that ISO 10993-7 does not mandate batchwise EO residue testing. Existing validated process has yielded similar acceptable results for the worst case sutures over the last three decades during annual requalifications. In written submissions to the show cause notice, the EO analyzed for worst case samples were provided to the Food and Drugs Administration.

63. Expert's affidavit of Mr. Scott Weis, who is part of American Committee of ISO which frames standardization rules in relation to EO sterilization has affirmed that ISO standardization does not mandate batchwise testing of EO residue content and that EO residual testing process followed by the petitioner is in compliance with ISO 11135-1, ISO/TS 11135-2 and ISO 10993-7 standards. The expert's affidavit has not been dealt with.

64. He submits that general information of the USP was referred to for the first time in the affidavit. Year of the annexed USP, however, has not been made clear. It is being referred to that from USP as available on line, perhaps ISO has been removed. Besides referring to methods of sterilization, it does

not lay down any detailed process and does not deal with testing of EO residue at all. It is further pointed out that USP refers to ISO 11135 and not ISO 10993-7 referring the reader to said ISO for complete description of process development, validation and routine control of ethylene oxide sterilization process. An argument with reference to this has been advanced that this is a sufficient indication that ISO compliance is not mandatory.

65. He submits that ISO standards are neither prescribed under the D C Act or the Rules nor their compliance is condition of licences under Form 25 and Form 28. ISO, for exercise of powers under rule 85 of the D C Rules is inapplicable.

66. Mr. Shah submits that estimation of EO residue content not being carried out batchwise, would not be a failure to comply with any statutory provision and for over twenty three years, several inspections were carried out and licences to the petitioner had been renewed five times, which carries presumption about fulfillment of requirements to the satisfaction of the licensing authority.

67. He submits that rule 78(c) (ii) Schedule U, Part B: Parenteral Preparation: Entries 13 and 16 and Notes to Schedule U were cited for the first time during the course of hearing. He

submits that products of the petitioner do not fall under the category of *'Parenteral Preparations'* at all, neither it appears to be the case of the respondents and the same would be clear from Schedule C. He submits that products of the petitioner fall under the heading A of Schedule U : *'Substance other than parenteral preparations in general'*. Schedule U is not relevant as it does not specify the tests or frequency. Note to schedule U, is of little relevance.

68. He further refers to Schedule M, Part I which deals with Good Manufacturing Practices for premises and materials. He also refers to Schedule U in respect of particulars to be shown in the manufacturing records and refers to clauses 13 and 16 under heading B Parenteral Preparations. He submits that the petitioner has an inventory of all raw materials being used and the petitioner maintains records required under Schedule U.

69. He submits that although USP has been referred to during proceedings after the show cause notice, yet the same does not make ISO mandatory under its norms. He submits that even otherwise, the petitioner has already demonstrated that it has been complying with the ISO 10993-7 for EO sterilization.

70. Referring to the entire process of sterilization and Aeration, he submits that ppm count in the worst case product is far below the count suggested by Food and Drugs Administration and submits that products are released in market only after fourteen to sixteen days during which period the EO dissipates (evaporates) further.

71. He submits, the petitioner has started testing each batch of product sterilized by EO and the same has been accordingly communicated to Food and Drugs Administration and further that the same has been confirmed by the Food and Drugs Administration. He submits that various inspections thereafter have been carried out by the Food and Drugs Administration and has not found that the residual content of EO was beyond the prescribed limit and has not cited any instance of breach of permissible EO residue. He, therefore, submits that apprehension relating to safety are based on assumptions and presumptions.

72. It is contended that the respondents have not produced any iota of evidence to show that any safety or efficacy issue in respect of product in question can be raised. The same is not rebutted by the respondents.

73. With regard to issue No. 2 about EO sterilization of product from its Baddi facility, he submits that the provision cited by Food and Drugs Administration would not require the petitioner to obtain a loan licence, which is meant for third party. The manufacturing facilities at Baddi and at Aurangabad having manufacturing licences are of one single entity.

74. He submits that rule 68 has been referred to during the course of hearing requiring licence to the premises where manufacturing activity is carried out in more than one premises. He submits that the petitioner complies with the requirement since manufacturing facilities at Baddi and Aurangabad do have manufacturing licences for products under Form No.28. He submits that rule 75-A was referred to and since the manufacturing facilities at Aurangabad and Baddi are owned by the petitioner, rule 75-A about loan licence is not applicable. He purports to refer to explanation under rule 75-A and Form 27-A.

75. He submits that moreover, the Baddi facility had informed Food and Drugs Administration at Baddi about sterilization process at Aurangabad, way back in 2008 when application for manufacturing licence had been submitted. Baddi Food and Drugs Administration did not require the petitioner any additional

licence in this regard. The process flow chart shows sterilization processing of Baddi product at Aurangabad facility.

76. He submits that, however, since the show cause notice had been issued with reference to the same, Baddi facility had applied for a loan licence and the same has been granted. During inspection, the Food and Drugs Administration has confirmed the compliance. This compliance had been pointed out to appellate authority, however, appellate authority has not taken the same into account.

77. In respect of allegation about violation of section 18 (b) and 18 (c) for non information to Food and Drugs Administration about catgut polishing activity, it is stated that catguts from M/s Ovis Biosurgical are sent to a third party - Alliance Formulations for polishing. He submits that since material received from M/s Ovis Biosurgical is not a raw material and are strands and before the same is raw material for manufacturing process, those are required to be polished. Polishing of strands is not a manufacturing of suture polish. Said activity is pre-manufacturing. Section 3 (f) is for the first time referred to during the hearing contending manufacturing activity requires licence from authority. He submits that this was not the

allegation in the show cause notice or in the inspection. The process of polishing material is not manufacturing activity. Process of manufacturing product suture commences from the stage of swaging. Pre manufacturing activities are not under the purview of pharmaceutical process and as such, would not be covered by the D C Act or the Rules. The licenced manufacturing activity at Aurangabad commences with receipt of polished strands at Aurangabad. The petitioner has not violated section 3 (f) of the D C Act. It is further submitted that Aurangabad Food and Drugs Administration may not have power in respect of activity carried out outside its jurisdiction and, as such, rule 85 (2) of the D C Rules cannot be invoked.

78. He submits that while Schedule M, Paragraph 10.1 read with Schedule U had not been referred to in the show cause notice, the Food and Drugs Administration order purports to refer to the same alleging its non compliance. He submits that Schedule M, Paragraph 10 and Schedule U require to have inventory of all raw materials to be used and to maintain record according to Schedule U. He submits that the petitioner complies with both the requirements.

79. Besides aforesaid, learned senior Advocate Mr. Shah submits that in April, 2008 M/s Alliance Formulations, third party, had informed Baddi Food and Drugs Administration of its intention to process strands for ensuring uniform thickness requesting to note the same. M/s Alliance Formulations had also enclosed copy of process flow for polishing. This has been acknowledged by the Baddi Food and Drugs Administration. Baddi Food and Drugs Administration had knowledge about this fact and had not objected to the same nor had required Alliance Formulations to obtain a licence. He submits that while Food and Drugs Administration, Aurangabad had indicated that the permission of Baddi authority be obtained for polishing its raw material at Alliance Formulations, the petitioner had accordingly submitted a letter to said Food and Drugs Administration with copy of 2008 letter of M/s Alliance Formulations and had asked any other or further requirements to be complied with. Yet, it is alleged that the petitioner has not taken adequate efforts for getting licence at Baddi, ignoring that Baddi Food and Drugs Administration had been aware about the process and had not insisted on a licence by Alliance Formulations. Moreover, petitioner has now discontinued polishing activity at Alliance Formulations.

80. In respect of allegation about petitioner carrying out only physical tests of raw materials and that there is breach of provision of rule 74 (c), he submits that rule 74 (c) relates to products under licence form No. 25, which had not been part of show cause notice. Rule 78 (c) (ii) which applies to form No. 28, does not specify nature of test to be carried out in relation to raw material like sutures. None of the provisions of the D C Act or Rules specify the nature of tests to be carried out on raw material. Besides, he submits that Food and Drugs Administration order goes beyond show cause notice alleging violation of Schedule M, Part I, paragraph 10.4. He submits that Schedule M, Part I paragraph 10.4 requires examination of each consignment of raw material for integrity of package and seal. This, however, has been dropped in the appellate order. He particularly submits that during course of hearing respondents purport to refer to Schedule II to the Act and the monograph under USP, yet it will have to be considered that monograph is applicable to final sutures and not in relation to raw material of sutures. He submits that there is only one monograph available for test of sutures and in the absence of monograph of raw material of suture, the petitioner carries out physical tests and relies on certificate of analysis received from its affiliate.

81. He purports to point out that the petitioner had asked the Food and Drugs Administration as to which tests should be carried out. However, Food and Drugs Administration has not responded to the same. He further submits that raw material specifications have been modified incorporating testing of diameter and tensile strength from October, 2013 and such measures are found to have been undertaken by the petitioner during inspection by the Food and Drugs Administration.

82. He submits that the second schedule to the rules has been referred to which provides for standards prescribed in other countries to be adhered to in the absence of Indian pharmacopoeia providing for the same and submits that USP does not mandate adherence to ISO provisions.

