BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

ORDER RESERVED ON :01.09.2022

ORDER PRONOUNCED ON : 27.09.2022

CORAM:

THE HONOURABLE MR.JUSTICE R.VIJAYAKUMAR

W.P.(MD).Nos.19436 &19437 of 2015
and
MP(MD).Nos. 1 & 2 of 2015 and WMP(MD).No.1705 of 2020 and
MP(MD).Nos.1 &2 of 2015 and WMP(MD).No.1727 of 2020

P.Radhakrishnan
Proprietor
M/s.Sara Pharmaceuticals
Nos.4 & 15, Industrial Estate
Nagercoil 629 009 .....Petitioner in both petitions

Vs

1.The Director of Drugs Control
DMS Campus, Anna Salai
Teynampet
Chennai 600 006

2.The Drug Inspector
Office of the Assistant Director of Drugs Control
Villivakkam Range, Zone -II
Office of the Assistant Director of Drugs Control
Zone II, DMS Campus, Anna Salai
Chennai 600 006

3.The Director (In-charge)
Central Drugs Laboratory
No.3, KYD Street
Kolkata 700 016 ....Respondents in both petitions

Prayer in W.P(MD).No.19436 of 2015: This Petition filed under Article 226 of the Constitution of India, to issue a Writ of Certiorari to call for the records relating to the procedure of 3rd respondent Form-2 Certificate of Test or Analysis in No.2-1/2015-SS/CC-222/888 dated 21.04.2015 and to quash the same for having been issued in violation of mandatory requirements of law.

Prayer in W.P(MD).No.19437 of 2015 : This Petition filed under Article 226 of the Constitution of India, to issue a Writ of Certiorari to call for the records relating to the procedure of 3rd respondent Form-2 Certificate of Test or Analysis in No.2-1/2015-SS/CC-223/895 dated 24.04.2015 and to quash the same for having been issued in violation of mandatory requirements of law.

(In both petitions)

For Petitioner	: Mr.G.Sankaran
For R1 & R2	: Mr.S.Shanmugavel Additional Government Pleader
For R3	: Mrs.L.Victoria Gowri Deputy Solicitor General of India

COMMON ORDER

The above writ petitions have been filed challenging Form-2 Certificate of test issued by the third respondent herein in relation to two batches of Neostigmine Methyl Sulphate IP as contemplated under Rule-6 of the Drugs and Cosmetics Rules 1945.

2.According to the petitioner company, they are manufacturing drugs for over 36 years without any remarks. The petitioner had contended that they are manufacturing Neostigmine Methyl Sulphate IP (hereinafter referred as the Drug) ín terms of conditions of licence. The second respondent herein had drawn samples of following two batches for analysis:

(i).Batch No.NE1101, date of manufacture 11/2013, expiry date 04/2015.

(ii).Batch No.NE40301, date of manufacture 03/2014, expiry date 08/2015.

3.After drawing the said samples, the second respondent had sent one portion of sample for analysis to the Government Analyst in Chennai and the same was received by the Government Analyst on 02.06.2014. The Government Analyst vide report Nos.248 and 280 respectively dated 21.07.2014 and 06.08.2014 found that the sample confirms to the requirement of Indian Pharmacopeia 2014 for nominal Volume, PH, Identification and sterility, but the sample does not confirm the requirement of assay of the drug as per I.P.2014. Based upon the said report, the Drug Inspector had addressed a letter dated 30.7.2014 and 11.08.2014 to Tamil Nadu Medical Services Corporation, Chennai requesting them to disclose the name and address of the person from whom the drug was purchased. The said Corporation has sent a reply on 09.08.2014 and 12.08.2014 disclosing that

the said drug was purchased from the petitioner herein under Invoice Nos.B592 dated 15.02.2014, B602 dated 16.01.2014 and B21 dated 16.04.2014. Based upon the said reply, the Drug Inspector had sent a show cause notice to the petitioner on 09.08.2014 and 25.08.2014 as contemplated under Section 18(a)(i) of the Drugs and Cosmetics Act, 1940. Even before the expiry of the period provided in the show cause, the Drug Inspector has forwarded the report to the Director of Drugs Control on 26.08.2014 requesting for a sanction order for prosecuting the petitioner for the alleged contravention.

