

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

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

Memo No. DIS-2017/1095

Dated, Chandigarh the:- 18.7.2017

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/NSQD/02/2017-18/1561, 1594-1547 Dated 03.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 : chandigarh@cdsco.nic.in

भारत सरकार

केन्द्रीय औषध मानक नियन्त्रण

संगठन (बढ़ी)

(स्वास्थ्य सेवाओं का महानिदेशालय)

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

आरोग्य केंद्र निगम लिमिटेड

गौतम शीतलपुर, तहसील बदी

जिला सोलन (ही. प्र.)- 173205

Phone no. 01795-247112

Ref No. NZBD-SZO/NSQD/02/2017-18/1561

To,

1561

Dated:

03 JUL 2017

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

Subject: - Testing of Sample No: LS/AP/BAD/2017/61, OFSTAN-OZ, Ofloxacin & Ornidazole Tablets, Batch No. MT170442, D/M: 04/2017, D/E: 03/2019, Manufactured by M/s Medox Lifesciences, Plot No. 222-223, Industrial Area, Phase-III, Sansarpur Terrace HP-176501 declared as "Not of Standard Quality" regarding.

Reference:- Test report no. LSD/RDTL/0250/17-18 dated 20.06.2017 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/0250/17-18 dated 20.06.2017 for the reason that the sample does not conforms to the claim as per Patent & proprietary in respect to the Assay of Ofloxacin (70.71%) & Ornidazole (78.46%).

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/1393/16-17 dated 08.05.2017.

Copy for information and necessary action to:

1. State Drugs Controlling Authority, 2nd Floor, HIMUDA Complex, Phase-I, Baddi, Distt. Solan, Himachal Pradesh.
2. Joint Commissioner (Drug), Food and Drug and Chemical Examine Laboratory, Kharar, Distt. Mohali, Punjab, Punjab.
3. Drugs Controller-Cum-Licensing Authority, Chandigarh Administration, Homeopathic Dispensary, Near Police Station, Sector 34, Chandigarh.

**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: **Arum Kumar Prakash Drugs Inspector (India) CDSCO Sub Zone**
Budh-473205
2. Serial No. and date of Inspector's Memorandum: **NZ/CH SZO/AP/18/2017-18/824 dated - 22.05.17**
3. Number of Sample: **1 SAAP/BAD/2017/61**
4. Date of receipt: **23.05.17**
5. Name of drugs purporting to be contained in the sample: **Ofloxacin and Ornidazole Tablets (OFSTAN-07 TABLETS)**
6. Condition of seals on the [packet or on portion of sample or container]:
Seals were intact & identical to the specimen impression of 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.	D/Mfg.	D/Exp.	Mfd. By
ESD-RD/FL-0250/17-18 MT170472	Apr/2017	Mar/2019	Medox Lifescience
			Plot No 222/223, Phase-III, Ind. Area, Sansarpur Terrace (H.P.)

COMPOSITION

Each film coated tablet is purported to contain:

Ofloxacin IP 200 mg
Ornidazole IP 500 mg

Result & Protocols

Description: Orange elongated biconvex film coated tablet scored on one side. Packed in blister pack

Identification: Positive for Ofloxacin and Ornidazole

Average weight: 100.02 mg

Uniformity of weight: Complies

Disintegration Test: Complies

Each film coated tablet on an average contains:

ASSAY	Claim	Obtained	Limits	Protocol
Content of Ofloxacin	200.00mg	70.71%	90% to 110%	RDTL-SIP-006
Ornidazole	500.00mg	78.46%	90% to 110%	RDTL-SIP-006

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

The sample does not conform to claim as per Patent & Proprietary in respect to the Assay of Ofloxacin, Ornidazole.

Dated: 20/06/17

End Of Report

Page 1 of 1



GOVERNMENT ANALYST
 Dr. Jitendra Kumar Singh
 Regional Government Analyst
 Regional Drugs Testing Laboratory
 G. Lalitpur (P.O. No.) CDSCO (DHS)
 Sector 29, Chandigarh
 Ministry of Health & Family Welfare
 Govt. of India
 Phone: 2733336
 Sector 29-C, Chandigarh-160036

A : cdscobaddi@gmail.com

भारत सरकार

केन्द्रीय औषध मानक नियन्त्रण
समूह (बढ़ी)

(स्वास्थ्य सेवाओं का महानिदेशालय)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
केन्द्रीय कॉर्पोरेशन ऑफ इंडिया बिल्डिंग
गाँव शीतलपुर, तहसील बड़ी
जिला सोलन (एच।पी.)- 173205
दूरभाष. 01795-247112

भारत सरकार



GOVERNMENT OF INDIA

E mail : cdscobaddi@gmail.com
GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
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/NSQD/AB/2017-18/001/545-1547

Dated:

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
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7. The Dy. Drugs Controller (India), CDSCO, Zonal Office, Ahmadabad
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 TRAMAJACK (Tramadol HCl Injection), Batch No.: I-12259, M/D: Sep/2016, D/E: Aug/2018, M/s Jackson Laboratories Pvt. Ltd., Bye Pass, Majitha Road, Amritsar - 143001 - regarding

Reference:- Test report no 32-18/2017-SS/DCA(C)-42/1104 dated: 16.06.2017 issued by Govt. Analyst, CDL, Kolkata.

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, Central Drugs Laboratory, Kolkata vide its report no. 32-18/2017-SS/DCA(C)-42/1104 dated: 16.06.2017 for the reason that the sample does not conform to standard quality for the reason stated under "Assay"

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. Samantaryay)
Deputy Drugs Controller (India)

Encl: Copy of test Report No. 32-18/2017-SS/DCA(C)-42/1104 dated: 16.06.2017.

Copy for information and necessary action to:

1. Sh. Navneet Marwaha, State Drugs Controller, Baddi, Dist. Solan, Himachal Pradesh.
2. Joint Commissioner (Drugs), Food and Drug Administration, Civil Hospital Kharar, Distt. Mohali, Punjab.
3. Drugs Controller-Cum-Licensing Authority, Chandigarh Administration, Homeopathic Dispensary, Near Police Station, Sector 34, Chandigarh.

ਧਾਰਮਿਕ - 13 / FORM NO - 13
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(ਫੋ 45 ਫੋ ਫੋ) / (See Rule 46)