83. He submits, Schedule M, Part I paragraphs No. 10, 16, 17 of the Rules are referred to during the hearing, however, none of these refer to exact nature of tests to be performed on the raw material in question as such, there is no violation of any of the provisions by the petitioner.

84. It is further being submitted that the impugned orders purport to suspend Form No. 25 licence and that the show cause

notice does not refer to any breach in respect of product items covered under Form No. 25.

85. Suspension of licence and products under Form No. 25 licence is an error apparent on the face of record and is arbitrary, absolutely improper, illegal, unsubstantiated and legally untenable, since none of the allegations relate to products under Form No. 25 licence and when none of the four issues cover Form No. 25.

86. Case of *"Mst Saleha Khatun Bewa V/s The State of Assam and Others" [AIR 1977 Gau 18]* has been referred to submitting that if a drug is covered by licence in particular form, the question of cancellation of licence in other form would not arise and that the drug controller had no vested jurisdiction by law to cancel the other licence in respect of which there is no violation. He submits that since there is no allegation in respect of violation of any provisions in respect of products under Form No. 25 licence, suspension of Form No. 25 licence of the petitioner is not proper and is untenable.

87. It is further being submitted that no infirmity has been alleged in respect of 29 products out of 95 products covered under Form No. 28 however, entire form No. 28 has been

suspended. It is submitted that the impugned orders are liable to be set aside to the extent they apply to 29 products out of 95 products covered under Form No. 28 in the absence of allegations in relation to them. The licence has been suspended without any cause in respect of the same.

88. *"Universal Drug House Pvt. Ltd., V/s State of Bihar and Others" [AIR 2004 Patna 86]* has been relied upon to submit that cancellation of whole of the licence covering many items would not be proper, if irregularities in regard to a few of them are covered by the licence are alleged.

89. It is further being submitted that appellate proceedings have been defective for non observance of principles of natural justice as respondent No. 2 who had passed order, had appeared before respondent No. 1.

90. Mr. Shah, submits that apprehension expressed about products manufactured by the petitioner pose risk to public safety are conjectures and surmises. He submits that the respondents have not been in a position to produce any evidence whatsoever to show that there has been any safety or health hazard by the products in question. This has been asserted by the petitioner and has not been rebutted by the respondents.

91. Show cause notice is non specific and does not show contravention of any rule or statutory provision and the allegations are general in nature having no nexus to the facts.

92. Respondents have been improving their case at each stage after issuing show cause notice causing grave prejudice to the petitioner. Even single day's suspension would gravely prejudice the petitioner and the petitioner stands risk of being disqualified in making application. This would cause severe prejudice even to government procurements, the petitioner being one of the largest suture manufacturer. Suspension would adversely affect the petitioner and the supply of suture will have ill impact on patient care.

93. He submits that it is impermissible to go beyond the scope of show cause notice and to improve the case at each stage of litigation. The defence and the replies have not been appreciated, much less properly and the orders suffer non application of mind to the relevant aspects. It is submitted that allegations are nothing but apprehension expressed without any factual basis.

94. He submits, impugned orders are product of incorrect interpretation and application of legal provisions and are bad in

law. Invoked provisions seldom would apply to the facts. The impugned orders go beyond the allegations in the show cause notice. Impugned orders are arbitrary.

95. Impugned orders fail to observe the established principles of statutory interpretation and are bad for non application of mind.

96. It is submitted that impugned orders are vague, go beyond allegations in show cause notice, which does not disclose any cause of action.

97. He submits that certain additional provisions are sought to be invoked alleging violation not finding place in show cause notice or the impugned orders.

98. It is contended that additionally allegations have been made before High Court which were neither alleged in the show cause notice nor during the proceedings before respondents No.1 and 2. According to the petitioner, each one of the same has been appropriately explained that this would seldom affect the case of the petitioner, same being legal, proper and scientific.

99. Learned senior advocate for the petitioner refers to and relies on a decision in the case of *"K. V. Acharya and Another V/s State of Maharashtra and Others" [2000 (3) Mh.L.J. 90]* to emphasize that when

competent authority renews licence in favour of the petitioner, after an offence, licensing authority has no power, competence or jurisdiction to take such offences into consideration for cancellation or suspension of licence and submits that in said judgment the court has relied on a decision of this court in the case of *"M/s Hotel K. K. Sansar V/s Dy. Commissioner of Police and Others".*

100. Case of *"Hukam Chand Shyam Lal V/s Union of India and Others" [(1976) 2 SCC 128]* has been referred to stress on that where power is to be exercised by a certain authority in certain way, it should be exercised in that manner or not at all and the other modes are necessarily forbidden. Food and Drugs Administration authorities have been improving their case at different junctures going beyond show cause notice and since the same being beyond show cause notice, order to suspend licence is not proper.

101. *"State of U. P. and Another V/s Raja Ram Jaiswal and Another" [(1985) 3 SCC 131]* has been pressed into service to lay stress on that power should be exercised on relevant considerations. This has been referred to contending that exercise of powers in this case not only being not in the manner as required, but the same has been oppressive and arbitrary.

102. *"Tolaram Reluman and Another" (supra)* has been referred to emphasize that while two possible constructions are there, court must lean to a construction which exempts the subject from penalty rather than which imposes and also to place stress on that it would not be legitimate to stretch rule beyond fair and ordinary language, however, beneficent its intention may be.

103. Learned senior advocate further purports to point out order dated 28th March, 2014 passed by division bench, wherein interim relief had been granted for the reasons referred to therein. He submits that since the division bench had granted interim relief and had considered it appropriate that required measures be undertaken by the petitioner and those are now adopted and implemented, the same would weigh while considering the writ petition finally.

104. Learned senior advocate, with reference to paragraph No. 6 of the judgment of the Supreme Court in the case of *"The Siemens Engineering & Manufacturing Co of India Ltd., V/s The Union of India and Another" [(1976) 2 SCC 981]* contends, as observed therein, even in this case, neither respondent No. 2 nor respondent No. 1 have given any cogent reason, much less have dealt with the submissions, facts and law as required, contemplated and desired. The impugned orders tend to be cryptic, are without any

reasons and without application of mind and thus are unsustainable.

105. Learned senior advocate goes on to submit that neither respondent No. 2 nor respondent No.1 has taken into account the objections raised by the petitioner. He submits that the impugned orders suffer from inherent lack of jurisdiction inasmuch as those go beyond scope of rule 85 and are based on extraneous grounds and the reasons to support and justify those are not referable to any provision of law. The impugned orders are deficient of appreciation of material facts and relevant provisions of law. He submits that order passed in appeal is passed without application of mind and the same is evident as it does not specify provisions under the Act and Rules in relation to any of the allegations and mechanically repeats order by respondent No. 2 and cursorily states that this is not expected by law.

106. It is submitted that none of the submissions of the petitioner, written or oral, have been considered or dealt with, but have been summarily rejected, without assigning any reason.

107. He, therefore, urges to allow the writ petition.

108. Mr. Yatish Gujrathi, learned Assistant Government Pleader (AGP), on behalf of respondents No. 1 and 2, states that while the premises of the petitioner had been inspected in accordance with rules, on 14th and 15th June, 2013, quite a few discrepancies and breaches were noticed. He submits, ostensibly it may be a matter appearing to be technical, but it relates to medicine and drugs which cause effect on patients and public at large.

109. Mr. Gujrathi contends, sutures being used for stitching of internal and external wounds in the body, if do not adhere to prescribed norms, that may pose danger to life. Authorities are required to function under DC Act and keep check on the products to ensure those are as per norms fixed. The norms are based on international studies. Excess residual of ethylene oxide than acceptable level is known to cause effects like irritation, organ damage, mutagenicity and carcinogenicity in humans and animals.

110. He refers to affidavit in reply filed on behalf of respondents No. 1 and 2, and submits that petitioner had applied for licence and has obtained product permissions under United States Pharmacopoeia [USP] monographs and other monographs from

the respondents. Monographs require sterilization by ethylene oxide and satisfaction of norms prescribed by International Standard Organization (ISO) 11135 for a complete description of process development, validation and routine controls of sterilization process. The petitioner had accepted and is obligated to follow ISO 11135-1 and ISO 10993-7 norms. ISO 10993 -7 : 2008 (E) being annexure R-4 to the reply refers to requirements for development, validation and routine control of ethylene oxide sterilization process for medical devices. Referring to that in the introduction to ISO 11135-1 : 2007, it has been considered, it is important to ensure that the levels of residual EO, ethylene chlorohydrin and ethylene glycol (EG) pose a minimal risk to the patient in normal product use. It has been further referred to that the requirements thereunder are in addition to the ones indicated in ISO 19903-7. However, petitioner does not carry out ethylene oxide residual test for each product which is a mandatory requirement under paragraph 4.1 of ISO 10993-7. Batchwise EO residual estimation was not being done. It is submitted that there is a serious possibility of people having affected because of residual contents of EO which have mutagenicity and carcinogenicity. It has been contended that though Schedule M, Part III had not been referred to in the

show cause notice, however, the same is implied and relevant to consider that it would be obligatory to have EO residual estimation for each batch.

111. He submits, contention of the petitioner that test would be conducted of only one product annually and the worst case be selected for estimation of ethylene oxide residual content, however, is a hypothesis. It is submitted that each and every product requires separate licence and, therefore, it is necessary to carry out test on each and every product separately.

