

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

President
Chandigarh Chemist Association
SCF No. 16, Sector-19-C,
Chandigarh

Memo No. DIS-2017//1094

Dated, Chandigarh the:-12.7.2017

Subject:- Drugs Reported to be " **Not of Standard Quality**"-regarding.

In reference to the letter received from Dy. Drugs Controller, Govt of India, CDSCO, Baddi, Ref No. NZ/BD-SZO/NSQ-05/sample/UA/MV/2017-18/1686-89, Dated 10.july.2017 regarding List of "**Not of Standard Quality**" Drugs-Reported communicated.(Copy enclosed herewith).

You are hereby directed to further inform the retail & whole sale chemists to not purchase/ sale of these particular batches of these drugs & if any drugs stock is available them, then immediately inform to this office.


Drugs Inspector
Chandigarh Administration
Chandigarh

ई मेल : cdscobaddi@gmail.com

भारत सरकार

केंद्रीय औषध मानक नियन्त्रण

संगठन (बट्टी)

स्वास्थ्य सेवाओं का महानिदेशालय)

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारतीय संदेनर मिशन डिस्ट्रिक्ट

गौतम शीतलपुर, तहसील बट्टी

जिला सोलन (बी. प्र.)- 173205

Phone no. 01795-247112

भारत सरकार



GOVERNMENT OF INDIA

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROLS
ORGANISATION (BADDI)

(Directorate General of Health Services)

Ministry of Health & Family Welfare

Container Corporation of India Building

Village Sheetalpur, Tehsil Baddi

District Solan (HP)-173205

Phone no. 01795-247112

Ref No. NZ/BD-SZO/NSQ-05/Sample/UA/MV/2017-18 /194-189 Dated: 14.07.2017

To,

1. The Drugs Controller General of India, CDSCO, HQ, FDA Bhawan, New Delhi.
2. The Dy. Drugs Controller (India), CDSCO, North Zone, Ghaziabad.
3. The Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai
4. The Dy. Drugs Controller (India), CDSCO, East Zone, Kolkata.
5. The Dy. Drugs Controller (India), CDSCO, South Zone, Chennai
6. The Dy. Drugs Controller (India), CDSCO, Zonal Office, Hyderabad
7. The Dy. Drugs Controller (India), CDSCO, Zonal Office, Ahmedabad
8. The Dy. Drugs Controller (India), CDSCO, Zonal Office, Bangalore
9. The Asst. Drugs Controller (India), CDSCO, Sub-Zonal Office, Jammu
10. The Asst. Drugs Controller (India), CDSCO, Sub-Zonal Office, Indore
11. The Asst. Drugs Controller (India), CDSCO, Sub-Zonal Office/Port Office, Goa;

Subject: - Drugs reported to be "Not of Standard Quality (NSQ)" of Amiodipine Tablets IP (LOPIN-5 Tablets), Baddi

No.MNT-152913, D/M: Mar/2016, D/E: Feb./2018, Mid. By: M/s Terrace Pharmaceuticals (P) Ltd., 3-B (a), Phase

III, Industrial Area, Sansarpur Terrace-176501, Himachal Pradesh-regarding

Reference:- Test report no LSD/RDTL/0074/17-18 dated: 12.06.2017 issued by Govt. Analyst, RDTL, Chandigarh.

Sir,

With reference to above, the subject sample was drawn by Drugs Inspector of this office under the provision of Drugs & Cosmetics Act 1940. The sample on test/analysis has been declared as "Not of Standard Quality (NSQ)" by Govt. Analyst, Regional Drugs Testing Laboratory, Chandigarh, vide its report no. LSD/RDTL/0074/17-18 dated: 12.06.2017 for the reason that the sample does not conforms to claim as per IP 2014 ADD, 2016 in respect to the related substances.

You are therefore, requested to alert the machinery and Inspector of Drugs under your control on movement of subject batch of Drug and take necessary action if required under intimation to this office.

Yours Faithfully

B.K. Samantary
Deputy Drugs Controller (India)

Encl: Copy of test Report No. LSD/RDTL/0074/17-18 dated: 12.06.2017.

Copy for information and necessary action to:

1. The State Drugs Controller, Licensing cum Controlling Authority, Second floor HIMUDA Complex, Sai Road, Baddi, Himachal Pradesh.
2. Joint Commissioner (Drugs), Food and Drug Administration, Civil Hospital Kharar, Distt. Mohali, Punjab.
3. Drugs Controller-Cum-Licensing Authority, Chandigarh Administration, Homoeopathic Dispensary, Near Police Station, Sector 34, Chandigarh.

FORM 13

(See rule 46)

**CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25 (1) OF THE DRUGS AND COSMETICS ACT, 1940**

1. Name of Inspector from whom received : Minakshi Vashistha, Drugs Inspector (India), CDSCO Baddi,
(Container Corporation of India Ltd, Complex)
Village-Sheetalpur, Tehsil-Baddi, District-Solan
Himachal Pradesh-173205
2. Serial No. and date of Inspector's Memorandum : NZ/CH-SZO/MV18/2016-17/4492 dated : - 29/03/17
3. Number of Sample : LS/MV/CDG/2016/164
4. Date of receipt : 10/04/17
5. Name of drugs purporting to be contained in the sample : Amlodipine Tablets IP (LOPIN-5 TABLETS)

6. Condition of seals on the [packet or on portion of sample or container] : Seals were Intact & Identical to the specimen impressic the seal received from the Drug Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Reg.No	B.No	D/Mfg.	D/Exp.	Mfd. By
LSD/RDTL/0074/17-18	MNT-152913	Mar./2016	Feb./2018	Terrace Pharmaceuticals (P) Ltd, '3-B (a), Phase-III, Industrial Area, Sansarpur Terrace-176 501.

COMPOSITION

: Each uncoated tablet is purported to contains:

Amlodipine Besylate IP
eq. to Amlodipine

5 mg

Result & Protocols

: As per IP 2014 Addendum 2016

: Blue, round, biconvex, uncoated tablet. Packed in blister pack.

: Complies with IP.

: 265.41mg

: *Does not comply with IP.*

Dissolution

: Complies with IP

(Amlodipine Besylate

calculated as Amlodipine)

Uniformity of content

(Amlodipine Besylate

calculated as Amlodipine)

ASSAY

Content of

Amlodipine Besylate

calculated as Amlodipine

: Each uncoated tablet on an average contains:

: Obtained

: 5.23mg

Claim

5.00mg

Obtained

104.60%

Limits

90% to 110%

Protocol

IP 2014

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in the Drug Cosmetics Act, 1940, and Rules there under for the reasons given below :-

The sample does not conforms to claim as per IP 2014 Addendum 2016 in respect to the Related substances.

Dated : - 12/06/17

End Of Report

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GOVERNMENT ANALYST