4.The petitioner had further contended that on receipt of the memo, he had notified his intention to adduce evidence in contravention of the report as contemplated under Section 25(3) of the Drugs and Cosmetics Act, 1940. However, the second respondent has not forwarded the sample to the third respondent. Hence, the petitioner had filed W.P.Nos.30895 and 30896 of 2014 to direct the respondents 1 and 2 to forward the samples of the drug for analysis by the first respondent herein. This Court had passed final orders on 27.01.2015 directing the respondents to consider and pass orders within a period of two weeks. Thereafter, the samples were forwarded to the first respondent for analysis and report.

5.The petitioner had further contended that the third respondent had issued a communication on 30.01.2015 to the first respondent herein informing that they do not have Reference Standard/Working Standard for analysis to forward the drug. Hence, they requested the first respondent to obtain the same and send it to the third respondent at Kolkata. Consequently, the first respondent addressed a communication to the second respondent to obtain sample. Thereafter, the second respondent requested the petitioner on 26.02.2015 to submit the Reference Standard/Working Standard. A reminder was also sent by the second respondent to the writ petitioner on 25.03.2015 to send the Reference Standard/Working Standard with test certificate to his office so as to forward the same to CDL Kolkata. However, the petitioner could not forward the Reference Standard/Working Standard.

6.The petitioner had further submitted that by way of an impugned order dated 21.04.2015 and 24.04.2015, the third respondent has arrived at a finding that the samples do not confirm to Indian Pharmacopoeia with respect to the test of identification and assay of the drug. The said two impugned orders issued under Form-2 for two different batches of the drug are under challenge in the present writ petitions.

7.Contentions of the learned counsel for the petitioner are as follows:

(i).The samples drawn by the Drug Inspector on 30.04.2014 was

received by the Government Analyst on 02.06.2014. The Government Analyst has submitted his report with regard to two batches in Report Nos. 248 and 280 dated 02.06.2014 and 06.08.2014 respectively. The Government Analyst has specifically found that the samples confirm to the requirement of Indian Pharmacopoeia 2014 for nominal Volume, PH, Identification and Sterility. He has only found that the sample does not confirm the requirement of assay of the drug as per IP 2014. Hence, the impugned order under Form-2 is completely in contradiction with the report of the State Government Analyst.

(ii)Any sample that is referred to the Government Analyst or the third respondent herein should be analysed only with the help of Reference Standard /Working Standard. When the third respondent had requested the second respondent for sending the Reference materials, the respondents 1 and 2 have categorically informed that they are not having the Reference Standard. They made a request only to the petitioner for supply of the said Reference Standard which the petitioner could not do so. Hence, it is clear that neither the respondents 1 and 2 nor the third respondent were having Reference Standard/Working Standard in order to test or analyse the samples that were drawn by the second respondent herein. Therefore, any test or analysis said to have been conducted are in violation of the statutory provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder.

(iii). The learned counsel for the petitioner had further contended that the third respondent has not conducted the test or analysis in accordance with identification test mentioned in Pharmacopoeia 2010 or 2014 for continuation of Standard of drug which is mandatory. The entire test with identification of assay of the drug was carried out by the third respondent without Reference Standard or Working Standard which is clearly in violation of the mandatory condition as prescribed in Indian Pharmacopoeia 2014. The learned counsel had further contended that the report of the third respondent declares Nil in the drug sample which is clearly in contravention of the report submitted by the State Government Analyst which declares 455.05 and 455.47% respectively. The contradiction between the report of the said analysis and the third respondent herein will clearly disclose that no proper Reference Standard/Working Standard was followed by both the authorities which has resulted in contradictory result. These contradictory results should be found in the light of the fact that both these authorities have jointly declared that they are not having any Reference Standard or Working Standard so as to test or analyse the drug in dispute.