112. Compliance of conditions of Form No. 28 and clauses 5.2, 5.3, 4.4.3 and D.1.6 of ISO 10993-7 is claimed to have been faltered alleging breach of rules 78 (p) and 78 (c) (ii) of the D C Rules and second schedule and official monograph of the relevant products.

113. It is further submitted that in case of drugs/medicines not included in the Indian pharmacopoeia but included in official pharmacopoeia of any other country, norms/standards thereunder, such, as identity, purity and strength specified for drugs are required to be complied with, purporting to allege that the petitioner has not adhered to the standards under such pharmacopoeia which has resulted in violation of provisions of

the DC Act. For said purpose, second schedule of DC Rules and USP monograph have been referred to.

114. Referring to schedule-M, Part-III, clause 6 of the DC Act, providing for sterilization, he submits that a licencee is required to provide requisite equipments with required controls and recording device for sterilization of medical devices by ethylene oxide gas in its own premises or make arrangements with some institution approved by licencing authority for sterilization. The products so sterilized are supposed to be monitored to assure acceptable levels of residual gas and its degradation products and it is purported to contend that in this respect, there is inaction on the part of the petitioner.

115. As in the reply affidavit, he contends that manufacture of suture '*prolene*' at Baddi plant in Himachal Pradesh on the basis of licence granted by Himachal Pradesh licencing authority and bringing the same to Aurangabad plant for sterilization of the product is without obtaining requisite permission of said authority according to rule 68 as the licence for carrying out activities within the domain of respondent is mandatory. Mr. Gujrathi submits that plants at Baddi in Himachal Pradesh and at Aurangabad are two separate entities having separate licences and part process of ethylene oxide sterilization would be

'manufacture' pursuant to section 3 (f) of the D C Act. It is, therefore, contended that sterilizing being part of process, manufacturing licence would be necessary. As such, a separate loan licence would be required. While the licence is issued to petitioner for specific purpose and specific reason, the contention of the petitioner that it has two units, one at Aurangabad and other at Baddi and thus is not required to obtain separate licence is not sustainable. He further submits that batches of *Prolene* brought for EO sterilization at Aurangabad are sent back without any testing, without any licence from local licensing authority is in violation of rules 78 (p), 78 (c) (ii), second schedule and official monograph of the relevant products.

116. Rule 75-A of the D C Rules relating to loan licence has been referred to, which according to the authority, can be issued to a firm if it applies for the same and the petitioner does not have loan licence as per rule 75-A, and it is only after show cause notice had been issued and impugned order had been passed by respondent No. 2, petitioner had applied for loan licence and the same has been granted. It is further contended that, however, violations and infractions by petitioner till such time would not be pardonable.

117. When petitioner purchases raw materials from M/s Ovis Bio Surgical, Navi Mumbai for Aurangabad and sends the same to Baddi in Himachal Pradesh for polishing, he submits that having regard to section 3(f) of the D C Act each activity for product would fall within definition of 'manufacture'. Thereafter it is brought to Aurangabad for further process of manufacturing. Contention of the petitioner that the product procedure starts only after polishing of the raw material is contrary to definition of 'manufacture' and such activity cannot be undertaken without obtaining due licence from the competent authority. Petitioner has not obtained permission and, as such, the same is in violation of law.

118. Schedule M, part-I, paragraphs 10, 16 and 17 of the D C Act, he submits, require manufacturer to perform all the tests for raw material. Pursuant to licence conditions under rule 78 (p) of D C Rules, licencee shall comply with requirements of good laboratory practices as laid down in schedule L-I and good manufacturing practices in terms of schedule M.

119. It is submitted, contention of the petitioner that in the monographs or elsewhere there is no provision for testing of raw material is not correct. According to respondents,

schedule M, part I, clause 16.13 provides for sampling, specifications, testing, documentation release procedure which ensure that the tests are carried.

120. He purports to rely on clause 16.13 of schedule M, part I to contend that the material is not to be released for use or for sale or supply until its quality has been approved. Clause 17.1(c) has been referred to for the purpose of qualitative and quantitative acceptance limits of raw material. It is further being referred to that petitioner is expected to develop its own norms for compliance of clauses 16.13 or 17.1 (c) which the petitioner, according to the respondent authority, has not adhered to. Whereas the petitioner is carrying out only visual inspection of the raw materials which is not permitted under the D C Act and Rules.

121. The reply affidavit refers to that impugned order has been passed by following the principles of natural justice in view of general public health as the threat is posed to human life.

122. It has been further contended that rule 85 (2) empowers the authority, on noticing defects and deficiencies in manufacturing process, to stop entire production activity. It is further submitted that the D C Act and Rules are self regulatory

and provide clearly defined norms and expects strict compliance from all concerned and also provides for penal measures against those not working within framework of the Act.

123. He submits that the case of *"Tolaram Reluman and Another" (supra)* would not be applicable in the facts of present case. Said case relates to Bombay Rent Restriction Act and in regard to interpretation in respect of receipt of premium and grant or release of any premises. In the present matter, according to the respondents, penalty is required to be imposed on the admitted conduct of the petitioner violating provisions of official monograph, conditions of licence and provisions of D C Act and Rules.

124. Learned AGP submits that case cited on behalf of the petitioner *1976 (2) SCC 981 "Siemens Engineering and Manufacturing Company India Limited V/s Union of India and Others"* is distinguishable and is to be considered as not applicable and not holding present case, for, it relates to grammatic structure of the sentence *"not otherwise specified"* . It is submitted that although in said case the Supreme Court has considered that administrative tribunal and authority must give sufficient, clear and explicit reasons while exercising *quasi* judicial functions and powers, the case is

entirely different on facts and question involved therein cannot be made applicable to present case. According to learned AGP, it is not that the judgments by the *quasi* judicial authorities should be as specific and precise as judgments of the court and that respondents No. 2 and 1 have given sufficient reasons.

125. He purports to contend, respondents do reason out the orders, albeit those may not be specific or with precision as judgment of the courts. It is contended that while the petitioner has accepted position about having carried out compliance, the same substantiates case of the respondents and the impugned orders cannot be said to be without any valid reasons. It is being further contended that while the impugned orders have been challenged claiming those to be illegal, conduct of the petitioner would disclose that since requisite steps and corrective action had been taken as required thereunder, it would not be a case that impugned orders can be said to be illegal and these were not questions involved in the cited case which had been delivered in different context.

126. Case of *"M/s Larsen and Toubro Ltd., V/s The State of Gujrath" [AIR 1998 SC 1608]* is sought to be distinguished stating that the case deals with the Land Acquisition Act and it is a cardinal principle

of law that a definition of one statute having different object would not be applied mechanically to another statute and this principle has been reiterated in the case of *"Medley Pharmaceuticals Limited V/s Commissioner of Central Excise and Customs, Daman" [(2011) 2 SCC 601]* referring to paragraphs No. 29 and 30 therein.

127. The other cases cited on behalf of the petitioner are being stated by the respondents to be not applicable in the present context. Violations of monograph, conditions of licence and provisions of D C Act and Rules would give rise to penal action.

128. He submits while petitioner has now been taking care of all the conditions, yet, disobedience of law is a serious concern and strict action would be necessary to have deterrent effect. The action of the authorities is in accordance with law, provisions of the D C Act and the Rules.

129. He submits, the object of D C act and rules is to maintain quality of drugs as drugs. Said act regulates manufacture of drugs for sale or distribution as drug, which is in furtherance of its object.

130. He submits, the matter will be required to be considered from public safety angle and action is taken by authorities in larger public interest. Scope of object of the action is of public

interest and public health as referred to in *"Medley Pharmaceuticals" (supra)*.

131. It is further being contended that compliance was done during proceeding after getting interim relief, however, these are not the considerations which are relevant.

132. It is being submitted on behalf of the respondents that although the petitioner has started taking care, but since it has emerged that there is contravention of the law and the same being serious, the past conduct of the petitioner does not deserve to be condoned absolutely without visiting the petitioner with punishment. While action of the authorities is in accordance with law, rules and regulations and the same being not irregular or *malafide*, and having been taken in public interest, the same be maintained. Therefore, he urges to dismiss the writ petition.

133. Additional affidavit has been filed on 23-04-2014 on behalf of respondents no. 1 and 2. It refers to that officials of the respondents had carried out inspection and had found that the petitioner has started frequent estimation of residual EO content but not of each batch.

134. In aforesaid additional affidavit by respondents, it has been referred to that the petitioner was required to obtain licence from Himachal Pradesh licencing authority for production of raw material, action for which had been found not to have been undertaken and that past lapses are in violation of the requirements under the law. It appears that such a direction had been issued on 17th April, 2014 and additional affidavit has been filed on 23rd April, 2014.

135. The contentions and reiterations in the additional affidavit in reply have been met with by response by petitioner by filing rejoinder to additional affidavit referred to above.

136. In the rejoinder filed on 25-04-2014 to aforesaid additional affidavit, the petitioner has referred to that it had started testing EO residue for each batch of products and the same has been communicated to respondent no. 2 albeit it is being further referred to that testing of each batch is not mandatory and requirement under law, while observations by inspecting authorities about batchwise testing are stated to be without hearing the petitioner.

137. In the rejoinder by petitioner, it has been explained in respect of polishing activity that the service provider had

informed in 2008 to the authorities at Baddi in Himachal Pradesh about the activity being carried on and said authority had not insisted upon permission or licence under the DC Act or rules thereunder.

