BY REGD. POST WITH ACK. DUE

DEPARTMENT OF DRUGS CONTROL ADMINISTRATION TAMIL NADU

PROCEEDINGS OF THE DIRECTOR OF DRUGS CONTROL (i/c), CHENNAI –6,

Present:Thiru. S. Abdul Khader, B.Pharm.,

D.Dis.No: 2083/IW3/NSQ-263/2013-14 Dated: 25.08.2015

Sub: Drugs – Drugs and Cosmetic Act 1940 and rules thereunder – Sample of Metoclopramide Injection IP, B.No. MP-2207B, M/D. 12/2012, E/D.05/2014, Manufactured by M/s. Sara Pharmaceuticals, No.4&15, Industrial Estate, Nagercoil - Declared as Not of Standard Quality - **Suspension Order** issued – Reg.

Ref: This Office show cause memo even No, Dated: 10.06.2015.

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M/s. Sara Pharmaceuticals, No.4&15, Industrial Estate, Nagercoil are holding valid drug manufacturing licence in Form 28, Bearing No.98, Dated: 01.12.1984 Valid to 31.12.2016 to manufacture drugs as endorsed in their licence.

M/s. Sara Pharmaceuticals, No.4&15, Industrial Estate, Nagercoil have manufactured Metoclopramide Injection IP, B.No. MP-2207B, under licence in Form 28.

The Drugs Inspector, Thiru. V.Balamarie, Ramanathapuram Range, office of the Assistant Director of Drugs Control, Virudhunagar Zone, drew sample of Metoclopramide Injection IP, B.No. MP-2207B, manufactured by the said firm on 19.08.2013 from Government Hospital, Kattu Paramakudi (T.K) for analysis.

The Government Analyst, Drugs Testing Laboratory, King Institute, Guindy, Chennai - 32 in her report No. 328 Lab No.151/13-14, dated. 03.02.2014 has declared the sample as Not of Standard Quality for the reason that the sample does not Pass Test for Description.

M/s. Sara Pharmaceuticals, No.4&15, Industrial Estate, Nagercoil have contravened the section 18 (a) (i) of the Drug Cosmetic Act 1940 by having manufactured for sale and sold the subject Drug/Cosmetic which is declared as Not of Standard Quality.

In this office show cause memo dated. 10.06.2015 referred to above M/s. Sara Pharmaceuticals, No.4&15, Industrial Estate, Nagercoil were directed to show cause as to why their manufacturing licence in Form 28, bearing No.98, dated. 01.12.1984 should not be **suspended** for a period of **Two Weeks** in respect of the product i.e., Metoclopramide Injection IP.

..2..

From,
K.ParthibanM.Pharm.,
Assistant Director of Drugs Control,
Virudhunagar Zone,I/c.,
Virudhunagar-1.

To,
The Director of Drugs Control,
Tamil Nadu
Chennai-6

Ref No: 551/E3/VNR/2015 Dated:23.02.2015

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of Diclofenac Sodium Tablets I.P. 50 mg, B.No. D-30904, M/D. 09/2013, E/D. 08/2015, Manufactured By. M/s. Sudarshan Pharmaceuticals Pvt Ltd, No.17-B, 18-A, Sector F, Industrial Area, Sanwar road, Indore – 452 015 – Declared as Not of Standard Quality- Interim Report submitted- regarding.

Ref:
1. Form 13 report No. 05385-D/2014-15 dated 9.02.2015 of the Government Analyst(Drugs), Chennai-6.
2. 483/DI/RMD/2015 Dated: 23.02.2015 of the Drugs Inspector, Ramanathapuram Range, Virudhunagar Zone.

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With references to the above, I submit that a sample of Diclofenac Sodium Tablets I.P. 50 mg, B.No. D-30904, M/D. 09/2013, E/D. 08/2015, Manufactured By. M/s. Sudarshan Pharmaceuticals Pvt Ltd, No.17-B, 18-A, Sector F, Industrial Area, Sanwar road, Indore – 452 015, drawn for analysis by Tmt.V.Balamarie, Drugs Inspector, Ramanathapuram Range, Virudhunagar Zone from M/s. Primary Health Centre, Pamban, has been reported as 'Not of Standard Quality' by the Government Analyst, (Drugs Special) Chennai-6. The reason stated that the sample does not conform to I.P. specification for Enteric coated tablets with respect to Disintegration n Acid Medium.

