

By Registered Post

DEPARTMENT OF DRUGS CONTROL ADMINISTRATION
TAMIL NADU

2505/11

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,
Madhya Pradesh,
Idgah Hill, Indore
Bhopal - 462 001

K.Dis No. 7195/IW3/NSQ-32/2014-15, Dated: 19.08.2014

Sir,

Sub: Drugs - Drugs and Cosmetics Act 1940 and the Rules made there under - Sample of Benzyl Penicillin Injection IP, B.No. TBN-1204, M/D. 10/12, E/D. 09/14, Manufactured by M/s. Nandani Medical Laboratories Pvt. Ltd., Indore, M.P. - Declared as Not of Standard Quality-Reg.

Ref: 1. Test Report No. 58 / Laboratory No. 169/13-14, dated. 29.04.2014, of the Government Analyst, Drug Testing Laboratory, King Institute, Guindy, Chennai - 32.

2. This Office Ref.No:7195/IW-3/NSQ-32/2014-15, Dated: 08.05.2014.

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 failed in Description 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. Nandani Medical Laboratories Pvt. Ltd., Indore, 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

From,
K.Parthiban, M.Pharm.,
Asst. Director of Drugs Control ,
Virudhunagar Zone I/c.,
Virudhunagar-1

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

Ref. No. 2365/E3/VNR/2013, dated:16.07.2014

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of Sample of Benzylpenicillin Injection I.P. , B.no. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore - Declared as Not of Standard Quality- Final report- Forwarding - Regarding.

Ref: 1. Ref.No. 2267/DI/SVG/14, dated: 30.06.2014 of the Drugs Inspector, Sivaganga Range.

With reference to the above, I submit that a sample of the drug, Benzylpenicillin Injection I.P., B.No. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt. Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore drawn for analysis on 21.8.13 from the stocks of the M/s. TNMSC, District Drug Ware House, Sivaganga by Thiru R.Satish, Drugs inspector, Sivaganga Range, On 21.8.13 has been declared as Not of Standard Quality by the Government Analyst, King Institute, Guindy, Chennai-32, wherein it has been reported that the subject drug is of 'not of standard quality' for the reason that the sample does not pass test for Description.

On 7.5.14, the Drugs Inspector inspected /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 was handed over to 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.

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On 7.5.14, Thiru. K.Subramanian, ware house in-charge cum Pharmacist gave letter, wherein it was disclosed that the subject drug was acquired from the manufacturer, M/s. Nandani Medical Laboratories Pvt. Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore vide Inv. No. 02729 dt: 1.12.12 (1500 vials) and he stated that they have no stock of subject drug at present.

On 12.5.14, a show cause notice, was sent by Registered post with A/D to the manufacturer, M/s. Nandani Medical Laboratories Pvt. Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore, 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 reports 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 57 dated: 21.8.13, was sent, as per section 23(4)(iii) of the said Act.

A reminder letter dated: 2.6.14 was sent by Registered post with A/D to the manufacturer, M/s. Nandani Medical Laboratories Pvt. Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore, 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: 2.6.14 was received on 17.6.14, from M/s. Nandani Medical Laboratories Pvt. Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore, along with the enclosures. The firm is having valid license in form 28 (No.28/4/99) renewed up to 31.12.12, with endorsement for Benzylpenicillin Injection I.P. further in the reply they had 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". Also description is not coming standards and tests in official monograph in IP.

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".

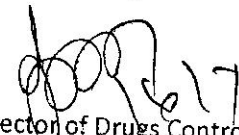
Based on the above, the Drugs Inspector submits that the sample drug passes the test for sterility and fails only in Description.


The Drugs Inspector reported the subject drug fails only in description and the manufacturer of the subject drug is situated at Madhya Pradesh. Hence, this matter may be referred to the concern state authorities for taking necessary action.

I also concur with his opinion and the matter may be referred to the concerned state drugs control authorities of Madhya Pradesh for taking further necessary action with a ^{copy} intimation to this office.

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

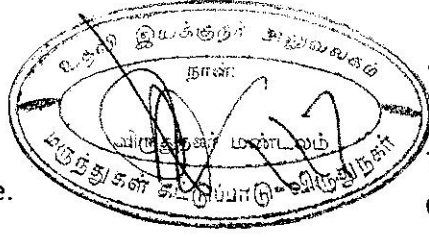
Yours faithfully,


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


6-1-14


16/7/14

From,
R.Satish,
Drug Inspector,
Sivaganga Range.