138. Further affidavit by Mr Scott E. M. Weiss has been filed on behalf of petitioners in June, 2014 in support of petitioner's earlier contention about non requirement of batchwise tests and to claim that surprise inspections by respondents observing that the petitioner is not conducting batchwise EO tests on products is of no relevance.

139. On behalf of respondents, further additional affidavit has been filed on 11-09-2018 wherein it has been referred to that the petitioner has commenced testing procedure for individual batches from June, 2014 and contended that there is no licence taken for polishing material at Baddi in Himachal Pradesh and referring to that petitioner is showing tax invoice from Bombay office to Aurangabad. It is referred to that suspension of licence is for past violations.

140. The sum and substance of the submissions advanced by learned senior advocate for the petitioner is that the impugned orders travel far too beyond the scope of show cause notice. The

Food and Drugs Administration is not in a position to point out that there has been breach or contravention of any of the provisions of the D C Act, Rules or conditions of licence. It is submitted that section 18 of the D C Act and rule 85 of D C Rules can be triggered only when a particular breach is pointed out and in the absence of breach of other provisions, said provisions would not be available for activation and would not be applicable. It appears to be submission that those are otherwise dormant by nature.

141. According to petitioner, so called deficiencies/short comings would not amount to failure to comply with any statutory provisions. On the whole, according to petitioner, the allegations in the show cause notice and the impugned orders may at the best goad the petitioner on, to adopt procedure as desired by authorities.

142. The petitioner has submitted that the products in question do not pose any safety risk upon use by the public. The petitioner has contended that respondents have neither cited a single case of any public harm caused by the petitioner's products nor have caused the petitioner to destroy its product. Impugned orders do not show that respondents give any incident

or a particular reason for that products in question in fact has posed any safety risk to public.

143. It would be pertinent to briefly refer to the ISO norms, paragraphs/clauses thereof, relevant extracts of schedules to and provisions of D C Act and Rules *viz;*

(a) (i) ISO 10993-7 : 2008 (E) refers to that its scope is to specify allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO – sterilized medical devices, procedures for the measurement of EO and ECH and methods for determining compliance so that devices may be released.

(ii) ISO 10993-7 : 2008 (E), Clause 4.1 refers to maximum allowable residues for ethylene oxide (EO) for medical devices.

(iii) Clause 4.4.3 thereof relates to product sampling, it is provided that, samples for residual analysis be selected in such a manner as would be representative of the product and while selecting samples, attention shall be given to factors described in Annex D and also provide for removal of the product samples for analysis.

(iv) Clause 5 relates to product release, which provides that it may be possible to group devices for quality assurance testing based on similarity of materials, manufacturing processes and use (Annex D) and also that for release of batches of EO sterilized product, one of the two methods in 5.2 and 5.3 respectively shall be used.

(v) Clause 5.2 relates to release of products without dissipation curve data.

(vi) Clause 5.3 relates to procedure for product release using residue dissipation curves and further provides that release of products manufactured and sterilized under controlled conditions, as described in ISO 11135-1 : 2007 may be carried out if data are pooled from a minimum of these sterilization lots run at different times.

(vii) ISO 10993-7;2008 Clause 1.6 of Annex D is about sample retrieval, referring to that caution be exercised when product samples are removed for analysis from sterilization soon after process is completed.

(b) ISO 11135-1:2007 is about sterilization of health care products – Ethylene Oxide, requirements for development, validation and routine control of a sterilization process for medical devices.

(c) Schedule L-I of D C Rules relates to *'Good Laboratory Practices and Requirements of Premises and Equipments'*,

(d) (i) Schedule M, Part-I, of D C Rules is titled as "*Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products*", and the note under the same reads, thus, -

> *" **Note** : To achieve the objectives listed below, each licensee shall evolve appropriate methodology, systems and procedures which shall be documented and maintained for inspection and reference; and the manufacturing premises shall be used exclusively for production of drugs and no other manufacturing activity shall be undertaken therein except in respect of units licensed prior to 11 December, 2001 "*

(ii) Schedule M, Part-I clause 1.4 is with respect to disposal of waste.

(iii) Schedule M Part-1 clause 10, is about raw materials.

(iv) Schedule M, Part-I clause 10.1 refers to that licencee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per schedule – U.

(v) Schedule M, Part-I, Clause 10.4 requires appointment of authorized staff which may include personnel from quality control department, which shall examine consignment on receipt and check each container for integrity of package and seal.

(vi) Clause 16 relates to quality control system and clause 16.13 is about each specifications for raw material, intermediates, final products and packing materials shall be approved and maintained by the quality control department.

(vii) Schedule M, Part-I, Clause 17 is for specifications and 17.1 relates to raw material and packaging materials. Clause 17.1 (c) thereof relates to qualitative and quantitative requirements with acceptable limits for raw materials and packaging materials.

(viii) Schedule M, Part I, Clause 26.1 stipulates validation studies to be essential part of Good Manufacturing Practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures.

(ix) Schedule M, Part-III of D C Rules is in respect of *" Requirements of factory premises for manufacture of medical devices "*. Clause 6 thereof relates to *'sterilization',* requiring that licencee shall provide requisite equipments with required controls and recording device for sterilization of

medical devices by Ethylene Oxide Gas and its degradation products and an area of 10 square meters is recommended for basic installation of such facility.

(e) (i) It is pertinent to refer to that Schedule U/I is captioned *" Particulars to be shown in the manufacturing records "*.

(ii) Schedule U/I - A is, "*Substances other than parenteral in preparations in general* " and item 16 thereof is *'reference to analytical report number stating the result of test and analysis '* and Schedule U/I-B is *'Parenteral preparations'* and item 13 sterility test, reference on bulk batch wherever applicable, whereas clause 16 refers to 'records of tests employed as to ensure that sealed ampoules are leak-proof, to check presence of foreign particles, Pyrogen test, wherever applicable, toxicity test, wherever applicable'.

(f) Relevant extract of Section 18 of the D C Act, is

> ***18. Prohibition of manufacture and sale of certain drugs and cosmetics.*** *—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf,* ***no person shall himself or by any other person on his behalf —***
>
> ***(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—***
> *(i) ….*
> *(ii) ….*
> *(iii) ….*
> *(iv) .....*
> *(v) ……*
> ***(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;***
>
> ***(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;***
>
> ***(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:***

(g) Rules 68, 74, 78, 79, 81, 83 and 85 of the D C Rules read, thus-

(i) ***68. Manufacture on more than one set of premises****.—If drugs are manufactured on more than one set of premises a separate application shall be made and a separate licence shall be issued in respect of each such set of premises."*

(ii) ***74. Conditions of licence in Form 25 and Form 25F****.—A licence in Form 25 and Form 25F shall be subject to the conditions stated therein and to the following further conditions, namely:—*
(a) …..
(b) …..
(c) the licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority under Part XV (A) of these rules test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of five years from the date of manufacture;
……..

(iii) ***78. Conditions of licence.—****A licence in Form 28, Form 28-B or Form 28-D shall be subject to the special conditions, if any, set out in Schedule F or Schedule F (I) , as the case may be, which relate to the substance in the respect of which the licence is granted and to the following general conditions:—*
(a) …..
(b) ….
(c) *(i) The licensee shall maintain records of manufacture as per particulars given in Schedule U.*

(ii) The licensee shall either in his own laboratory or in any laboratory approved by the licensing authority under Part XV (A) to these rules test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date if fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of five years from the date of manufacture;

…….
……..
……..

(p) The licensee shall comply with the requirements of Good Manufacturing Practices as laid down in Schedule L-I and "Good Manufacturing Practices" as laid down in Schedule M.

(iv) *79.Inspection before grant or renewal of licence.—Before a licence under this part is granted or renewed the licensing authority or Central Licence Approving Authority, as the case may be, shall cause the establishment in which the manufacture is proposed to be conducted or being conducted to be inspected by one or more Inspectors appointed under the Act with or without an expert in the field concerned. The Inspector or Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardising and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the Technical Staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the 'Requirements of Good Manufacturing Practices' and the 'Requirements of Plant and Equipment' as laid down in Schedule M read with the Requirements of Maintenance of records as laid down in Schedule U.*

(v) *81. Procedure of licensing authority.—*
(1) If the licensing authority or Central Licence Approving Authority as the case may be after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the rules under the Act will be observed, he shall issue a licence under this Part.

(2) If the licensing authority or Central Licence Approving Authority as the case may be, is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

(vi) *83. Renewal.—On application being made for renewal, the licensing authority may cause an inspection to be made and, if satisfied that the condition of the licence and the rules under the Act are, and will continue to be observed he shall*

prepare a report to that effect *in respect of those drugs which have been notified by the Central Government under rule 68-A* ***and forward it along with the application*** *to the Central Licence Approving Authority,* ***and shall issue a certificate of renewal under this Part****.*

(vii) ***85. Cancellation and suspension of licences****.—*
(1) …...