I am herewith forwarding the Interim Report submitted by the Drugs Inspector, Ramanathapuram Range, Virudhunagr Zone.

I will submit the final report, after receiving the same from the Drugs Inspector, Ramanathapuram Range, Virudhunagr Zone.

This is for your kind information and perusal.

Yours faithfully,

o/c

Assistant Director of Drugs Control,
Virudhunagar Zone, I/c.,
Virudhunagar

23.2.15

23/2/15

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ılamarie,
ıgs Inspector,
amanathapuram Range,
/irudhunagar zone.

To
The Assistant Director of Drugs Control,
Virudhunagar zone,
Virudhunagar-1.

Ref.No. 483/ DI/RMD/2015 dated: 23.2.15

Sir,

Sub: Drugs- Drugs and Cosmetics Act1940 and Rules there under- Sample of Diclofenac sodium tablets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road,Indore-452015 Drawn for analysis – Reported as 'not of standard quality' – interim report submitted- regarding.

Ref: 1. Form 13 report No.05385-D/2014-15 dated 9.2.2015 of the Govt. Analyst, Drugs Testing Laboratory, Chennai-06

With reference to the above, I submit that a sample of the drug, Diclofenac sodium tablets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road,Indore-452015 drawn for analysis from the Primary Health Centre, Pamban has been reported as 'not of standard quality' by the Govt. Analyst,Drugs Testing Laboratory, Chennai-06. I am herewith submitting the interim report for the same. I shall submit the final report after completion of further investigation.

Encl: Copy of the form 13 report.

Yours faithfully,

V. Balamarie
Drugs Inspector,
Ramanathapuram Range.

INTERIM REPORT

1. Name of the Drugs Inspector	V.Balamarie
2. Range, Zone	Ramanathapuram range, Virudhunagar zone
3. Name of drug, Batch No. Mfg. date and Exp. Date	Diclofenac Sodium tablets 50mg, D-30904, M/D:09/2013, E/D:08/2015
4. Name of the manufacturer	M/s Sudarshan Pharmaceuticals Pvt.Ltd
5. Address of the manufacturer	No: 17-B,18-A,SECTOR-F,Industrial area,sanwer road,Indore-452015
6. Place of sampling	Primary Health Centre, Pamban
7. Form 17 No. and date	077317, Dt:10.10.14
8. Sample No. & date	VB/66/RMD/14 dated:10.10.14
9. Form 18 memorandum No. & date	66/VB/RMD/14 dated:10.10.14
10. Form 13 report No. and date	05385-D/2014-15 dated 9.2.2015
11. Date of receipt of the report by the Drugs Inspector	16.2.14
12. Source of supply	District Drug Warehouse, TNMSC Ltd, Ramanathapuram
13. Reason for failure	Does not confirm to I.P specification for enteric coated tablets with respect to disintegration in Acid medium

14. Action taken

a. Letter dated 19.2.15 handed over to the Pharmacist PHC, Pamban to disclose under section 18-A of the Drugs and Cosmetics Act1940.
b. Reply received from the Pharmacist on 19.2.15, where in it was stated that they had 1,100 tablets of the above said batch No which was isolated and further returned to TNMSC, Ramanathapuram.
c. Letter handed over to the Warehouse in-charge, TNMSC Ltd, Virudhunagar on 19.2.15
d. Reply received from the Warehouse in-charge on 19.2.15, wherein it was stated that the stock of above batch of drug was not available.
e. Show cause notice sent to the manufacturer on 23.2.15, along with the form 13 report, as per section 25 (2) of the said act and the third portion of the sample, as per section 23 (4) (iii) of the said act, to explain for the contravention.

Jwrisankar Vennila., M.Pharm.,
irector of Drugs Control ,
hunagar Zone,
hunagar-1

To,
The Director of Drugs control,
Tamil Nadu
Chennai-600 006.

Ref No: 551/E3/VNR/2015

Dated: 31.03.2015

Sub: Drugs- Drugs and Cosmetics Act 1940 and Rules there under- Drugs- Drugs and Cosmetics Act 1940 and Rules there under- Sample of Diclofenac sodium tablets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road,Indore-452015- – Drawn for analysis – reported as **'not of standard quality' –Final report** submitted- forwarding -- regarding.

