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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 Drug Control Authority
Food & Drug Administration,
No.9, Jagat Narayan Road,
Lucknow,
Uttar pradesh

K.DisNo.15091/IW3/NSQ-151/2014-15, Dated: 4.12.2014

Sir,

Sub: Drugs – Drugs and Cosmetics Act 1940 and the Rules made there under – Sample of ON & ON Tablets (Ondansetron Tablets IP), B.No. DT - 127, M/D. 09/13, E/D. 02/15, Manufactured by M/s. Dafodills Pharmaceuticals Ltd., Meerut - 250 001, U.P. - Declared as Not of Standard Quality-Reg.

Ref: 1. Test Report No. 05898-D/2013-14, dated. 03.09.2014, of the Government Analyst, Drug Testing Laboratory, Chennai - 6.

2. This Office Ref.No.15091/IW-3/NSQ-151/2014-15, Dated: 25.09.2014.

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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 with respect to the Content of Ondansetron in Ondansetron Hydrochloride (Contains 83.9%) and Dissolution 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. Dafodills Pharmaceuticals Ltd., Meerut - 250 001, U.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

n M.Pharm.,
Director of Drugs Control, I/c.,
agar Zone,
agar-1.

Ref no: 3945/E3/VNR/14

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

Dated: 18.09.2014

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of ON and ON Tablets, Ondansetron Tablets I.P., B.No. 127, M/D. 09/2013, E/D. 02/2015, Manufactured By. M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, meerut-250 001 – Declared as Not of Standard Quality- Interim Report submitted- regarding.

Ref:
1. Form 13 report No.05898/2013-14 dated 03.09.2014 of the Government Analyst, Chennai-6.
2. 3813/DI/SVG/2014 DT: 17.09.2014 of the Drugs Inspector, Sivaganga Range.

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With references to the above, I submit that a sample of ON and ON Tablets, Ondansetron Tablets I.P., B.No. 127, M/D.09/2013, E/D.02/2015, Manufactured By. M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, meerut-250 001, drawn for analysis by Thiru.R.Satish, Drugs Inspector, Sivaganga Range from the District Drug Warehouse, TNMSC Ltd, Panangadi Road, Annanagar, Sivaganga has been reported as 'Not of Standard Quality' by the Government Analyst, (Drugs Special) Chennai-32. The reason stated that the sample does not conform to I.P. specification for Ondansetron Tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.

I am herewith forwarding the Interim Report submitted by the Drugs Inspector, Sivaganga Range.

I will submit the final report, after receiving the same from the Drugs Inspector, Sivaganga Range.

This is for your kind information and perusal.

அனுப்பப்பட்டது

Yours faithfully,

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

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To,

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

or
ange

Ref No. 05898/DI/SVG/14, dt: 8.9.14

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Mfg by M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001–Declared as Not of Standard Quality- interim report submitted Regarding.

Ref: 1) Form 13 No. 05898/13-14, Dated: 3.9.14 of the Govt. Analyst (Drugs), Chennai-6.
2) Form 17 No. 076290, dt: 6.1.14 of the Drugs Inspector, Sivaganga Range.

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With reference to the above, I submitting the interim report for the not of standard quality drug and the details is as follows-

1.	**Name and details of the Drug**	ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Mfg by M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001
2.	**Place of sampling with Form 17 No. and Date**	District Drug Ware House, TNMSC, Panangadi Road, Annanagar, Sivaganga. Form 17 No. 076290, dt: 6.1.14
3.	**To whom the sample was sent with Form 18 No. and Date.**	Govt. Analyst (Drugs Special), Chennai -32, Form 18 No. RS/5/SVG/14, DT:6.1.14
4.	**Report No, Dated**	05898/13-14, Dated: 3.9.14
5.	**Reason for Failure**	The sample does not conform IP specification for Ondansetron tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.
6.	**Source of Supply**	M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001–Inv. No 1574 dt; 16.12.13
7.	**Physical stock position**	3200 tablets stocks as on 16.9.14 with undertaken to not to dispose the stocks until further orders.

I will submit the final report as soon as the investigation is completed in this matter. This is for your kind perusal and favour of information.