(2) ***The licensing authority may****, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed,* ***by an order in writing stating the reasons therefor, cancel a licence issued under this part or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates*** *or direct the licensee to stop manufacture, sale or distribution of the said drugs and thereupon order the destruction of drugs and the stocks thereof in the presence of an Inspector,* ***if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.***

(3) ***A licensee whose licence has been suspended*** *or cancelled by the Central Licence Approving Authority or licensing authority under sub-rule (1) or sub-rule (2), as the case may be,* ***may*** *within ninety days of the receipt of a copy of the order by him* ***prefer an appeal to*** *the Central Government or* ***the State Government****, as the case may be,* ***and*** *the Central Government or* ***the State Government may*** *after giving the licensee an opportunity of being heard,* ***confirm, reverse or modify such order.***

144. From the issues raised in show cause notice, four circumscribe the petition, the first one ending up in satisfaction of authorities over explanation, as referred to herein before earlier (paragraph No. 11).

145. The second allegation in show cause notice is with regard to EO process validation and residue estimation purporting to allege non compliance of norms of international standards ISO 10993-7; 2008 (E) Biological evaluation of medical devices –

Part -7. It also purports to consider that there is breach of Schedule M, Part I clause 26.1 and additionally rule 78 (p) and section 18 (c).

146. Whereas in respect aforesaid, it may have to be adverted to that, in the order of respondent No. 2, clauses 5.0, 4.4.3, D.1.6 of ISO 10993-7; 2008 (E); Schedule M, Part-I, Clause 26.1; and Schedule M, Part – III, clause 6, rule 78 (p) and section 18 (c) have been considered. In the appellate order passed by respondent No. 1, Schedule M, Part III, clause 6 have been dropped.

147. In the affidavit, however, ISO 10993-7:2008 (E) (paragraph 4.1), second schedule, USP monograph, ISO 11135-1: 2007 are referred to. Schedule M, part III; clause 6 has been re-agitated during the course of arguments, Schedule II and official monograph are canvassed as well.

148. Schedule M pursuant to its head-note requires, to achieve objectives under the same, licencee to evolve, documentation, methodology, system, procedure and maintenance of record. It is, thus, discernible that manufacturer is to evolve its own protocols. Clause 26.1 from Part I of Schedule M, shows that validation study shall be essential and shall be conducted as per

predefined protocols. The petitioner has stated that it has been following its own protocols in accordance with the international standards ISO 10993-7; 2008 (E) Biological evaluation of medical devices – Part -7 and also refers to an expert opinion and the standards being followed in the industry.

149. It has been referred to that the petitioner has evolved its protocols and those are being duly followed and adhered to. It is submitted that in the absence of prescription of specific details of standards, petitioner had been following globally acceptable standards. The petitioner had been voluntarily adhering to the international industry standards (ISO documents), which provide for requirements and guidance for EO sterilization residuals *viz.,* ISO 11135-1 ISO/TS 11135-2, ISO 10993-7. It has been particularly submitted that petitioner has comprehensive validation process in place which is in line with globally accepted standards, such as ISO 11135-1, which involves extensive predefined protocol for critical process and copy of protocol had been submitted to the authorities during show cause notice proceedings and the same has not been disputed. It is sought to be pointed out that applicable law does not prescribe testing for EO residuals estimation regularly or for each batch as considered by the Food and Drugs Administration.

150. While clause 26.1, Schedule M, Part-I provides for validation studies would be part of good manufacturing practices, it had been particularly referred to that there are no specific standards prescribed under Indian law for validation studies and this would be conducted as per pre-defined protocols, which includes validation of processing, testing and cleaning procedure.

151. It has been referred to that ISO 10993-7 (ANNEX C 3.5) allows grouping of similar products and worst case testing. Accordingly, the petitioner had grouped similar products and had validated its process for testing residual EO for worst case product *viz., braided Vicryl*. Worst case product is that it would retain higher amount of residual EO, this would in turn mean that EO residuals would be even less in case of other products which obviates need to carry out validation exercise or testing for each product in the group. It is further referred to that ISO 10993-7, does not indicate any time interval for EO residual testing when releasing product from a validated aeration process. The petitioner confirms residual EO during annual revalidation exercise and after any process, packaging or product change is carried out. As such, it is being submitted that residual estimation is carried out on regular basis. In reply to the show cause notice, the same has been specifically referred to, which

according to the petitioner would show that the products are complying with the requirements of EO estimation including referable to clause 4.1 of ISO 10993-7.

152. No allegations formed part of show cause notice with reference to rule 78 (p) and Schedule U. Right from the beginning, the petitioner has particularly contended that it is following the prescriptions under ISO 10993-7 and ISO 11135 - Part I and it is not being shown by respondents, the same to be not proper.

153. According to the respondents EO residual beyond prescribed limits would pose danger to human life and animals as referred to in ISO norms. The annual validation process and its results as have been referred to in reply to the show cause notice which are stated to be in the limits prescribed by the Food and Drugs Administration, the position is not disputed by respondents.

154. The situation emerges that even the respondents have accepted that the petitioner is carrying out terminal sterilization of sutures by ethylene oxide. Though it is being claimed by the respondents that it is not in accordance with or is in contravention of ISO standards and particularly, section 18 (c)

and rule 78 (p) of the D C Act and Rules, the respondents have not pointed out as to how ISO 10993-7 : 2008 (E) Part -1 and ISO 11135-7:2007 or official monograph require batchwise EO residual estimation or for that matter productwise revalidation of process. The case of respondents that product specific validation and batchwise estimation is a norm under the ISO standards, is specifically borne out is not shown.

155. Allegation in the impugned order is about non testing residual content of EO after sterilization for each batch is in violation of clause 6 of Schedule M, Part III. It is contended that the authorities had not given fair opportunity to respond to aforesaid allegation of non compliance and said schedule is not enforced.

156. It has been explained by referring to that clause 6 of Schedule M, Part III provides for equipment with required controls and recording devices in the premises or in arrangement with some institution approved by licensing authority and its monitoring to assure acceptable levels of residual gas and area of 10 square meter is recommended for installation of facility. There is no allegation about there being no such facility available. With reference to the same it has been submitted that

petitioner has been complying with those all along. It is thus claimed that there is sufficient compliance with Schedule M, Part III, clause 6. Said provision does not appear to require a licencee to carry out EO residual testing for each batch and that monitoring would mean testing of each batch. It is contended that Schedule M, Part III is not part of the Act and the Rules and yet the same has been relied on, to consider that batchwise test of EO residual estimation is obligatory. The sterilization runs are being monitored abiding by higher internationally accepted technical standards as specified in ISO 11135-1 and in each sterilization run, process parameters as required under section 10 of ISO 11135-1 such as time, temperature, pressure changes and/or operation of the air supply (if used) during aeration are monitored by manufacturing and quality assurance personnel.

157. Allegations in respect of non compliance are being met with resistance contending that neither D C Act or Rules nor the conditions of licences in Form No. 25 and 28, nor do ISO standards specifically prescribe compliances desired by respondents and thus the same would be an extraneous consideration in exercise of power under rule 85(2) of D C Rules.

158. To all aforesaid submissions there is no specific and particular answer or explanation coming forth on behalf of

respondents. It is the case of the petitioner that EO estimation regularly is being done yearly since first date of licence and the record in respect of its analyses is maintained. It is not the case of the respondents that grouping of products or EO estimation being done annually and the worst case testing/validation being carried out, is not in accordance with standards prescribed internationally. The conditions under licence also do not refer to such exercise being required batchwise/productwise. No specific rule prescribing standards about EO estimation and sterilization of products falling under Form No. 28, is referred to by respondents. Submission on behalf of the petitioner has been that the impugned orders do not give any reason as to why explanation of the petitioner is not acceptable.

159. It has been particularly emphasized that petitioner has ensured that EO residual of its product has always been within acceptable limits, particularly, the ones prescribed by Food and Drugs Administration referring to table annexed to reply to the show cause notice.

160. It is further being particularly referred to that authorities have no evidence to show that any product manufactured under the Form No. 28 licence has a higher EO residual content than is

permitted under the Indian and International standards. Further, it is not the case of Food and Drugs Administration that on verification of sample of surgical sutures, residue content of EO was found beyond prescribed limits. There is no specific allegation that any product has contravened acceptable levels of residual gas.

161. It is submitted that compliance with ISO 10993-7, is neither statutory requirement nor a condition of licence, but the petitioner has complied with the requirement of the same. Alternatively, without prejudice, it is submitted that even if it is to be considered that there is technical non compliance with such standards, it would not be a case wherein violation of applicable law or conditions of licence can be imputed and alleged against the petitioner.

162. Neither second schedule, official monograph, Schedule M, Part-III, Clause-6, nor for that matter clauses 5.0, 4.4.3, D.1.6, of ISO had been part of show cause notice. Those are referred to after show cause notice, in impugned orders and during the course of submissions. These tend to be rather vague submissions as to monograph, second schedule, Schedule-M, Part-III, clause-6, clauses 5.0, 4.4.3, D.1.6 of ISO in absence of

specific reflection on the same from the respondents.

163. Impugned orders do not reflect upon that response of the petitioner to show cause notice or otherwise is insufficient or inappropriate with respect to compliances of ISO 10993-7. The orders are deficient of reasons as to how petitioner can be said not to have complied with provisions of clauses 5.0, 5.2, 5.3, 4.4.3 and D.1.6 or for that matter Schedule M, Part III, Clause 6 or USP, official monograph or rule 78 (p) in the circumstances, imputation in respect of Section 18 (c) of the DC Act does not appear to be substantiated. Clauses 5.0, 4.4.3, D.1.6 and Schedule-M, Part-III, clause 6 or USP and monograph were not referred to in show cause notice and were directly considered in the impugned order, violating principles of natural justice, depriving the petitioner of responding to these aspects.