Ref:
1. 2168/IW-3/NSQ-331/2014/15 Dated: 23.02.2015 of the Director of Drugs Control, Chennai-6.
2. 483/DI/RMD/2015 Dated:30.3.2015 of the Drugs Inspector, Ramanathapuram Range.

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With reference to the above, I submit that a sample of the drug, Diclofenac Sodium tablets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road, Indore-452015- was drawn for analysis by the Drugs Inspector, Ramanathapuram Range from the Primary Health Centre, Pamban, on 10.10.14 and one portion of sample drawn was sent for analysis to the Government Analyst, Drugs Testing Laboratory, Chennai-06 under form 18 memorandum.

On 16.2.14, the report of analysis in Form 13 report No.05385-D/2014-15 dated 09.02.15 was received from the Govt. Analyst, Chennai-06, wherein it has been reported that the subject drug is of 'not of standard quality' for the reason that the sample does not conform **to I.P specification for enteric coated tablets with respect to disintegration in Acid medium.**

On 19.2.15, the Drugs Inspector has inspected the Primary Health Centre, Pamban. Thiru A.Chitrarasu , Pharmacist, PHC,Pamban was present during the inspection. A letter dated 19.2.15, was handed over to the Chief Pharmacist, requesting to disclose under section 18-A of the Drugs and

DESPATCHED

'er I.P 2010 it states that If the tablet has a soluble external coating, immerse the basket in t room temperature for 5minutes. Then suspend the assembly in the beaker containing 0.1M hloric acid.

On verification of Batch Manufacturing Record and the test of analysis for raw materials furnished them the coating materials like lake color (Red iron oxide) and color coat yellow are insoluble in ater.

However the protocol of testing by the Government Analyst, it is done for enteric coated tablets with soluble external coating. Further in the batch manufacturing record the process of testing of coating materials are not clearly mentioned. Their reply was not found to be satisfactory.

The Drugs Inspector stated that the manufacturer is situated at Indore and the drug is of short expiry 08/2015, it is of the opinion that the entire file may be referred to concerned State Drug Control Authorities for further investigation and necessary action or as decided by the licencing Authority.

On the basis of the above said report along with its enclosures, I also concur the report of Drugs Inspector the entire file may be referred to concerned State Drug Control Authorities for further investigation and necessary action or as decided by the licencing Authority.

I am herewith enclosing the report submitted by the Drugs Inspector, Ramanathapuram Range, Virudhunagar Zone for your kind perusal and further orders.

Yours faithfully,

31.3.15

Assistant Director of Drugs Control,
Virudhunagar Zone,
Virudhunagar-1.

31.3.15

31/3/15

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551/15

marie,

s Inspector,

anathapuram Range,

udhunagar Zone,

irudhunagar-1

To

The Director of Drugs Control,

Tamilnadu,

Chennai-6

Through The Assistant Director

Of Drugs Control,

Virudhunagar zone,

Virudhunagar-01

Ref.No.483/DI/RMD/2015 dated.30.3.2015

Sir,

Sub: Drugs- Drugs and Cosmetics Act 1940 and Rules there under- Drugs- Drugs and Cosmetics Act 1940 and Rules there under- Sample of Diclofenac sodium tablets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road,Indore-452015- – Drawn for analysis – reported as **'not of standard quality' –Final report** submitted- regarding.

Ref: 1. Form 17 bearing No. 077317 dated 10.10.14 addressed to the Pharmacist, Primary Health Centre, Pamban.

2. Form 18 memorandum No. 66/VB/RMD/14 dated 10.10.14 addressed to the Government Analyst, Drugs Testing Laboratory, Chennai-06.

3. Form 13 report No.05385-D/2014-15dated 09.02.15 of the Govt. Analyst, Drugs testing laboratory,Chennai-06.

4. Letter dated 19.2.15 handed over to the Pharmacist, primary health centre, Pamban.

5. Reply dated 19.2.15of the Pharmacist, Primary health centre, Pamban.

6. Letter dated 19.2.15 handed over to the Warehouse in-charge, TNMSC Ltd. Ramanathapuram.

7. Reply dated 19.2.15 of the Warehouse in-charge, Dist. Drug Warehouse, TNMSC Ltd, Ramanathapuram.

8. Show cause notice dated 23.2.15 sent by RPAD to M/s Sudarshan

maceuticals,Pvt.Ltd, Indore-452015

Reply dated 13.3.15 from the M/s.Sudarshan Pharmaceuticals, Pvt.Ltd,Indore-452015 received on 23.3.15.