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

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

2365/14

Sir,

Ref.No. 2267/DI/SVG/14, dt : 30.6.14

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of Sample of Benzylpenicillin Injection I.P. , B.no. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore - Declared as Not of Standard Quality- Final report submission- Regarding.

- Ref:**
1. Form 17 bearing No: 076256 dated: 21.8.13 addressed to the Pharmacist incharge of M/s: TNMSC limited, District Drug Ware House, Sivaganga .
 2. Form 18 memorandum No: 57 dated:21.8.13 addressed to the Government Analyst, King Institute, Guindy, Chennai-32.
 3. Form 13 report No: 58 dated: 29.4.14 of the Govt.Analyst,King Institute of Preventive Medicine and Research,Guindy,Chennai-32
 4. Letter dated: 7.5.14 handed over to the Warehouse in charge, TNMSC, Sivaganga.
 5. Reply dated: 7.5.14 of the Warehouse incharge, Dist. Drug Warehouse, TNMSC, Sivaganga.
 6. Show cause notice dated: 12.5.14 sent by Registered Post with A/D to M/s. Nandani Medical Laboratories Pvt.Ltd, Indore.
 7. A reminder letter dated: 2.6.14 sent by Registered Post with A/D to M/s. Nandani Medical Laboratories Pvt.Ltd, Indore.
 8. Reply received dated: 17.6.14 from Nandani Medical Laboratories Pvt.Ltd, Indore.

With reference to the above, I submit that a sample of the drug, Benzylpenicillin Injection I.P. , B.No. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore was drawn for analysis on

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21.8.13 from the stocks of the M/s. TNMSC, District Drug Ware House, Sivaganga, vide reference 1 cited above. On 21.8.13 one sealed portion of sample drawn was sent for analysis to the Government Analyst, King Institute, Guindy, Chennai-32, under form 18 memorandum, vide reference 2 cited above.

On 6.5.14, the report of analysis in form 13 report No: 58 dated: 29.4.14, was received from the Govt. Analyst, Chennai-32, 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 pass test for Description.

On 7.5.14, I inspected /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:7.5.14, vide reference 4 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 7.5.14, Thiru. K.Subramanian, ware house incharge cum Pharmacist gave letter, vide reference 5 cited above, wherein it was disclosed that the subject drug was acquired from the manufacturer, M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore vide Inv. No. 02729 dt: 1.12.12 (1500 vials) and he stated that they have no stock of subject drug at present.

On 12.5.14 , a show cause notice vide reference 6 cited above, was sent by Registered post with A/D to the manufacturer, M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore , 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 57 dated:21.8.13, was sent, as per section 23(4)(iii) of the said Act.

A reminder letter dated:2.6.14 was sent by Registered post with A/D to the manufacturer, M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore , , 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: 2.6.14 was received on 17.6.14, vide reference 8 cited above, from M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore, along with the enclosures.

It is having valid license in form 28 (No.28/4/99) renewed up to 31.12.12, with endorsement for Benzylpenicillin Injection I.P..

In the reply they had 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". Also description is not coming standards and tests in official monograph in IP.

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, I submit that the sample drug passes the test for sterility and fails only in Description.

Hence, it is of the opinion that the entire file may be referred to the concerned state drugs control authorities of Madhya Pradesh for taking further investigation and necessary action for the following reasons:

1. The subject drug fails only in description and
2. The manufacturer is situated in the state of Madhya Pradesh .

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

Your's Faithfully

R. 

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	Benzylpenicillin Injection I.P. , B.no. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore
3. Expiry date of the sample	09/2014
4. Receipt of Form 13 with date	Form 13 No. No: 58 dated: 29.4.14
5. Reason for failure	the sample does not pass test for Description
6. Date of interim report submitted	12.5.14
7. Details of memo issued & reply received with date	<ol style="list-style-type: none">1. Letter dated: 7.5.14 handed over to the Warehouse in charge, TNMSC, Sivaganga.2. Reply dated: 7.5.14 of the Warehouse incharge, Dist. Drug Warehouse, TNMSC, Sivaganga.3. Show cause notice dated: 12.5.14 sent by Registered Post with A/D to M/s. Nandani Medical Laboratories Pvt.Ltd, Indore.4. A reminder letter dated: 2.6.14 sent by Registered Post with A/D to M/s. Nandani Medical Laboratories Pvt.Ltd, Indore.5. Reply received dated: 17.6.14 from Nandani Medical Laboratories Pvt.Ltd, Indore.
8. Date of final report submitted	30.6.14
9. Recommended for	
a) Prosecution Reason	-
b) Suspension	-
c) Cancellation	-
d) Referred to other state	Since manufacturer of the subject drug is situated in other state i.e., Madhya Pradesh (M.P.) the matter may be referred to