Encl: As above

Yours faithfully,

Drugs Inspector
Sivaganga Range

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

;hiban M.Pharm.,
;tant Director of Drugs Control,
udhunagar Zone, I/c.,
udhunagar-1.

Ref. No.3945 /E3/VNR/2014 dated 11.10.2014

Sub: Drugs – Drugs and Cosmetics Act 1940 and Rules there under- Sample of ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Manufactured in India by M/s Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 – drawn for analysis- reported as 'Not of Standard Quality'- FINAL REPORT- submitted– regarding

Ref:
1. Form 13 report No. 05898 / 2013-14 dated 03.09.2014 of the Government Analyst, Chennai-6.
2. 3813/DI/SVG/2014 DT: 21.10.2014 of the Drugs Inspector, Sivaganga Range.
3. Interim dated: 18.09.2014

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With references to the above, I submit that a sample of the drug, ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15: Manufactured in India by M/s Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 drawn for analysis by Thiru.R.Satish Drugs Inspector, Sivaganga Range from M/s. TNMSC, District Drug Ware House, Sivaganga on 15.09.2014, has been reported as 'Not of Standard Quality' by the Government Analyst, Chennai-6, for the reason that the sample does not conform to IP specification for Ondansetron tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.

After completing investigation, the Drugs Inspector reported that the subject sample of the drug, ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15: Manufactured in India by M/s Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 was failed in content of Ondansetron in Ondansetron Hydrochloride (83.9%) and Dissolution (~~83.9%~~) and passed all other parameters. The said manufacture is having valid drug licence in form 25 & 28 and bearing No respectively 10 of 1996 and 08/SC/P of 1996, valid upto

endorsement of the subject drug. Hence, he recommended to refer this be referred to concern state or appropriate action deemed fit may kindly be rector of Drugs Control, Tamil Nadu.

On the basis of the above said report along with its enclosures, I also concur the drugs inspector and this matter may be referred to the concerned state drugs control orities of Uttar Pradesh for taking further necessary action with a intimation to this office.

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

Yours faithfully,

Assistant Director of Drugs Control,
Virudhunagar Zone, I/c.,
Virudhunagar-1.

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atish
ugs Inspector,
ivganga Range.

To
The Director of Drugs Control,
Tamilnadu,
Chennai-6
Through
The Assistant Director of Drugs Control,
Virudhunagar Zone,
Virudhunagar-1.

Ref.No.3813 /DI/SVG/14 dated 6.11.14

Sir,

Sub: Drugs- Drugs and Cosmetics Act 1940 and Rules there under- Sample of ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Mfg by M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001–drawn for analysis- reported as 'Not of Standard Quality'- **Final report** submitted- regarding.

Ref:
1. Form 13 No. 05898/13-14, Dated: 3.9.14 of the Govt. Analyst (Drugs), Chennai-6.
2. Form 17 No. 076290 , dt: 6.1.14 of the Drugs Inspector, Sivaganga Range.
3. Form 18 No. 5 dated 6.1.14 addressed to Govt. Analyst (Drugs), Chennai-6.
4. Interim report dt: 17.9.14
5. A Show Cause Memo dated 15.9.14 issued to TNMSC, District Drug Ware House, Sivaganga.
6. Reply dt: 15.9.14 of TNMSC, District Drug Ware House, Sivaganga.
7. Inv no. 1574 dt: 10.12.13 of M/s Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 supplied to M/s. TNMSC Limited, Sivaganga.
8. A show cause memo dt: 17.9.14 sent to M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001.
9. A reminder dated 8.10.14 sent to M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001
10. Reply dt: 15.10.14 received on 21.10.14 of M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001

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With reference to the above, I submit that, a sample of the drug, namely ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Mfg by M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001 which was

n vide ref. 2nd cited and sent for analysis has been declared by the Govt. Analyst (Drugs nennai-6 vide ref. 1st cited as not of standard quality for the reason that the sample does ot conform IP specification for Ondansetron tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.

