

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

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

Memo No. DIS-2017/750

Dated, Chandigarh the:- 25-10-2017

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

In reference to the letter received from Dy. Drugs controller, Govt of India, CDSCO, Baddi, Ref. No. NZ/BD-SZO/MISCnsq/2017-18/1957-1958 , NZ/BD-SZO/NSQ-II/2016-2017/3396 & NZ/BD-SZO/LEGL/AK/NSQ-02/2017-18/2377-2380 on dated 24.jul.2017, 18.Aug.2017 & 19.Jan.2017 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



फार्म संख्या - 13 / FC / M NO - 13
को ओ 8 / DL-8
(नियम 46 देखिये) / (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. निरीक्षक का नाम जिसमें प्राप्त हुआ
Name of the Inspector from whom received : Munish Kakar, Drugs Inspector (I), O/o Asstt. Drugs Controller (I), CDSCO (Sub Zone, Chandigarh), Ground Floor, Sector - 39-C, Opp. Meteorological Department, Chandigarh - 160 036.
2. निरीक्षक के ज्ञापन की क्रम संख्या व तारीख
Serial No. and date of Inspector's memorandum : NZ/CH-SZO/MK18/2016/1897 dt. 03-10-2016
3. नमूने की संख्या
Sample No. : LS/MK/CDG/2016/124
4. प्रति की तारीख
4. Date of receipt : 13-10-2016
5. उस औषध का नाम जो नमूने में भिठाई जानी है
Name of drug purporting to be contained in the sample : Mikascot™ - 500 (Amikacin Injection I.P.), Batch No : V10729, D/M - 06/2016, D/E - 05/2018, M/s. B.M. Pharmaceuticals, Plot No. 47-48, Industrial Area, Phase-II, Chandigarh - 160 002.
6. पैकेट अथवा नमूने के हिस्से पर अथवा पात्र पर मूहर की स्थिति
Condition of seal on the packet or on portion of sample or container : Intact and Identical with Specimen.
7. जांच अथवा विश्लेषण का परिणाम, किये गये परीक्षणों की प्रामाणिकता सहित
Result of test or analysis with protocols of tests applied :
मेरे विचार में उक्त नमूना निम्नलिखित कारणों से औषध अधिनियम, 1940 और तंत्राधीन नियमों में यथापरिभाषित नामक कोटि का है / नहीं है : In the opinion of the undersigned the sample referred to above is / is not of standard quality as defined in drugs Act, 1940 and rules thereunder for reasons given below:-

Dates of testing : 25-10-2016 to 26-10-2016, 08-11-2016 to 22-11-2016

Method : I.P.

Description	: Colourless liquid containing particles visible by unaided eye, supplied in rubber-capped, sealed, transparent glass vial.		
Identification	: Gives positive test for Amikacin Sulphate.		
pH	: 4.43 (Limit : 3.5 to 5.5)		
Related substances	: Complies.		
Bacterial Endotoxins	: Passes the test.		
Particulate matter	: Does not comply.		
Extractable volume	: 2.06 ml (Claim : 2 ml/vial)		
Sterility	: Complies.		
Assay	Found/2 ml	Claim /2 ml	Limit
Amikacin	506.65 mg (= 101.33% of claim)	500 mg	90% to 120% of claim

Reason for declaring the sample as not of standard quality

Remarks : The sample is not of standard quality for reason stated under the test for 'Particulate matter'.

संख्या / No. 32-18/2016-SS/DCA(C) - 27/1829
तारीख / Dated: 19-12-2016

Central Drugs Laboratory
Government of India,
3, Kyd Street, Kolkata-16

(Dr. Subir Kr. Basu)
सरकारी विश्लेषक / Government Analyst

1. प्रतिनिधि, औषध नियंत्रक, भारत, स्वास्थ्य सेवा महामिर्देशालय, नई दिल्ली - 110 011 को सूचनाएं प्रेषित।
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. Subir Kr. Basu)
सरकारी विश्लेषक / Government Analyst
Central Drugs Laboratory

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

ई मेल : cdscoabaddi@gmail.com

भारत सरकार

आयुष्य मानक नियन्त्रण

समाप्त (बढ़ी)

(स्वास्थ्य सेवाओं का महानिदेशालय)

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारतीय कंटेनर निगम लिमिटेड

गांव शीतलपुर, तहसील बदी

जिला सोलन, हिमाचल प्रदेश 173205

Phone no. 01795-247112

भारत सरकार



GOVERNMENT OF INDIA

E mail : cdscoabaddi@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/MISC NSQ/2017-18/

Dated:-

To,

1. Sh. Navneet Marwaha, State Drugs Controller, Baddi, Dist. Solan, Himachal Pradesh.
2. Joint Commissioner-cum- Licensing Authority, Food and Drugs Administration, Drug, Food & Chemical testing laboratory, Kharar, Dist. Mohali, Punjab.
3. Drugs Controller-Cum-Licensing Authority, Chandigarh Administration, Homoeopathic Dispensary, Near Police Station, Sector 34, Chandigarh.

Subject: -Drugs reported to be "Not of Standard Quality" (NSQ) -regarding

This office is recipient of test reports for the below mentioned list of drug products declared as "Not of Standard Quality".