(iv)The learned counsel for the petitioner had further contended that as per Rule-6 of the Drugs and Cosmetics Rules 1945, the result to the test or analysis should be communicated with protocol of the test applied and the

same shall be supplied forthwith to the sender in Form-2. Otherwise Form-2 will be clearly in violation of Rule-6 and the said Form-2 cannot be treated as a consequential one. He had further pointed out that the impugned Form-II does not disclose any protocol whatsoever that are said to have been followed in analysing the samples of two batches of the drugs in dispute.

(v).The learned counsel for the petitioner had further contended that a common counter was filed in both these writ petitions by the third respondent in which it was contended that in Paragraph No.2 that the Reference Standard/Working Standard was available in store/Reference Standard Wing of Central Drugs Laboratory, Kolkata which was used to test the samples of the said drugs. The learned counsel for the petitioner after relying upon the said counter, had contended that only Indian Pharmacopeia is statutorily entitled to create Reference Standard/Working Standard. The impugned Form-II has been issued relying upon certain Reference/Working Standard that were available in CDL itself. Hence, the test report under Form-II is completely in violation of the statutory provisions, rules and the forms attached to the said rules.

(vi). The learned counsel for the petitioner had further contended that the counter affidavit is clearly in violation of the letter dated 30.01.2015 issued by the third respondent herein which categorically stated that the

Reference Standard /Working Standard with test certificate for the drug is not available with them. The said communication was also addressed to the learned X-Metropolitan Magistrate Court, Egmore, Chennai from where they have received the samples. Therefore, the counter affidavit is clearly in contradiction to the letter of the third respondent dated 30.01.2015. He had further contended that the impugned Form-II issued by the third respondent does not attach protocol of the test applied as required under Rule-6 of the Drugs and Cosmetics Rules, 1945 and it suffers from serious legal infirmity. He had further pointed out that no details about the lot of numbers of the Reference Standard is found in Form-II. The counter affidavit also does not disclose that Reference Standard that was utilised for test whether it was Indian Pharmacopeia Reference Standard or any other Pharmacopeia Standard/Working Standard. He had relied upon 2nd schedule of the Drugs and Cosmetics Act and Section 16(i)(a) of the Act and contended that for the drugs that are included in the Indian Pharmacopeia, the standard of identify, purity and the strength prescribed under the Indian Pharmacopeia should alone be followed. It is an admitted case that the drugs in question is included in the Indian Pharmacopeia. Hence, no other Pharmacopeia could be followed for conducting the test.

(vii). The learned counsel for the petitioner had further contended that a better counter affidavit has been filed by the third respondent herein in which it has been stated that Reference Standard/Working Standard was procured from the United State Pharmacopeia (USP) and the same was used as a Reference Standard as prescribed by the Indian Pharmacopeia. Relying upon the said counter, the learned counsel for the petitioner has contended that the statutory Form-II does not reflect about the usage of Reference Standard from United State Pharmacopeia.

(viii).The learned counsel for the petitioner had further contended that this is quite contrary to the counter filed in the first occasion. The learned counsel further pointed out that the third respondent is taking different standard on different occasions. Originally they have contended that they do not have any Reference Standard/Working Standard. Thereafter, in the first counter they had contended that they were able to procure the Working Standard from the Wing of Central Drugs Laboratory, Kolkata. Now in the better Counter, they have taken completely different standard that Reference Standard was procured from United State Pharmacopeia. Therefore, the impugned Form-II is vitiated for non mentioning of the proper protocol as contemplated under Rule6 of the Drugs and Cosmetics Rule, 1945.

(ix). The learned counsel for the petitioner had further contended that when the drug in dispute is included in Indian Pharmacopeia, the third respondent is not legally entitled to procure samples as per United State Pharmacopeia and use it for the test or analysis of the drug in dispute. He had further contended that a medicine manufacturer in India who is confirming to the Indian Pharmacopeia cannot be put to test on the basis of the Reference Standard of the United State Pharmacopeia. He had further contended that as per Advisory Note of USP, it is the responsibility of the user to determine the suitability of USP Reference Standard for non-/USP compendial uses.