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With reference to the above, I submit that a sample of the drug,Diclofenac sodium lets I.P.50mg, Batch.No:D-30904, Mfg.date:09/2013, Exp date:08/2015, Manufactured in India by SUDARSHAN Pharmaceuticals Pvt.Ltd, 17-B,18-A,Sector-F,Industrial area, sanwer road,Indore-452015- was drawn for analysis from the Primary Health Centre, Pamban vide reference 1 cited above, on 10.10.14 and one portion of sample drawn was sent for analysis to the Government Analyst, Drugs Testing Laboratory, Chennai-06 under form 18 memorandum, vide reference 2 cited above.

On 16.2.14, the report of analysis in Form 13 report No.05385-D/2014-15 dated 09.02.15 was received from the Govt. Analyst, Chennai-06, vide reference 3 cited above, wherein it has been reported that the subject drug is of 'not of standard quality' for the reason that the sample does not conform **to I.P specification for enteric coated tablets with respect to disintegration in Acid medium.**

On 19.2.15 I inspected the Primary Health Centre, Pamban. Thiru A.Chitrarasu , Pharmacist, PHC,Pamban was present during the inspection. A letter dated 19.2.15, vide reference 4 cited above, was handed over to the Chief Pharmacist, requesting to disclose under section 18-A of the Drugs and Cosmetics Act 1940, the name, address and other particulars of the person from whom the subject drug was acquired. One copy of the report in form 13 was also handed over to him as per section 25 (2) of the Drugs and Cosmetics Act 1940.

On 19.2.15, Thiru.A.Chitrarasu, the Pharmacist gave a letter, vide reference 5 cited above, wherein it was disclosed that the subject drug was acquired from the District Drug Warehouse,M/s TNMSC Ltd, Ramanathapuram under OGR No.12096 dated 17.1.14 (5000 tablets) and at present they had 1100 tablets which were isolated and later returned to TNMSC, Ramanathapuram.

On the same day, I inspected the District Drug Warehouse, M/s TNMSC Ltd, Ramanathapuram and handed over a letter dated 19.2.15 vide reference 6 cited above, requesting to disclose under section 18-A of the Drugs and Cosmetics Act 1940, the name,

and other particulars of the person from whom the subject drug was acquired. One opy of the report in form 13 was also handed over for information.

On 19.2.15 itself, Thiru. C.K.Selvakumar, the Warehouse in-charge gave a reply, vide eference 7 cited above, disclosing that the subject drug was acquired from the manufacturer, M/s Sudarshan Pharmaceuticals Pvt Ltd,17-B,18-A,Sector-F, Industrial area, sanwer road, Indore-452015 under invoice No. 216 dated 24.10.13(date of receipt) (Qty:470000) . It was also stated that at present they do not have any stock of the subject drug.

On 23.2.15, a show cause notice dated 23.2.15, vide reference 8 cited above, was sent by RPAD to the manufacturer, M/s Sudarshan Pharmaceuticals Pvt Ltd,17-B,18-A,Sector-F, Industrial area, sanwer road, Indore-452015 requesting to explain for the contravention of section 18 (a) (i) of the Drugs and Cosmetics Act 1940 for having manufactured for sale and sold a 'not of standard quality' subject drug and to furnish particulars and information under section 18-B of the Drugs and Cosmetics Act 1940. One copy of the form 13 report was also sent as per section 25 (2) of the Drugs and Cosmetics Act 1940. The third portion of the sealed sample of the subject drug, marked as VB/66/RMD/14 dated 10.10.14, was also sent along with the show cause notice, as per section 23 (4) (iii) of the said Act.

Reply dated:13.3.15 was received on 23.3.15,vide reference 9 cited above, from the M/s.Sudarshan Pharmaceuticals Pvt Ltd,Indore-452015. In their reply they had stated their tablets donot have soluble external coating and there is no requirement of immersing the tablets in water for 5 minutes as in the analysis report. Due to immersing the tablets in water the enteric coating of tablets get weak due to neutral P^H and the tablet gets disintegrated.