On 15.9.14, I inspected M/s. TNMSC, District Drug Ware House, Sivaganga and observed no stock of the subject drug. Thiru. K.Subramanian, the ware house incharge - Pharmacist was present. A letter dt:15.9.14, vide reference 5 cited above, was handed over to the him, 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 her as per Section 25(2) of the Drugs and Cosmetics Act 1940.

On 15.9.14, Thiru. K.Subramanian, ware house incharge cum Pharmacist gave letter, vide reference 6 cited above, wherein it was disclosed that the subject drug was acquired from the manufacturer, M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001 vide Inv. No 1574 dt; 16.12.13 (12000 tabs) and he stated that they have 3200 tabs of the subject drug at present.

On 17.9.14 , a show cause notice vide reference 6 cited above, was sent by Registered post with A/D to the manufacturer, M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001 , 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 5 dated 6.1.14 was sent, as per section 23(4)(iii)of the said Act.

A reminder letter dated: 8.10.14 was sent by Registered post with A/D to the manufacturer, M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001 , 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.

A reply dated: 15.10.14 was received on 21.10.14 , vide reference 8 cited above, n M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001 ong with the enclosures.

It is having valid license No., 10 of 1996 & 08/SC/P of 1996 granted on the Form-25 & 28 valid till 31.12.2016 with endorsement for ON and ON tablets. Ondansetron Tablets I.P. Thiru. Prateek chaudhary, Thiru. chaudhary and Thiru. Amit Singh are the Directors of the firm.

In the reply they had stated that the third portion sent was tested by their quality control department and declared as standard quality in respect of assay and dissolution test and they are followers of good manufacturing practices and they will be more cautious in future.

On verification of tne records / documents submitted by the proprietor, along with his reply, it was observed that the batch was stared on 24.9.13 and completed on 27.9.13 and Batch size was 96,000 tabs and in the Indent of Raw materials the expiry date is not mentioned for the raw materials issued.

Based on the above, I submit that the sample drug fails in the content of Ondansetron in Ondansetron Hydrochloride and Dissolution, Hence, it is of the opinion that the entire file may be referred to the concerned state drugs control authorities of Uttar Pradesh (U.P.) for taking further investigation and necessary action for the following reasons:

1. The subject drug fails in the content of Ondansetron in Ondansetron Hydrochloride and Dissolution and
2. The manufacturer is situated in the state of Uttar Pradesh .

I am herewith enclosing the copies of the records for your kind perusal.

Your's Faithfully

R. Sen

Drugs Inspector,
Sivaganga Range

Encl: As above.

CHECK LIST

1. Name of the Drugs Inspector/Range	R. Satish, Sivaganga Range, Virudhunagar Zone.
2. Details of the sample	ON and ON tablets. Ondansetron Tablets I.P., B.No. DT-127, M/D. 09/13, E/D. 02/15, Mfg by M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, Rohta Road, Meerut-250001
3. Expiry date of the sample	02/2015
4. Receipt of Form 13 with date	05898/13-14, Dated: 3.9.14
5. Reason for failure	The sample does not conform IP specification for Ondansetron tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.
6. Date of interim report submitted	17.9.14
7. Details of memo issued & reply received with date	1. A Show Cause Memo dated 15.9.14 issued to TNMSC, District Drug Ware House, Sivaganga. 2. Reply dt: 15.9.14 of TNMSC, District Drug Ware House, Sivaganga. 3. Inv no. 1574 dt; 16.12.13 of M/s Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 supplied to M/s. TNMSC Limited, Sivaganga. 4. A show cause memo dt: 17.9.14 sent to M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001. 5. A reminder dated to M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001 6. Reply dt: 15.10.14 received on 21.10.14 of M/s. Dafodills Pharmaceuticals Ltd, Jawahar Nagar, rohta Road, Meerut-250001
8. Date of final report submitted	6.11.14

9. Recommended for	
a) Prosecution Reason	-
b) Suspension	-
c) Cancellation	-
d) Referred to other state	The sample does not conform IP specification for Ondansetron tablets with respect to the content of Ondansetron in Ondansetron Hydrochloride and Dissolution. Content found to be 83.9% as against 95% to 110%.
10. If final report submitted after expiry date Reason	-
11. Signature of the Drugs Inspector	