(x). The learned counsel for the petitioner had further contended that the impugned Form-II does not disclose about the fact that the Reference Standard of United State Pharmacopeia was used and what is nature of the test or analysis that was conducted the lot numbers of USP Reference Standard, it's expiry date and the date on which it was procured. He had further contended that the Reference Standard have also an expiry date. Unless expiry date of the Reference Standard is also mentioned in Form-2 certificate, the same cannot be used as a Reference Standard. The learned counsel had further contended that the use of United States Pharmacopeia Reference Standard is illegal as per Indian Pharmacopeia Commission and it is not authenticated with lot numbers and expiry date of the Reference Standard of the U.S. Pharmacopeia. In case if any Reference Standard other

than the Indian Pharmacopeia is used, it should be mentioned in the protocol in Form-II as contemplated under Rule-6.

(xi). The learned counsel had further contended that in view of the statutory violation as stated above and non-mentioning of the protocol as contemplated under Statutory Form-II, the impugned Form-II is liable to be set aside in both the writ petitions. Hence, he prayed for allowing the writ petitions.

8.The Contentions of the learned Deputy Solicitor General for the third respondent are as follows:

(i). The learned Deputy Solicitor General mainly relied upon a better counter affidavit filed by the third respondent on 09.09.2022 to address her submissions:

(ii). Initially the third respondent had searched for availability of Reference Standard/Working Standard at the laboratory itself for conducting the test/analysis of the drug in dispute. Since the Reference Standard was not readily available in the laboratory, requests were made to the concerned State Drugs Controller and other relevant sources to provide relevant Reference Standard/Working Standard for the drugs.

(iii). The learned Deputy Solicitor General had further contended that separate requests were addressed simultaneously to other offices to provide Reference Standard/Working Standard if it is available with them. In case, if

there is any delay in receiving the said Standards, the drug samples would cross the expiry date.

(iv). The learned Deputy Solicitor General had further contended that in order to meet out the emergency needs, Reference Standard/Working Standard are procured from Indian Pharmacopeia Commission (I.P.C) or from authorized agencies from United State Pharmacopeia (USP) or from British Pharmacopeia (BP) on payment, if the same is not available from the stock to meet emergency requirement.

(v). The learned Deputy Solicitor General had further contended that the third respondent was compelled to use the United State Pharmacopeia (USP) Reference Standard for drug in dispute from available stock preserved to meet the emergency requirement with respect to the test of Identification and Assay of the drug in dispute. The relevant test was carried out during 30.03.2015 to 31.03.2015 and report (Form-2) was issued correctly on 21.04.2015.

(vi). The learned Deputy Solicitor General had further contended that after careful test and analysis, the third respondent has arrived a a finding that the drugs do not confirm to the relevant standard. She had further contended that the United State Pharmacopeia (USP) Reference Standard for the drug was used correctly as Reference Standard for analysis as prescribed by Indian Pharmacopeia (I.P) and strictly followed relevant method of test as prescribed

thereunder keeping in mind the directives of the Hon'ble Court and also the date of expiry of the relevant drug samples. She had further contended that the test report in Form-2 with regard to content of the drug is Nil was correctly submitted and there was no violation of statutory provisions in submitting the report by the third respondent. The learned Deputy Solicitor General had further contended that all the provisions under the Drugs and Cosmetics Act, relevant Rules and Forms attached thereunder were strictly followed in analysing the drug samples with relevant Reference Standard/Working Standard. Hence, the order impugned in the writ petitions should be sustained.

9. I have considered the submissions made on either side and perused the materials available on record.

10.The samples of two batches of Neostigmine Methyl Sulphate Injection IP manufactured by the petitioner company was drawn by the second respondent herein and they were sent for Government Analyst. The Government Analyst in his two reports, though confirmed that the samples confirm the requirement of Indian Pharmacopeia 2014 for nominal Volume, PH, identification and sterility, but held that the sample does not confirm the requirement of assay of Neostigmine as per Indian Pharmacopeia 2014.