As Per I.P 2010 it states that If the tablet has a soluble external coating ,immerse the basket in water at room temperature for 5minutes. Then suspend the assembly in the beaker containing 0.1M Hydrochloric acid.

On verification of Batch Manufacturing Record and the test of analysis for raw materials furnished by them the coating materials like lake color(Red iron oxide) and colour coat yellow are insoluble in water.

However the protocol of testing by the Government Analyst, it is done for enteric coated tablets with soluble external coating.Further in the batch manufacturing record the process of

coating materials are not clearly mentioned. Their reply was not found to be tory.

the manufacturer is situated at Indore and the drug is of short expiry 08/2015, it is of the nion that the entire file may be referred to concerned State Drug Control Authorities for urther investigation and necessary action or as decided by the licencing Authority.

This is humbly submitted for your kind perusal and further orders.

Encl: As above.

Yours faithfully,

V. Balamurugan

Drugs Inspector,

Ramanathapuram Range

Registered Post

1566
551/15

DEPARTMENT OF DRUGS CONTROL ADMINISTRATION
TAMIL NADU

From
Thiru. S. Abdul Khader, B.Pharm.,
Director of Drugs Control,(i/c)
359, Anna Salai,
Chennai - 600 006,
Tamil Nadu.

To
The Drugs Controller,
Food and Drugs Administration,
Idgah Hill, Indore
Bhopal – 462 001
Madhya Pradesh.

K.DisNo.2168/IW3/NSQ-331/2014-15, Dated: 7 .05.2015

Sir,

Sub: Drugs – Drugs and Cosmetics Act 1940 and the Rules made there under – Sample of Diclofenac Sodium Tablets IP 50mg, B.No. D-30904, M/D. 09/2013, E/D. 08/2015, Manufactured by M/s. Sudarshan Pharmaceuticals Pvt. Ltd. Sanwer Road, Indore - 452 015 (M.P) - Declared as Not of Standard Quality - Reg.

Ref: 1. Test Report No. 05385-D/2014-15, dated: 09.02.2015, of the Government Analyst, Drug Testing Laboratory, Chennai - 6.

2. This Office Ref.No.2168/IW-3/NSQ-331/2014-15, Dated: 23.02.2015.

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With reference to the letters cited, I am to inform that the subject sample has been declared as Not of Standard Quality by the Government Analyst, Drugs Testing Laboratory, Chennai – 6, for the reason that the sample does not conform to IP specification for Enteric Coated Tablets with respect to Disintegration in Acid Medium and requested action at your end vide this office reference 2nd cited.

As per the investigation, it is revealed that the subject drug has been manufactured and sold by M/s. Sudarshan Pharmaceuticals Pvt. Ltd. Sanwer Road, Indore - 452 015 (M.P) which is situated in your State.

Hence, I request that necessary action may be taken against the manufacturer at your end and the action taken may kindly be informed to this office.

Yours faithfully,

DIRECTOR OF DRUGS CONTROL (i/c)

Copy to: The Assistant Director of Drugs Control, Virudhunagar Zone - for information.

Spare copy-1

R. No. 221/E2/15 Dated 11.5.15
Copy Communicated for necessary action

Received V. Balamani 15.5.15

12.5.15
A.D.D.C

To : The DI/RMD Range.

From
S.A.Govindakumar,B.Pharm,
Asst. Director of Drugs Control ,
Virudhunagar Zone.
Virudhunagar-1.

To
The Director of Drugs control,
Tamil Nadu
Chennai-600 006.

Ref No. 811 /E3/2014 dt: 19.2.14

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of METOCLOPRAMIDE INJECTION, Batch No:MP2207B, Mfg.date:12/2012, Expdate:05/2014, Manufactured by Sara Pharmaceuticals , No: 4 & 15, industrial estate, Nagercoil- TN–Declared as Not of Standard Quality- Interim report submission–Regarding.