164. While after a period of thirty years the Food and Drugs Administration purports to insist product-wise validation and batchwise estimation of EO residue, petitioner had been, willing to take steps and ready to meet with the expectations of Food and Drug Administration. This court, while granting interim protection has taken note of stated developments and actions by the petitioner. The petitioner had undertaken to comply with and

is stated to have adapted to the requirements considered by Food and Drugs Administration, since April, 2014. Although the same had been initially grudged about by the respondents, however, in affidavit of 2018 the case of the petitioner has been accepted. While compliance is insisted upon and is expected and the petitioner having worked on the same, it appears that it would not be a gross case. Petitioner has submitted that it has been carrying out batchwise estimation and product wise validation.

165. In respect of third issue about (loan) licence, the show cause notice does not refer to Schedule M, Part – III, clause 6 or Schedule – U, yet, have been considered in order by respondent No. 2. In the affidavit, however, reference to section 3 (f); rules 68 and 75-A; Form 28 is made and during the course of arguments, rules 78 (p) and 78 (c) (ii) and Schedule II and official monograph are referred to.

166. Petitioner has licences to manufacture *Prolene* at both the manufacturing facilities, Aurangabad as well as Baddi. Product permission has been available at both the places. *Prolene* sutures are brought from Baddi for sterilization to Aurangabad facility. Drug Control Administration of Himachal Pradesh had

been apprised of the fact that *Prolene* sutures undergo sterilization at Aurangabad facility and had submitted a copy of process flow chart showing that semi-finished materials would be sent to Aurangabad for sterilization. Himachal Pradesh Administration had not required any approval to be obtained by the petitioner for sterilization process conducted at Aurangabad. Legal entity at both the places is one and the same. It had been believed that no permission is required as activities at both the places/plants had been licenced.

167. It has been contended, while law does not require to have a loan licence for processing its own licenced product, it would not be proper to insist upon a loan licence for processing its own product.

168. Neither show cause notice nor the impugned order reflect upon any specific provision obligating requirement of such permission. Reference to rule 75-A in order by respondent No. 2 has been made, however, in that respect, it is contended that it is in the event of third party involvement. Aurangabad facility already has licence to process *Prolene.*

169. After referring to that EO sterilization process is completed at Aurangabad before sending back the product to

Baddi, attention is drawn to that testing at the stage of product release does not arise at Aurangabad facility as there is further processing carried out at Baddi. It is further being submitted that testing carried out for each sterilization run at Aurangabad shows compliance with Schedule M, Part-III, Clause 6.

170. At a stage beyond the show cause notice, activity being objected to referring to section 3 (f) to impute contravention for want of furnishing information, is in excess of considerations under the show cause notice and would not be in consonance with principles of natural justice. It is not the case of respondents in respect of sterilization process taking place at Aurangabad on *Prolene* from Baddi is with a view to sell or distribute. It would not be a case that processing taking place at Aurangabad on *Prolene* from Baddi would be afflicted specially when the FDA at Baddi, as would emerge, had been apprised of the operations taking place, and Baddi FDA had not insisted upon any permission from it. Although section 3 (f) is being referred to the same is for the first time being invoked before this court. It had never been a case in the show cause notice nor any time during proceedings before respondent No. 2. Matter, in the circumstances, will have to be considered from that context. It does not appear that imputations in respect of

sterilization processing of *Prolene* from Baddi at Aurangabad would be infringing section 18 (a) (vi) and 18 (c) of the D C Act would be said to be substantiated.

171. In the absence of imputations with reference to second schedule or official monograph, Schedule M, Part-III, clause 6, section 3 (f), rules 68, 75-A of the D C Rules, it appears that on these counts petitioner had seldom any opportunity to tender explanation. Explanation with reference to them from the petitioner during show cause notice proceedings would not be expected. Said considerations are in excess of the scope of show cause notice. It is a case without giving proper opportunity to the petitioner to explain the same. It is well settled that authorities would not be able to improve upon their case at different stages.

172. However, Aurangabad Food and Drugs Administration proposed requirement of a permission and it was submitted that in case a loan licence is required, it would be applied for. Additionally, it has been referred to that the petitioner had applied, under protest, for grant of loan licence and Baddi manufacturing facility appears to have obtained loan licence from respondent No. 2 in February, 2014.

173. Despite willingness to abide by and comply with the suggestions by the authorities, the remarks in additional affidavit in reply that licencee has shown an un-excusable unwillingness to abide by the provision of the law, while it appears that such a direction had been issued on 17th April, 2014 and additional affidavit has been filed on 23rd April, 2014, are unwarranted having regard to response by petitioner.

174. The fourth issue is about contravention of section 18 (c) and 18 (b) of the D C Act, alleging that material purchased from M/s Ovis Biosurgicals is being sent to Baddi for polishing without informing the licensing authority.

175. In respect of polishing of raw material at Baddi, while show cause notice does not refer to Schedule M, Part-I, clause 10.1, Schedule U, those have been considered by respondent No. 2. Whereas the appellate order drops aforesaid clause 10.1 and Schedule U. In the affidavit, section 3 (f) and during the hearing 18 (a) (vi) are referred to.

176. So far as sending material received from M/s Ovis Biosurgicals to Baddi for polishing is concerned, it had been referred to that it is imperative to consider that the licenced

manufacture process begins with swaging *viz.,* attachment of suture to needle. The raw material for the purpose is suture, which is ready to be attached to the needle. Manufacturing of the product starts with suture and needle and terminates with release of product. Material received from M/s Ovis Biosurgicals is not fit to be used as suture for swaging. It is required to be polished before it can be raw material for manufacture. The strands that are received at Aurangabad facility are sent to Baddi, with contractual arrangement with third party for polishing of strands. Requisite record in respect of the same is maintained. The catgut transfers referred to in the show cause notice are claimed to be for pre-manufacturing activity for the raw material and is not part of activity of manufacture of licenced surgical sutures at Aurangabad. It is submitted that pre-manufacturing activities would not be under the purview of pharmaceutical processing and would not be covered by D C Act or licence conditions and polishing process does not require any permission from the Food and Drugs Administration.

177. A case is being sought to be developed by respondents after show cause notice that it is a manufacturing activity. It is contended to be an activity for creation of raw material for manufacturing activity at Aurangabad. It appears that such an

activity was being carried out from long time at least since 2008. It will have to be adverted to that even case of the respondents is not that such a process has been done with a view to sell or distribute product. It is denied that there is violation of section 18 (c) or 18 (b) of the D C Act.

178. It has been specifically submitted that Schedule M, clause 10.1 read with Schedule U, requires licencee to keep inventory of all raw materials being used and maintain records as per Schedule U and accordingly the petitioner has inventory of all raw materials being used and the petitioner maintains record as per Schedule U and this position is not disputed, albeit, this aspect is not part of show cause notice.

179. Neither the show cause notice nor the orders by the respondents claim that the process done at Baddi of polishing material has been with a view to distribute or sell the same. As such, it would not be said that polishing at Baddi would be afflicted specially when the FDA at Baddi, as would it emerge appears, had been apprised of the operations taking place, and Baddi FDA had not insisted upon Alliance Formulations for any permission from it. Although section 3 (f) is being referred to the same is for the first time before this court. It had never

been a case in the show cause notice nor any time during proceedings before respondent No. 2. Matter, in the circumstances, will have to be considered from that context.

180. It has emerged that Alliance Formulations which had been carrying out operation, had informed about its intention to process strands way back in 2008 including a copy of process flow sheet of polishing strands and Baddi Food and Drugs Administration had duly acknowledged the same and had not objected to said operation at Baddi nor had insisted upon any permission for the same. It has also emerged that while petitioner, under letter dated 12th March, 2014 to Food and Drugs Administration had asked clarity on the issue, the Food and Drugs Administration had sought details of third party service provider and their approvals and the petitioner had accordingly provided details about Alliance Formulations and has submitted a letter to Food and Drugs Administration with a copy of 2008 letter of Alliance Formulations about its intention to process stands of the petitioner. This has been objected to stating that the petitioner had not taken adequate efforts for getting licence at Baddi, completely ignoring that Baddi Food and Drugs Administration had not insisted upon permission. The petitioner eventually has discontinued polishing activity at Alliance

Formulations.

181. Although violation of sections 3 (f), 18 (c) and 18 (a) (vi) of the D C Act is being alleged, in the absence of any specific allegation in the show cause notice and while explanation has been given in this respect by the petitioner, the same has not been met with in decision with reasons. In this respect, it does not appear that imputations about section 18 (a) (vi), 18 (c), Schedule M, Part-III, clause 10.1, Schedule U are substantiated.

182. The next ground in the show cause notice is about lack of testing of imported raw material and releasing the same only on some physical tests on certificate of analysis given by supplier. In respect of the same the show cause notice had referred to rule 74 (c) and section 18 (c) alleging contravention of licence conditions, whereas the order of respondent No. 2 makes reference to rule 74 (c); Schedule M, Part-I, Clause 10.4 and rules 78 (c) and 78 (c) (ii) and the appellate order drops Schedule M, Part – I, clause 10.4. Whereas in the affidavit, before this court, Schedule M, Part I, clauses 10, 16.13, and 17, 17.1 (c) and rule 78 (p) Schedule L-I have been referred to and during the hearing and only rule 78 (c) (ii) has been referred to.