Hence, the Government Analyst had concluded that the sample is not of the standard quality. A show cause notice was issued why the prosecution should not be initiated. The petitioner company submitted their explanation and notified their intention to adduce evidence in contravention of the report as contemplated under Section 25(3) of Drugs and Cosmetics Act, 1940. Since the samples were not forwarded to the third respondent, the petitioner Company had filed W.P.Nos.30895 and 30896 of 2014 to direct the respondents 1 and 2 to forward the samples to the third respondent. The said writ petitions were allowed on 27.01.2015 and the respondents 1 and 2 were directed to forward the samples to the third respondent within a period of two weeks.

11.After the samples were received by the third respondent, they have addressed a letter to the first respondent herein on 30.01.2015 informing that they are not having Reference Standard/Working Standard with test certificate for the drugs and requested the first respondent to obtain the same and send it to the third respondent. In turn, the first respondent addressed a letter to the petitioner company on 26.02.2015 requesting them to send the Reference Standard/Working Standard. A reminder was also sent by the first respondent to the writ petitioner on 25.03.2015. Thereafter, two certificates under Form-2 have been issued by the third respondent herein on 21.04.2015

and 24.04.2015 with regard to the two batches of the drugs certifying that the samples do not confirm the I.P with respect to the test for identification and assay of Neostigmine Methyl Sulphate. These two certificates issued in Form-2 with reference to Rule 6 of the Drugs and Cosmetics Rules 1945 have been challenged by the writ petitioner company on various grounds. The primary ground on which the certificates are challenged is that the test/analysis have not been conducted by the third respondent in strict compliance under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules 1945.

12. Section 16(1)(a) defines standards of quality means in relation to a drug, that the drugs complies with standard set out within the second schedule. As per Serial No.5(a) of the second schedule, the standard of identity, purity and strength of the drugs have to be in conformity with Indian Pharmacopeia for the time being in force. It is also mentioned that standard of identity, purity and strength specified for drugs in the edition of such official Pharmacopeia of any country for the time being in force and such other standards as may be prescribed. The second schedule is referable to Sections 8 and 16 of the Drugs and Cosmetics Act, 1940. Section 8 falls under Chapter-III of the Act dealing with import of drugs and cosmetics. Section 16 falls under Chapter IV relating manufacture, sale and distribution

of drugs and cosmetics. Hence, it is clear that Chapter III deals with standard of quality relating to the imported drugs and cosmetics. While Chapter -IV deals with manufacture sale and distribution of drugs and cosmetics which are manufactured, sold and distributed in India. Therefore, it is clear that the second schedule is common to both the imported drugs and the drugs manufactured in India.

13.In the light of the above said facts, we have to consider Serial No. 5(a) of the second schedule. In the said Serial number, wherever the drugs are included in Indian Pharmacopeia, the standards have to be tested on the basis of the edition of Indian Pharmacopeia for the time being in force. It is also mentioned in the said serial number that the standards of quality, purity and strength should be in consonance with the official Pharmacopeia of any other Country for the time being in force. A drug which is included in Indian Pharmacopeia can never be expected to comply with standard of both Indian Pharmacopeia as well as the official Pharmacopeia of any other Country at the same time. Since the second schedule is relatable to both the imported drugs and the drugs manufactured in India, Serial No.5(a) of the said second schedule could only be interpreted to the effect that for the drugs which are manufactured in India (falling under Chapter -IV of Drugs and Cosmetics Act, 1940), the test/analysis should be only as per Indian Pharmacopeia and not the official Pharmacopeia of any other Country.

14.Rule 124(1)(a) of the Drugs and Cosmetics Rules 1945 will point out that for the drug included in the Indian Pharmacopeia, a standard for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopeia for the time being in force. As per Rule 124(2), the standards for identity, purity and strength shall be those as may be specified in the edition of the official Pharmacopeia for the time being in force, of any Country to which the drug claims to comply with. Hence, it is clear that once the standard for identity, purity and strength is specified in the edition of Indian Pharmacopeia, the same has to be followed for conducting the test/analysis and the respondents cannot follow any other method which is in violation of the statutory rules. Only for other drugs whose standards are not specified in the edition of Indian Pharmacopeia, the official Pharmacopeia of the Country which the drug claims to comply with has to be followed.