Ref: 1. Form 13 report No.328 dated 3.2.14 of the Govt. Analyst, King Institute of Preventive Medicine, Guindy, Chennai-32.
2. Ref No. 570 /DI/RMD/2014dt: 19.2.14of the Drugs Inspector, Ramanathapuram range

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With reference to the above, I submit that theDrugs Inspector, Ramanathapuram Range has submitted an interim report for the not of standard quality drug and the details is as follows-

1.	**Name and details of the Drug**	METOCLOPRAMIDE INJECTION, Batch No. MP2207B: Mfg. date- 12/2012: Exp. Date- 05/2014: Manufactured by Sara Pharmaceuticals, No:4 & 15, Industrial Estate, Nagercoil- TN
2.	**Place of sampling with Form 17 No. and Date**	Government Hospital,KattuParamakudi,Paramakudi(T.K), No:071360, DT:19.8.13
3.	**To whom the sample was sent with Form 18 No. and Date.**	Govt.Analyst (Drugs special), King Institute of Preventive Medicine and Research, Guindy, Chennai-32, Sample No: VB/8/RMD 13, DT:19.8.13
4.	**Report No, Dated**	Form 13 No.328, Dated: 3.2.14
5.	**Reason for Failure**	The sample does not **pass the test for Description.**
6.	**Source of Supply**	Manufacturer-M/s. Sara Pharmaceuticals, No:4 & 15, Industrial Estate, Nagercoil- TN
7.	**Physical stock position**	Nil stock on 18.2.14
8.	**Whether memo issued**	Yes and further action initiated

I will submit the final report as soon as the report received from the Drugs Inspector. This is for your kind perusal and favour of information.

Encl: As above

Yours faithfully,

Asst. Director of Drugs Control
Virudhunagar Zone.
Virudhunagar-1

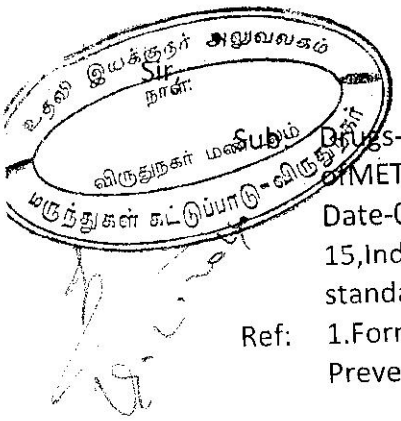
E3

811

From
V.Balamarie,
Drugs Inspector,
Ramanathapuram Range,
Virudhunagar zone.

To
The Assistant Director of Drugs Control,
Virudhunagar zone,
Virudhunagar-1.

Ref.No. 570/ DI/RMD/2014 dated:19.2.2014



Sub: Drugs- Drugs and Cosmetics Act1940 and Rules there under- Sample of METOCLOPRAMIDE INJECTION, Batch No.MP2207B: Mfg. date- 12/2012: Exp. Date-05/2014: Manufactured in India by Sara Pharmaceuticals, No: 4 & 15,Industrial Estate,Nagercoil-TN-Drawn for analysis – Reported as 'not of standard quality' – INTERIM REPORT- submitted- regarding.

Ref: 1.Form 13 report No. 328 dated:3/2/2014 of the Govt. Analyst, King Institute of Preventive Medicine and Research, Guindy, Chennai-32

With reference to the above, I submit that a sample of the drug, METOCLOPRAMIDE INJECTION, Batch No.MP2207B: Mfg. date- 12/2012: Exp. Date-05/2014: Manufactured in India by Sara Pharmaceuticals, No: 4 & 15,IndustrialEstate,Nagercoil-TN-drawn for analysis from the Medical Stores of the Govt. hospital,KattuParamakudi,Paramakudi(T.K)has been reported as 'not of standard quality' by the Govt. Analyst, Guindy, Chennai-32. I am herewith submitting the interim report for the same. I shall submit the final report after completion of further investigation.

Encl: Copy of the form 13 report.

Yours faithfully,

V. Balamarie 19.2.14

Drugs Inspector,
Ramanathapuram Range.

INTERIM REPORT

1. Name of the Drugs Inspector	V.Balamarie
2. Range, Zone	Ramanathapuram range, Virudhunagar zone
3. Name of drug, Batch No. Mfg. date and Exp. Date	METOCLOPROPAMIDE INJECTION ,Batch No. MP2207B: M/D: 12/2012: E/D: 05/2014.
4. Name of the manufacturer	M/s Sara Pharmaceuticals.
5. Address of the manufacturer	No:4 & 15, Industrial Estate, Nagercoil- TN
6. Place of sampling	Medical Stores, Govt.Hospital, KattuParamakudi, Paramakudi(T.K).
7. Form 17 No. and date	071360 dated 19.8.2013
8. Sample No. & date	VB/8/RMD/13 dated:19.8.2013
9. Form 18 memorandum No. & date	8/VB/RMD/13 dated:19.8.2013
10. Form 13 report No. and date	328 dated 3.2.14
11. Date of receipt of the report by the Drugs Inspector	17.2.14
12. Source of supply	District Drug Warehouse, TNMSC Ltd, Ramanathapuram
13. Reason for failure	Does not pass the test for Description.