183. It has been drawn attention to by petitioner that no specific tests have been suggested by respondents and whatever testing is appearing is sufficient. As to how further testing is not advisable and is not possible under the circumstances, has also been explained.

184. It has been referred to that before dispatch of incoming raw material to Aurangabad facility the materials are tested exhaustively at the other Johnson & Johnson sites where they are manufactured, which operate under the same quality management system. It has been submitted that sutures are moisture sensitive and come in air tight cans for preventing degradation of the material due to moisture entailing test reduced to physical verification, vacuum test of pouches, verification of labels before starting manufacturing process. Considering the moisture sensitive nature of products, those are transported in hermetically sealed packaging which cannot be tampered. It is particularly being referred to that there is no separate monograph available for the testing of raw material of sutures and there is only one monograph available for test of suture. In the absence of monograph for raw material, "in house" or "reduced" test is used for suture material based on a certificate of analysis received from other Johnson & Johnson

companies. Certificate of analysis gives indication of quality of product and since it is manufactured at other Johnson & Johnson facility, credibility of certificate is high and the certificates are monitored at Aurangabad. It is further being referred to that tests to be carried out for raw material and finished material are the same, as the raw material does not undergo any change in the course of manufacturing process. There is no change in input during processing. The suture and needle remain in the same form. All testing is carried out at finished goods stage for same physical parameters. Rule 74 (c) of the D C Rules does not prescribe the extent to which testing shall be conducted and petitioner had been testing physical parameters and was relying on Certificate of Analysis (COA) of the supplier which has been its affiliate. Thus, breach of rule 74 (c) of the D C Rules nor violation of section 18 (c) of the D C Act was accepted.

185. Neither rule 78 (c) (ii) of D C rules nor other provisions of the D C Act and Rules specify nature of testing to be carried out in relation to raw material. There is no specific prescription about extent to which testing must be carried out of the raw material, leaving it to licencee. The authorities were requested to clarify which other tests should be carried out by the petitioner. The authorities have neither clarified about tests to be carried out on

imported raw material nor those have been referred to in the impugned orders and possible tests are being taken is not denied by the respondents. Thus, there is non consideration of explanation given by the petitioner and request made to the authorities. In the absence of any specific tests being suggested, nor any rule being pointed out, mere imputations that no required testing is done and, therefore, it contravenes rules, does not carry substance in the allegations. As such, action by Food and Drugs Administration tends to be arbitrary.

186. While Schedule M, Part – I Paragraph 10.4 requires licencee to examine each consignment of raw material for integrity of package and seal, the petitioner, in quite some details, had explained that as to how in the absence of any specific test being prescribed by Food and Drugs Administration or under the Rules, it has been taking tests as would be possible looking at the nature of material pointing out sensitivity of the material further referring to that material specifications have been modified incorporating testing of diameter and tensile strength. During inspection, Food and Drugs Administration found measures undertaken by the petitioner were being complied with.

187. Although it is being sought to be alleged by the respondents that petitioner has failed to adhere to the standards under the official pharmacopoeia and the same would be in contravention of the D C Act and Rules, however, the same has not been substantiated with any specific incident or example as to what standards of identity, purity and strength prescribed have been violated as per the pharmacopoeia.

188. Eventually, it emerges that imputations with respect to sections 18 (a) (vi), 18 (b), 18 (c), rules 74 (c), 78 (c), 78 (c) (ii) and rule 78 (p), ISO 10993-7 clauses 4.1, 4.4.3, 5, 5.2, 5.3, D.1.6, Schedule M, Part-I, clauses 10, 10.4, 16.3, 17, 17.1 (c) Schedule-M, Part-III, clause 6, Schedule-L-I and Schedule U would not be said to be substantiated and apart from that lot of imputations are extra show cause notice, not affording proper opportunity to the petitioner.

189. In aforesaid respect reference to following extract of observations in paragraph No. 10 of the judgment of supreme court in the case of "*M/s Larsen and Toubro Ltd.,* etc. v/s *State of Gujrat" [AIR 1998 SC 1608]*, would be worthwhile,

> " *It is not enough to allege that a particular Rule or any provision has not been complied. It is a requirement of good pleading to give details, i.e. particulars as to why it is alleged that there is non-compliance with a statutory requirement. Ordinarily, no notice can*

> *be taken on such an allegation which is devoid (of) any particular. No issue can be raised on a plea, foundation of which is lacking* ”

further observing,

> “ *ordinarily department may have to place its full cards before the court .* ”

190. It would be pertinent to refer to observations by a division bench of Gauhati high court in the case of *“Mst. Saleha Khatun Bewa V/s State of Assam and Others” AIR 1977 Gauhati 18*, and particularly, following observations of paragraph No. 16,

> “ *In order to give the opportunity, in our opinion, it is absolutely essential that the licensee must be informed as to what are the real allegations made against the licensee and he should be furnished not only with the statements of allegation, but the nature of violation so that the licensee can show cause against them.* ”

191. While the allegation in the affidavit in reply is that for each and every product a separate licence is required, it appears that the two licences under forms 25 and 28 contain several product items.

192. It is submitted that show cause notice and order of respondent No. 2 do not take within their fold products falling under licence in Form No. 25. Form No. 25 products are non-absorbable and non sterile and, as such, allegations with regard to EO estimation would not be applicable to them; *Prolene* is not covered by licence Form No. 25. So is the case of polishing of material, which has no concern with licence form No. 25; So also

is the case about testing of imported raw material.

193. The show cause notice does not make any allegations about violation of rule 78 (c) (ii) of the D C Rules, a provision which is not related to Form No. 25, however, said provision has been relied on to hold violation by petitioner of conditions of licence in Form No. 25.

194. There are no reasons being given by respondents for action in respect of said products. It is grievance that in the circumstances, there is breach of principles of natural justice, depriving the petitioner of proper opportunity to address itself on the consideration in this respect.

195. Particular emphasis has been given on that even the inspection report or for that matter, the hearing did not relate to any product falling under licence Form No. 25. There appears to be error in suspending licence of the petitioner in form No. 25.

196. Although the case relied upon on behalf of the petitioner *"Mst. Saleha Khatun Bewa" (supra)* sought to be distinguished, yet, it appears that considering the obtaining position in the present case, observations therein would largely hold present situation.

197. It is pointed out that rule 74 (c) of the D C Rules is applicable to the products covered under licence Form No. 25 but is sought to be invoked to allege inadequate testing of raw material of certain products falling under licence Form No. 28. Action under said rule for alleged breach of products under licence 28 does not appear to be proper.

198. Petitioner has contended that out of 95 products covered by Form No. 28 licence, 29 products do not at all relate to allegations in the show cause notice and yet, whole licence Form No. 28 has been suspended and thus, the same is arbitrary and without authority and jurisdiction. A couple of authorities have been relied upon in this respect by the petitioner.

199. Respondents have contended that section 85 of the D C Act empowers them to take action against entire range of products included in a licence, the decision rendered by Patna high court in the case *"Universal Drug House Pvt. Ltd., V/s State of Bihar and Others" [AIR 2004 Patna 86]* depicts that such an action would be incongruous with said decision as well as of other high courts, particularly *"Mst. Saleha Khatun Bewa" (supra)*.

200. In *"Mst. Saleha Khatun Bewa" (supra)* it had been observed that -

> *" If it was a drug covered by licence in form No. 20, the question of cancellation of the petitioner's licence in form No. 21 cannot arise,*

and vice versa, for violating the terms of form No. 21, the Drugs Controller had no jurisdiction vested in ti by law to cancel the other licence in respect of which there was no violation. ”

201. *“Universal Drug House Pvt. Ltd.,” (supra)* emphasises that for allegations which do not relate to a kind of licence and if it relates to a few of the products from the other licence form, suspension of unrelated licence form and all the products under other licence form is erroneous.

202. In *“Universal Drug House Pvt. Ltd.,” (supra)* it has been referred to that a technical/minor violation with regard to one or some of the items covered by licence may not in all cases justify cancellation of whole licence covering many other items in regard to which there is no violation of any kind and cancellation of whole licence would amount to shutting down long standing business of licencee. This of course is an alternative submission, since it is all along being claimed that there is no violation of any sort.

203. While the petitioner has given explanation with respect to international practices, methods, procedure, protocols, and norms, it does not appear that Food and Drugs Administration has come out with any specific violation of any provision of the act or the rules. It has been submitted that while continually Food and Drugs Administration went on improving its stand in

the litigating stages, is a sufficient indication of that there is no contravention of any provision of the D C Act or the Rules.

204. Submission is that while the authorities have not been able to point out any particular breach/contravention of any specific rule, in the manner in which activities had been carried out, in such a case, neither section 18 (a) (vi) or 18 (b) or 18 (c) or for that matter rule 85 could have been invoked nor had these provisions any role to play which are submitted to be triggered only in case of specific breach of provisions of D C Act and Rules.