15.In the present case, it is not the case of the respondents that the petitioner company claims that the drugs in dispute claims to comply with the official Pharmacopeia of any other Country other than Indian Pharmacopeia. The third respondent herein in their original counter in Paragraph No.2 has contended as follows:

"2.It is humbly submitted that, in response to Para No.7, the petitioner inter alia submitted that the drug sample Neostigmine Methyl Suphate Injection IP quantity 4x50x1 ml, Batch No.NE40301, date of manufacture 03/2014, expiry date 08/2015 was drawn for analysis by one Mr.G.Saravanan, Drug Inspector on 30.05.2014.

The said drug samples stated to have forwarded to CDL, Kolkata, the third respondent herein for analysis and report. Simultaneously, it is also stated that third respondent have issued a communication in Letter No.2-1/014-SS/661 dated 30.01.2015 for " Reference Standard/Working Standard". Whereas the said communication letter dated 30.01.2015 relates to another drug samples bearing Batch No.NE.1101, date of manufacture 11/2013, date of expiry 04/2015 and not relates to the present petition.

The Central Drugs Laboratory, Kolkata consists of several Scientific Wings. Normally, matters are taken up with respective State Drugs Control Authority in case relevant "Reference Standard/Working Standard" is not readily available with the said particular Scientific Wind to test or analysis of drug sample(s) and at the same time requisition is also made simultaneously to Store/Reference Standard Wind of the laboratory for providing relevant " Reference Standard/Working Standard" to test or analysis of samples.

Accordingly, matter may have taken up with State Director of Drugs Control, Chennai in letter No.2-1/2014-SS/661 dated 30.01.2015 for another drug sample. In fact, "Reference Standard/Working Standard" to test or analysis of said drug sample Neostigmine Methyl Sulphate Injection IP was available in

Store /Reference Standing Wing of Central Drugs Laboratory, Kolkata which was used to test or analysis of the said drug sample in question. Copy of the said communication letter No.2-1/014-SS/661 dated 30.01.2015. Copy of letter annexed and marked as R/1".

16.However, in the Better Counter filed on 9th September 2022 in Paragraph No.9, it is contended as follows:

"9.Regarding Para-9 of the petition it is humbly submitted that the date of expiry of the relevant Injection ie. Neostigmine Methyl Sulphate Injection was 04/2015 as stand hereinbefore at Para-7. Thus the Central Drugs Laboratory cannot keep their finger crossed by sending a simple letter to the Stage Drugs Controller, Tamil Nadu to provide "Reference Standard/Working Standar"with test certificate for Neostigmine Methyl Sulphate for conducting test/analysis.

The matter was simultaneously taken up with other officers of the Government of India such as (1) Central Drugs Standard and Control Organisation (West Zone) Mumbai, (2) (North Zone) Gaziabad (3) (East Zone), Kolkata (4) Sub Zone, Chandigarh and (5) Krishnarajan Bangarurajan, Dy.Drug Controller of West Zone, to provide "Reference Standard/Working Standard"with test certificate for Neostigmine Methyl Sulphate if it is available with them vide mail dated 16.03.2015. Further matter was reminded on 19.03.2015 to all the above Central Drugs Standard and Control Organisation (Copy of mail attached and marked as Annexure-I)

Finally, the Central Drugs Laboratory, Kolkata was compelled to use the Unite State Pharmacopeia (USP) "Reference Standard"for

Neostigmine Methyl Sulphate from available stock preserved to meet the emergency requirement with respect to the test of "Identification"and Assay of Neostigmine Methyl Sulphate. The relevant test was carried out during 30.03.2015 to 31.03.2015 and report (Form-2) was issued correctly on 21.04.2015 that the sample does not conform to I.P with respect to the test for Identification"and Ässay"of Neostigmine Methyl Sulphate".