14. Action taken

a. Letter dated 18.2.14 handed over to the Chief Pharmacist, GH,Kattuparamakudi to disclose under section 18-A of the Drugs and Cosmetics Act1940.
b. Reply received from the Chief Pharmacist on 18.2.14
c. Letter handed over to the Warehouse in-charge, TNMSC Ltd, Virudhunagar on 18.2.14
d. Reply received from the Warehouse in-charge on 18.2.14, wherein it was stated that the stock of above batch of drug was not available.
e. Show cause notice sent to the manufacturer on 19.2.2014, along with the form 13 report, as per section 25 (2) of the said act and the third portion of the sample, as per section 23 (4) (iii) of the said act, to explain for the contravention.

From
S.A.Govindakumar, B.Pharm,
Asst.Director of Drugs Control,
Virudhunagar zone,
Virudhunagar-1

To
The Director of Drugs Control,
Tamil Nadu
Chennai-600 006

Ref No: 811 /E1/VNR/2014 dt:16.4.14

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under- Sample of METOCLOPRAMIDE INJECTION I.P ,B.No: MP2207B, Mfg.date: 12/2012, Exp.date: 05/2014, Manufactured by Sara Pharmaceuticals, No: 4 & 15, Industrial estate,Nagercoil, TN – Declared as Not of Standard Quality – Final report Submission – Regarding.

Ref: 1. Form 13 Report No:328 dt:3.2.14 of the Govt.Analyst, Chennai-32.

2. Ref.No: 570 /DI/RMD/14 dt: 16.4.14 of the Drugs Inspector, Ramanathapuram Range

****

With reference to the above cited, I submit that a sample of Metoclopramide injection I.P , B.No: MP2207B, Mfg.date:12/2012, Exp. Date: 05/2014, Manufactured by M/s. Sara Pharmaceuticals, No: 4&15, Industrial estate, Nagercoil, TamilNadu, was drawn for analysis from the Govt Hospital, Paramakudi on 19.8.13, by V.Balamarie, Drugs Inspector, Ramanathapuram Range. On 19.8.13 one sealed portion of sample drawn was sent for analysis to the Govternment Analyst, king Institute, Guindy, Chennai-32, under form 18 memorandum.

On 17.2.14, the report of analysis in form 13 report No:328 dt:3.2.14,was received from the Govt.Analyst, Chennai-32, wherein it has been reported that the subject drug is of

ne Drugs and Cosmetics Act 1940. One copy of form 13 report was also sent as per section 25(2) of the Drugs and Cosmetics Act 1940. The third portion of sealed sample of the subject drug, marked as VB/8/RMD/13 dated:19.8.13, was sent , as per section 23(4)(iii)of the said Act.

A letter dated:27.2.14 was received on 3.3.14, from M/s.Sara Pharmaceuticals, Nagercoil requesting to grant 20 days time for the submission of their reply with documents since their Proprietor was out of station.

A reply dated: 7.3.14 was received on 17.3.14 from the Proprietor of M/s. Sara Pharmaceuticals, Nagercoil, TN along with the enclosures. In the reply they had stated that "Description does not constitute standards. It is only a guideline according to the general notice of Indian Pharmacopeia 2010. Further in the report of the Government Analyst does not say what respect the product fails in description".

Further on referring Indian Pharmacopeia 2010- General notice, page 14, it is stated that, "the statement under the heading Description are not to be interpreted in a strict sense and are not be regarded as official requirements".

Based on the above, the Drugs Inspector has submitted that the sample, Metoclopramide injection I.P , B.No: MP2207B, passes the test for sterility and fails only in Description, hence the endorsement of the Product may be suspended for a period of 2 months or as decided by the Licensing Authority.