	concerned state licensing authority for taking further action in this matter
10. If final report submitted after expiry date Reason	-
11. Signature of the Drugs Inspector	R. Setu

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. 2365/E 2/2014, dt 19.5.14

Sir,

Sub: Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of Benzylpenicillin Injection I.P. , B.no. TBN-1204, M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore–Drawn for analysis –sent for analysis –Reported as Not of Standard Quality- Interim report submission- Regarding.


Ref: 1. Form 13 No. 58 , Dated: 29.4.14 of the Govt. Analyst (Drugs Special), Chennai-32.
2. Ref No. 2267/DI/SVG/2014 dt: 14.5.14 of the Drugs Inspector, Sivaganga Range.


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

1.	Name and details of the Drug	Benzylpenicillin Injection I.P. , B.no. TBN-1204 M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore
2.	Place of sampling	M/s. TNMSC, District Drug Ware House, Sivaganga
3.	Report No, Dated and reason of failure	Form 13 No. 58 , Dated: 29.4.14 The sample does not conform to the requirement for Description.
4.	Purchase/ receipt details of the subject drug obtained u/s 18A	Inv.No. 02729 dated 01.12.12 of Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore
5.	Whether any stock available if so action taken	No stock available on 7.5.14
6.	Whether further memo issued	1. A Show Cause Memo dated 7.5.14 issued to TNMSC, District Drug Ware House, Sivaganga. 2. Reply dt: 7.5.14 of TNMSC, District Drug Ware House, Sivaganga 3. A Show Cause Memo dated 14.5.14 issued to M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore

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.


19.5.14.
60
19/5/14

From,
R. Satish,
Drugs Inspector,
Sivaganga Range,

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

14/5/14 2365

Sir,

Ref No. 2267/DI/SVG/2014, dt: 14.5.14

Sub:

Drugs-Drugs & Cosmetics Act 1940 & Rules made there under – Sample of Benzylpenicillin Injection I.P. , B.no. TBN-1204 M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore –Drawn for analysis –sent for analysis –Reported as Not of Standard Quality- Interim report submission- Regarding.

Ref:

1. Form 13 No. 58 , Dated: 29.4.14 of the Govt. Analyst (Drugs Special), Chennai-32.
2. Form 17 No. 076256 , Dated: 21.8.2013 of the Drugs Inspector, Sivaganga Range.
3. Form 18 No. 57 dated 21.8.13 addressed to Govt. Analyst (Drugs Special), Chennai-32.

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

1.	Name and details of the Drug	Benzylpenicillin Injection I.P. , B.no. TBN-1204 M/d. 10/2012, E/D. 09/2014, MFD BY M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore
2.	Place of sampling	M/s. TNMSC, District Drug Ware House, Sivaganga
3.	Report No, Dated and reason of failure	From 13 No. 58 , Dated: 29.4.14 The sample does not conform to the requirement for Description.
4.	Purchase/ receipt details of the subject drug obtained u/s 18A	In No. 02729 dt 01.12.12 of M/s. Nandani Medical Laboratories (P) Ltd, Indore
5.	Whether any stock available if so action taken	No stock available on 07.05.14
6.	Whether further memo issued	1. A Show Cause Memo dated 7.5.14 issued to TNMSC, District Drug Ware House, Sivaganga. 2. Reply dt: 7.5.14 of TNMSC, District Drug Ware House, Sivaganga 3. A Show Cause Memo dated 14.5.14 issued to M/s. Nandani Medical Laboratories Pvt.Ltd, 221/5, Bicholi hapsi, kanadia Road, Indore

I will submit the final report as soon as the investigation is completed in this matter..

Yours faithfully,

Drugs Inspector
Sivaganga Range