17.Hence, it is clear that the third respondent himself is not clear about which standard was followed by them in order to test/analysis the drug samples of the writ petitioner company. The Better Counter affidavit dated 09.09.2022 is clearly in contradiction with the original counter affidavit filed on 30.08.2022. The Pharmacopeia which was followed for conducting the test on the samples completely differs in both the counter affidavit. Therefore, it is clear that the third respondent has not conducted the test/analysis as per Section 16 r/w 2nd schedule Serial No.5(a) of the Drugs and Cosmetics Act, 1940. Admittedly, the standards for drugs in dispute is specified in the edition of Indian Pharmacopeia. Therefore, the third respondent was not legally entitled to invoke the edition of U.S. Pharmacopeia for conducting the test/analysis, especially when the petitioner company does not claim that their drug samples comply with official Pharmacopeia of United States.

18.Rule -6 of the Drugs and Cosmetics Rules 1945 lays down the manner in which the test/analysis result should be supplied to the drug manufacturer. As per the said Rule, the result with full protocol of the test applied shall be supplied forthwith to the sender in Form-2. In the present case, the samples have been sent by the X- Metropolitan Magistrate Court, Egmore, Chennai before which a prosecution is pending as against the petitioner Company.

19.A perusal of Form-2 annexed to Drugs and Cosmetics Rules 1945 indicates that after the result, details of the result of the test or analysis with protocol of the test supplied should be furnished. A perusal of both the impugned orders reveal that the method followed for testing as I.P which means Indian Pharmacopeia. However, the Better Counter Affidavit filed on 09.09.2022, specifically refers that U.S. Pharmacopeia was followed for testing the samples in dispute. In fact in the Better Counter, the third respondent has contended that the Reference/Working Standard was not available in India and due to emergency they have procured the same from United States. Therefore, it is clear that the Indian Pharmacopeia standard was not followed by the third respondent but U.S. Pharmacopeia was followed for conducting the test/analysis. Therefore, the statutory Form-2 does not disclose the correct protocol that was followed by the third respondent for conducting the test/analysis of the drug in dispute.

20.As this Court has already held that, for the drug included in Indian Pharmacopeia, standard specified in Indian Pharmacopeia alone has to be followed in view of Section 16 of the Drugs and Cosmetics Act and Rule 124(1)(a) of the Drugs and Cosmetics Rules 1945. Only in cases where the drugs are not included in Indian Pharmacopeia, the question of looking for Reference/Working Standard of official Pharmacopeia for any other Country would arise as contemplated under Rule 124(2)(a) of the Drugs and Cosmetics Rules 1945. Rule 124 (2)(a), can be invoked only in cases where the manufacturer claims that the drug supplied complies with official Pharmacopeia of some other country. Hence, it is clear that the third respondent in clear violation of the statutory provision has utilised U.S Pharmacopeia standard for conducting the test/analysis of a drug which is included in Indian Pharmacopeia. However, while issuing a certificate in Form-2, it is recorded as if the test/analysis was conducted as per standard specified in Indian Pharmacopeia.

21.In view of the above said facts, it is clear that the testing of the samples of the drugs in dispute have been conducted in clear violation of the above said statutory provisions and the Rules thereunder. The result of the test certificate in Form-2 is also not in consonance with the test alleged to

have been conducted by the third respondent herein. Therefore, both the certificates issued under Form-II suffer from legal infirmity and hence, they are liable to be set aside.

22. In view of the above said discussion, the certificates under Form-II impugned in both the writ petitions are set aside. The writ petitions are allowed. No costs. Consequently, connected miscellaneous petitions are closed.

27 .09.2022

Internet : Yes/No
Index : Yes/No
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To

1.The Director of Drugs Control
DMS Campus, Anna Salai
Teynampet
Chennai 600 006

2.The Drug Inspector
Office of the Assistant Director of Drugs Control
Villivakkam Range, Zone -II
Office of the Assistant Director of Drugs Control
Zone II, DMS Campus, Anna Salai
Chennai 600 006

R.VIJAYAKUMAR, J.

msa

Pre-delivery order made in

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