205. Case of *"Hukum Chand Shyam Lal" (supra)* has been pressed into service to contend that impugned orders are liable to be faulted with for exercise of power not in accordance with and in the manner prescribed and/or contemplated under the provisions of the D C Act and Rules, particularly emphasizing following extract from paragraph No. 18 of said judgment.

> *" 18. It is well settled that where a power is required to be exercised by certain authority in a certain way it should be exercised in that manner or not at all, and all other modes of performance are necessarily forbidden. It is all the more necessary to observe this rule where power is of a drastic nature and its exercise in a mode other than the one provided will be violative of the fundamental principle of the natural justice. "*

206. Additionally, petitioner has referred to the case of *"State of U. P. and Another V/s Raja Ram Jaiswal and Another" [(1985) 3 SCC 131]* wherein, following extract of observations from paragraph No.

15 would be referred to, thus,

> *" 15. Licensing powers, an indisputable adjunct of controlled economy, take various forms and they are numerous. They are generally couched in a language giving wide scope for exercise of powers. Therefore the courts have been vigilant to see that they are not exercised in an oppressive or arbitrary manner. The powers being wide, the question of its exercise on relevant or considerations germane to the determination more often arises. If the licence is refused on grounds which appear to be irrelevant, the court can legitimately interfere. In this case the sole ground of refusal of licence is that it is not in public interest to grant it. "*

207. Apprehensions expressed by the Food and Drugs Administration were and have been seriously attended to and addressed, making efforts not to leave room on those counts. It is being particularly emphasized by petitioner that section 18 (a) (vi), (b), (c) and rule 85 are general provisions and can be triggered only if there is specific incident of violation of any other provision carries lot of force. Having regard to emerging position, in the absence of perceptible contravention of any specific provision or norm, sections 18 (a) (vi), 18 (b), 18 (c) or even rule 85 of the D C Act, it is difficult to consider could be brought into play.

208. While it is not disputed that the EO qualification estimation from 1991 and raw material testing or while it appears sterilization of Baddi products or for that matter polishing as referred to being carried out from 2008, in the same manner,

and it is not the case that the licences were not being granted to the petitioner all through these periods and up to the show cause notice, no exception/objection had been taken to such manner, the action under impugned orders would be abrupt.

209. Process of renewal of licence would have to be adverted to with reference to rules 79, 81 and 83 of the DC Act. After passing such scrutiny licences have been issued from time to time giving indication that the authorities hitherto were satisfied with the manner of activity. Thus, it is not a case wherein action as is sought to be taken by respondents against the petitioner would be imperative and the petitioner's all along have been readily and willingly responding to compliances sought by respondents. It is not case that petitioner has declined compliances desired by respondents.

210. It has emerged that licences granted to the petitioner had been renewed from time to time at least on five occasions, including licences in Forms No. 25 and 28. It is not disputed that the processes involved in EO sterilization are being followed since 1990-91. So is the case of tests of raw materials. Since 2008 sterilization at Aurangabad of goods from Baddi has been taking place, so is the case of polishing at Baddi. The processes,

protocols, analyses, procedure and practice had not been questioned till the show cause notice had been issued to the petitioner. Those were being found to be in order and the licences were being renewed. It is not the case by respondents that renewals of licences were without following proper procedure as per rules, particularly rules 79 to 83 of the D C Rules. Having regard to the same, the decision in the case of *"K. V. Acharya and Others V/s The State of Maharashtra and Others" [2000 (3) Mh.L.J. 90]* would be pertinent wherein it has been observed thus-

> *" When the aforesaid offences or incidents or breaches were not found sufficient by the concerned authority for denial of renewal of licence to the petitioners, the said offences, incidents or breaches cannot furnish grounds for cancellation or* ***suspension of licence which was renewed after the said offences, incidents or breaches had already taken place****. … When the aforesaid* ***offences or incidents or breaches were not found sufficient*** *by the concerned authority* ***for denial of renewal of licence*** *to the petitioners, the* ***said offences, incidents or breaches cannot furnish grounds for cancellation or suspension of licence which was renewed after the said offences incidents or breachers*** *had already taken place. "*

It has been observed in the judgment that while licences are renewed despite omissions, offences and breaches by licencee earlier thereto, it would mean that such licencee to be a suitable person for renewal of licence despite aforesaid aberrations and such aberrations would not form ground for suspension of licence. In the present matter as well, it would have to be adverted to that the licences had been renewed at

least on five occasions for Aurangabad plant, while the petitioner had been carrying on manufacturing in the same manner as referred to. Thus, it emerges that in the present matter, while aberrations being imputed now were not aberrations when licences were being renewed and particularly while those being aberrations with respect o any specific rule or norms is hardly substantiated. In the circumstances, present case would be much less a case which would call for suspension of licence.

211. While licence for the same products under Form No. 28 been renewed from time to time, for the same manner of activity, it presupposes satisfaction over the methodology, practices, manner and procedure being adopted by the manufacturer hitherto. It would be required to be considered that the rationale which went into the case of *M/s Hotel K. K. Sansar V/s Dy. Commissioner of Police and Others"* decided by this court had been referred to, relied on and quoted in *"K. V. Acharya and Another" (supra).* A sudden change in the stance without letting opportunity to the petitioner for taking action in respect of alleged aberration, would be incompatible with natural justice.

212. It does not appear that due opportunity had ever been afforded to the petitioner when continually, at every subsequent

stage respondents went on improving their case, adding new imputations. The force in the exercise of powers thus gets further depleted in the process for non observance of principles of natural justice.

213. "*Mst. Saleha Khatun Bewa" (supra)* has been relied on drawing attention to paragraph No. 20 thereof contending that the impugned orders are deficient of reflecting upon reasons and much less sufficient reasons for non acceptance of explanation of the petitioner, and the impugned orders suffer infirmity on many other counts. Application of mind to and appreciation of petitioner's case are found wanting.

214. Petitioner has also referred to *"The Siemens Engineering & Manufacturing Co of India Ltd.," (supra)* to further emphasise that when an authority makes an order in exercise of *quasi* judicial function, it must record its reasons in support of the order, if courts of law are to be replaced by administrative authorities and tribunals. It is essential that authorities should accord fair and proper hearing to the persons sought to be affected by orders and to give fair and explicit reasons in support of the orders made by them, which is basic principle of natural justice and the rule must be observed in its spirit and shall eschew pretence of

compliance which alone would justify creation of administrative authorities.

215. These citations have been relied on to support contention of the petitioner that despite valid explanation being given, impugned orders fall short of appreciation as well as application of mind to the same and to support those with reasons contending that impugned orders and imputations have been vague and have no foundational support.

216. Allegations in show cause notice and impugned orders if at all are to be taken into account, at the best, according to petitioner, would tantamount to aberration in the manner expected, and would not at all be considered as contravention of rules. As a matter of fact, petitioner has been resilient to the situation while the Food and Drugs Administration expects certain compliances as they desire, the petitioner has readied itself and is stated to have implemented the same.

217. The petitioner had been carrying out activities believed by the petitioner not to be, not compatible with or precluded by any law and licences been renewed from time to time it would be a case wherein the action under the impugned order could be said to be rather harsh, years down, while compliance as desired and

expected had not been considered to be in breach and in contravention of rules for decades. To suddenly turn around alleging breach/contravention of such a nature as to visit the petitioner with penalty under the impugned orders is capricious. It would emerge that the action in the face of situation would be uncalled for looking at its fall out.

218. Impugned orders ought not to have travelled beyond show cause notice, however, in good faith the petitioner has addressed to the new issues raised from time to time and has explained its position. The petitioner has been manufacturing from almost three decades without any untoward incident. In these circumstances, while the authorities have felt it desirable, petitioner has willingly complied with the same.

219. While it is not the case wherein it can be said that there has been alteration in law or for that matter norms, protocols, for allegations and impugned orders, wanting in reasons and substantiation, it would not be appropriate to visit petitioner with penal action when it is not denied that the petitioner is getting licences for decades working in the same manner and when the petitioner had been willing to adapt and comply with suggested method, procedure, etc.

220. The considerations while passing the impugned orders being in excess of allegations in the show cause notice, those appear to infringe principles of natural justice. Respondents purport to exercise power suddenly after letting the petitioner the manner of manufacture for decades and now veer around surprising it. Explanation of the petitioner is not accepted by the respondents with reasons referring to any infirmity in the same. It is not a case that the practices followed in the industry are not proper or for that matter, methodology adopted by the petitioner being in any way in breach of any specific rule. Coupled with the same, fact is that from at least almost three decades the petitioner has been engaged in manufacture of said products is not denied and no untoward incident is reported or pointed out with reference to the allegations in the show cause notice. Additionally it is ascertained that the petitioner is taking care and has been following international norms, and further it does not appear that the desired expectations are not being complied with, it would not be a case where there shall be a visit to the petitioner with penalty as imposed under the impugned orders, after such a passage of time especially while licences have been renewed from time to time.

221. In the light of aforesaid, action impugned tends to be arbitrary and too harsh and is capricious rendering it unsustainable in facts and circumstances.

222. Writ petition, therefore, is allowed. Impugned orders dated 2nd December, 2013 passed by respondent No. 2 and dated 25th February, 2014 passed by respondent No. 1 are set aside. Rule is made absolute in aforesaid terms.

[S. M. GAVHANE]
JUDGE

[SUNIL P. DESHMUKH]
JUDGE

drp/wp2120-14