I concur with the opinion of the Drugs Inspector. Further the failure in description does not come under the Guidelines for Prosecution.

I am herewith enclosing the report of Drugs Inspector, Ramanathapurm range along with its enclosures.This is for your kind perusal and favour of information sir.

Your's faithfully,

Asst. Director of Drugs Control

Virudhunagar zone

q/c

ılamarie, B.Pharm,
ug Inspector,
ramanathapuram Range.

To
The Director of Drugs Control,
Tamil Nadu,
Chennai-600 006.
Through,
The Assistant Director of Drugs Control,
VirudhuNagar Zone.
VirudhuNagar-1.

1469

Ref.No. 570 /DI/RMD/14, dt : 16.4.14

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under - Sample of Metoclopramide Injection I.P, B.No:MP2207B, Mfg.Date:12/2012, Exp.date: 05/2014, Manufactured in India by Sara Pharmaceuticals, No:4&15, Industrialestate,Nagercoil, TamilNadu - Declared as Not of Standard Quality- Final report submission- Regarding.

Ref:
1. Form 17 bearing No: 071360 dated: 19.8.13 addressed to the chief Pharmacist, Govt.Hospital, Paramakudi.
2. Form 18 memorandum No: 8/VB/RMD/13 dated:19.8.13 addressed to the Government Analyst, King Institute, Guindy, Chennai-32.
3. Form 13 report No: 328 dated: 3.2.14 of the Govt.Analyst,King Institute of Preventive Medicine and Research,Guindy,Chennai-32
4. Letter dated:18.2.14 handed over to the chief Pharmacist, Govt.Hospital, Paramakudi.
5. Reply dated: 18.2.14 of the Chief Pharmacist, Govt.Hospital, Paramakudi.
6. Letter dated: 18.2.14 handed over to the Warehouse in charge, TNMSC, Ramanathapuram.
7. Reply dated: 18.2.14 of the Warehouse incharge, Dist. Drug Warehouse, TNMSC, Ramanathapuram.
8. Show cause notice dated: 19.2.14 sent by Registered Post with A/D to M/s. Sara Pharmaceuticals, Nagercoil, Tamil Nadu.
9. A letter dated: 27.02.14 from M/s.Sara Pharmaceuticals, Nagercoil.

On the same day, I inspected Distict Drug warehouse, TNMSC, ınathapuram and handed over a letter dt: 18.2.14, vide reference 6 cited ɔve, requesting to disclose under section 18-A of the Drugs and Cosmetics Act .940, the name, address, and particulars of the person from whom the subject drug was acquired. One true copy of the report in form 13 was also handed over for information.

On 18.2.14 itself, Thiru.C.K.Selvakumar, warehouse incharge, gave a reply, vide reference 7 cited above, disclosing that the subject drug was acquired from the manufacturer,M/s. Sara Pharmaceuticals, No: 4 & 15, industrial estate, Nagercoil, TN, under invoice No:T802 dt:17.1.13(quantity 12000 ampoules) and at present they had no stock of subject drug .

On 19.2.14, a show cause notice dated: 19.2.14, vide reference 8 cited above, was sent by Registered post with A/D to the manufacturer, M/s. Sara Pharmaceuticals, No:4 & 15, industrial estate, Nagercoil, TN, requesting to explain for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act 1940 for having manufactured for sale and sold a ' not of standard quality' drug and to furnish particulars and information under Section 18-B of the Drugs and Cosmetics Act 1940. On copy of form 13 report was also sent as per section 25(2) of the Drugs and Cosmetics Act 1940. The third portion of sealed sample of the subject drug, marked as VB/8/RMD/13 dated:19.8.13, was sent, as per section 23(4)(iii)of the said Act.

A letter dated:27.2.14 was received on 3.3.14, vide reference 9 cited above, from M/s.Sara Pharmaceuticals, Nagercoil requesting to grant 20 days time for the submission of their reply with documents since their Proprietor was out of station.

A reply dated: 7.3.14 was received on 17.3.14, vide reference 10 cited above, from the Proprietor of M/s. Sara Pharmaceuticals, Nagercoil, TN along with the enclosures. In the reply they had stated that "Description does not constitute standards. It is only a guideline according to the general notice of Indian Pharmacopeia 2010. Further in the report of the Govt Analyst does not say what respect the product fails in description".