

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

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

Memo No. DIS-2017//329

Dated, Chandigarh the:- 07-2-2017

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-O/NSQD/AB/2017-18/003/2178-2181 Dated 03.Aug.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 to carryout purchase/ sale of these particular batches of these drugs & if any drugs stock is available with them, then immediately inform to this office.


Drugs Inspector
Chandigarh Administration
Chandigarh

ई मेल : cdscobaddi@gmail.com

भारत सरकार

केन्द्रीय औषध मानक नियन्त्रण

संगठन (बर्दी)

(स्वास्थ्य सेवाओं का महानिदेशालय)

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

कंटेनर कॉर्पोरेशन ऑफ इंडिया बिल्डिंग

गॉप शीतलपुर, तहसील बर्दी -

जिला सोलन (एच.पी.)- 173205

दूरभाष: 01795-247112

भारत सरकार



GOVERNMENT OF INDIA

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/2017-18/003/218 218

Dated: 03 AUG 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, 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 Amikacin Sulphate Injection IP 500 mg (2 ml), Batch No. P6D106, D/M: Apr/2016, D/E: Mar/2018, manufactured by M/s Arlon Healthcare, Village Kisharpura, Baddi, Dist. Solan - 174 101, Himachal Pradesh - regarding

Reference:- Test report no 32-18/2017-SS/DCA(BD)-6/2063 dated 18.07.2017 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(BD)-6/2063 dated 18.07.2017 for the reason that the above product does not conforms to IP with respect to the test for "Particulate Matter" and is also not of standard quality for the reason stated under 'Description'.

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. Samantaray)

Deputy Drugs Controller (India)

Encl: Copy of test Report No. 32-18/2017-SS/DCA(BD)-6/2063 dated 18.07.2017.

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.



फॉर्म संख्या - 13 / FORM NO -13
को और 30-8 / CDL-8
(नियम 46 देखें) / (See Rule 46)

औषध अधिनियम, 1940 की धारा 25(1) के अन्तर्गत के विश्लेषक द्वारा जांच या विश्लेषक करने का प्रमाण-पत्र
Certificate of Test or Analysis by Government Analyst under Section 25 (1) of the Drugs Act, 1940

1. विश्लेषक का नाम जिससे प्राप्त हुआ
Name of the Inspector from whom received : Ankur Bansal, Drugs Inspector (I), CDSCO Subzone Baddi, H.P. - 173 205.
2. विश्लेषक के अपने की केम संख्या व तारीख
3. Sample No. : LS/AB/BDI/2017/016
4. Serial No. and date of Inspector's memorandum : NZ/BD-SZO/AB18/2017-18/619 dt 09-05-2017
5. गन्ने की संख्या
उस औषध की नाम जो गन्ने में लिखाई जा रही है
Date of receipt : 22-05-2017
6. Name of drug purporting to be contained in the sample : Amikacin Sulphate Injection I.P. 500 mg - 2 ml,
Batch No. : P6D106, D/M - 04/2016, D/E- 03/2018, M/s Arlon Healthcare Vill. Kishanpura, Baddi, Dist Solan - 174 101 (H.P.).
7. शीट अथवा गन्ने के किसी पर अथवा पैक पर मुहर की स्थिति
Condition of seal on the packet or on portion of sample or container : Intact and identical with Specimen.
औषध अथवा विश्लेषण का परिणाम, बिना याद परखण की प्रामाणिकता से।
Result of test or analysis with protocols of tests applied :
गन्ने लिखा है उस गन्ने निम्नलिखित कारणों से औषध अधिनियम, 1940 और तदनुसार नियमों से उपर्युक्त है।
In the opinion of the undersigned the sample referred to above is not of standard quality as defined in drugs Act, 1940 and rules thereunder for reasons given below:-
Date of testing : 30-05-2017 to 13-06-2017 & 21-06-2017

Method : I.P.

Description	: Colourless liquid containing particles observed on visual inspection by unaided eye, in rubber capped aluminium sealed transparent glass vial.		
Identification	: Gives positive test for Amikacin Sulphate		
pH	: 4.48 (Limit : between 3.5 to 5.5)		
Related substances	: Complies with I.P.		
Bacterial Endotoxins	: Passes the test.		
Particulate matter	: Does not comply with I.P.		
Extractable volume	: Complies with I.P.		
Sterility	: Complies with I.P.		
Assay	Found / 2 ml	Claim/ 2 ml	Limit
Amikacin Sulphate equiv. to Amikacin	470 mg (= 94% of claim)	500 mg	90% to 120% of claim
Remarks	: The sample does not conform to I.P. with respect to the test for "Particulate matter" and is also not of standard quality for the reason stated under "Description".		

संख्या / No. 32-18/2017-SS/DCABD) - 6 / 2063
तारीख / Dated: 18-7-2017

Central Drugs Laboratory,
Government of India,
(Dr. Anjan Pal)

3, Kyd Street, Kolkata-16

1. प्रतिलिपि, औषध विभाग, भारत, भारत में भेजी जा रही है।
Copy to the Drugs Controller General (I), Dte. General of Health Services, FDA Bhawan, Kotla Road, Near Mata Sundari College, I.T.O., New Delhi - 110 011, for information.

(Dr. Anjan Pal)
राज्य औषध विभाग / Government Analyst
Central Drugs Laboratory

Report in red coloured paper indicates the sample is not of standard quality.