

From

Drugs Inspector  
Chandigarh Administration  
Chandigarh

To

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

Memo No. DIS-2017/ 1749

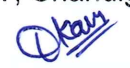
Dated, Chandigarh the:- 25-12-2017

Subject: Drugs Reported to be "Not of Standard Quality" (NSQ)- Regarding.

In reference to the letter received from Dy. Drugs controller, Govt of India, North Zone, Ghaziabd,, Ref. No. NZ/SMP/NSQ/SG/A-039/2016-17/2822-2830 & 2840-56 , on dated 29.12.2016 respectively regarding List of " Not of standard Quality" Drugs-reported communicated. (List enclosed herewith)

You are hereby directed to further inform the Retail & Whole Sale Chemists to not Purchase/Sale of these particular batches of Drugs & if any drugs stock is available them, then immediately inform to this office .

Draft letter placed below for signature please.

  
Drug Inspector  
Chandigarh Administration  
UT, 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 : S.GOPINATH, Drugs Inspector (India), CDSO (North Zone)  
CGO, Building No.1, First Floor,  
Kamla Nehru Nagar  
Ghaziabad, (UP), 201002
2. Serial No. and date of Inspector's Memorandum : NZ/SMP/SG/A/2016-17/2034/16 dated : - 07/09/16
3. Number of Sample : NZ/SMP/SG/A-042/2016-17
4. Date of receipt : 19/09/16
5. Name of drugs purporting to be contained in the sample : Diclofenac Sodium Tablets IP ( FENCO-50 TABLETS )
6. Condition of seals on the : Seals were Intact & Identical to the specimen impression of the seal received from the Drug Inspector  
[packet or on portion of sample or container]
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/0546/16-17 MT16-35 | Mar./2016 | Feb./2018 | Jocund India Limited | 27-30, Sector 6A, Integrated Industrial Estate,<br>Ranipur, Haridwar-249403 (Uttarakhand) |

COMPOSITION : Each film coated tablet is purported to contains:  
Diclofenac Sodium IP 50 mg

Result & Protocols : As per IP 2014

Description : Orange, round, biconvex, film coated tablet. Packed in blister pack.

Identification : Complies with IP.

Average weight : 175.75mg

Uniformity of weight : Complies with IP

Related substances : Not done due to technical reason.

Disintegration Test : Does not comply with IP

ASSAY : Each film coated tablet on an average contains:

| Content of        | Obtained | Claim   | Obtained | Limits      | Protocol |
|-------------------|----------|---------|----------|-------------|----------|
| Diclofenac Sodium | 45.70mg  | 50.00mg | 91.40%   | 90% to 110% | IP 2014  |

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 IP 2014 in respect to the Disintegration Test.

Remarks : As per IP-2014, Diclofenac Sodium Tablets is gastro-resistant.

Dated : - 21/11/16

End Of Report

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GOVERNMENT ANALYST

Dr. S. R. Singh  
Regional Drugs Testing Laboratory  
Ministry of Health & Family Welfare  
Govt. of India  
Sector 39-C, Chandigarh-160035

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 : S.GOPINATH, Drugs Inspector (India), CDSO (North Zone)  
CGO, Building No.1, First Floor,  
Kamla Nehru Nagar  
Ghaziabad, (UP), 201002
2. Serial No. and date of Inspector's Memorandum : NZ/SMP/SG/A/2016-17/2028/16 dated : - 07/09/16
3. Number of Sample : NZ/SMP/SG/A-039/2016-17
4. Date of receipt : 19/09/16
5. Name of drugs purporting to be contained in the sample : Cetirizine Hydrochloride Tablets IP ( CETFAST TABLETS )
6. Condition of seals on the : Seals were Intact & Identical to the specimen impression of  
[packet or on portion of sample or container] 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/0543/16-17 | 150451 | Dec./2015 | Nov./2018 | Syncom Healthcare Limited,<br>D-42, UPSIDC Industrial Area,<br>Selaqui, (Dehradun) 248197 Uttarakhand |

COMPOSITION : Each film coated tablet is purported to contains:  
Cetirizine Hydrochloride IP 10 mg

Result & Protocols : As per IP 2014

Description : White, elongated, biconvex film coated tablet scored on one side packed in blister pack.

Identification : Complies with IP.

Average weight : 170.89mg

Dissolution : (Cetirizine Hydrochloride) : Complies with IP (Limit: NLT 75%)

Related substances : Does not comply with IP

Uniformity of content : (Cetirizine Hydrochloride) : Complies with IP (Limit: 85% to 115%)

ASSAY : Each film coated tablet on an average contains:

| Content of               | Obtained | Claim   | Obtained | Limits      | Protocol |
|--------------------------|----------|---------|----------|-------------|----------|
| Cetirizine Hydrochloride | 9.95mg   | 10.00mg | 99.50%   | 90% to 110% | IP 2014  |

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 conforms to claim as per IP 2014 in respect to the Related substances.

Dated : - 29/11/16

End Of Report  
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GOVERNMENT ANALYST

डॉ. सुरेंद्र सिंह/Dr. R.A. Singh  
राज्यीय दवा परीक्षण/ Govt. Analyst  
क्षेत्रीय दवा परीक्षण प्रयोगशाला  
Regional Drugs Testing Laboratory  
प्लॉट नं. 39, सेक्टर-32, चण्डीगढ़, (HARYANA), CDSO (DRHS)  
स्वास्थ्य एवं परिवार कल्याण विभाग  
Ministry of Health & Family Welfare  
संघ राज्य सरकार/Govt. of India  
फोन नं. - 39 से. चण्डीगढ़ - 160035  
फैक्टर 39-C, Chandigarh-160030