Details of Samples are given below:-

S. No.	Reg. Number	Name of the product	Manufacturer Name	Batch No.	D/M	D/E	Reason for declaring "NSQ"
1	LSD/RDTL/0045/17-18 dated 25/05/2017 issued by the Govt. Analyst, RDTL, Chandigarh.	Ninnumac Tablets (Nimesulide Dispersible Tablets)	M/s Torque Pharmaceuticals Pvt. Ltd., 13B-14, EPIP-1, Jhamajri, baddi, Dist. Solan, H.P.	MB-178A	02/20 17	07/20 19	The sample does not comply with respect to the test for "Uniformity of Dispersion".
2.	13105/2017-18 dated 15/05/2017 issued by the Govt. Analyst, RDTL, Guwahati	Diclofenac Sodium Tablets	M/s Medipol Pharmaceuticals India Pvt. Ltd., 1199/3, Bhud, Dist. Solan, H.P.	TDCS-024	11/20 15	10/20 17	The sample does not comply with respect to the test for "Disintegration".
	RDTL/1511/16-17 dated 23/05/2017 issued by the Govt. Analyst, RDTL, Chandigarh.	MT-Protol XL 50 Tablets (Metoprolol Succinate Extended Release	M/s Preet Remedied PVT. L.TD., 183-186, hpside, Industrial Area, Baddi.	ZPR00 07	06/20 16	05/20 18	The sample does not comply to I.P. Standards with respect to the test for "Dissolution".

10. NZ/BD-SZO/MISCNSO/2017-2018/1457-1459

Dated:-

32-21/2017-SS/DCA(G)-1/590 dated 17/05/2017 issued by the Govt. Analyst, CDL, Kolkata.	Prior Injection (Pantoprazole Injection)	M/s MMG Healthcare, Trilokpur Road, Kolkata Amb. Dist. Simmur, H.P.	GN486 F	06/20 16	11/20 17	The sample does not comply with respect to the test for "Particulate Matter & Clarity of Solution".
32-10/2017-SS/DCA(S)-91/562 dated 16/05/2017 issued by the Govt. Analyst, CDL, Kolkata.	Aciclovir Dispersible Tablets IP 200 mg	M/s Oyster Pharma Pvt. Ltd., Kumharhati, dist. Soaln, H.P.	T- 163678	07/20 16	06/20 18	The sample does not comply with respect to the test for "Uniformity of dispersion, Disintegration & Assay".
32-18/2017-SS/DCA(C)-22/418 dated 04/05/2017 issued by the Govt. Analyst, CDL, Kolkata.	Cebactum 1500 (Ceftriaxone & Sulbactam for Injection) 1. For powder 2. For Sterile Water for Injection	1. M/s Leben Laboratories Pvt. Ltd. At M/s Ziess Pharmaceuticals Pvt. Ltd., Plot NO. 72, EPIP-1, Jhannagiri, baddi, Dist. Solan, H.P. 2. M/s Aculife Healthcare Pvt. Ltd., Sachana, Gujarat, India	1. 132160 20 2. 750411 7	1. 08/20 16 2. 06/20 16	1. 07/20 18 2. 05/20 21	The sample does not comply with respect to the test for "Particulate Matter".
13120/2017-18 dated 17/05/2017 issued by the Govt. Analyst, RDTL, Guwahati	Cipol-250 Tablets	M/s Medipol Pharmaceuticals India Pvt. Ltd., 1199/3, Bhud, Dist. Solan, H.P.	TCOL2 -013	07/20 16	06/20 18	The sample does not comply with respect to the test for "Physical Parameters".
32-11/2017-SS/DCA(A)-67/1105 dated 16/06/2017 issued by the Govt. Analyst, CDL, Kolkata.	Diethylcarbamazine Citrate tablets IP 50 mg	M/s Infinitive Pharmaceutical Industries, plot No. 63, GIDC, industrial Estate, Gujarat	287	07/20 15	06/20 17	The sample does not comply with respect to the tests for "Assay & Description".
32-5/2017-SS/SZE-686/954 dated 07/06/2017 issued by St. Scientific Officer, CDL, Kolkata.	Amitax Injection 100, 2ml (Amitacin Sulphate Injection IP)	M/s Alkem Laboratories Ltd., Central pendam Block, Durgalaka,	613094 8	04/20 16	03/20 18	The sample does not comply to IP Standards with respect to the test for "Particulate Matter and for the reason
2017-SS/SZE-687/055 dated	Amitax 250		613068	03/20	02/20	

4	32-10/2017- SS/DCA(S)-69/1093 dated 16/06/2017 issued by the Govt. Analyst, CDL, Kolkata.	Amirrust-250 (Amikacin Injection IP)	M/s Yeluri Formulations Pvt. Ltd., Sy. No. 296/7/6, I.D.A., Bollaram, Hyderabad - 502325	ZCVA B17001	06/20 16	05/20 18	The sample does not comply to IP Standards with respect to the test for "Particulate Matter and for the reason stated under Description".
15	LS/D/RDTL/0084/17- 18 dated 06/06/2017 issued by the Govt. Analyst, RDTL, Chandigarh.	Pacipik-650 tablets (Paracetamol tablets IP 650 mg)	M/s AARPIK Pharmaceuticals Pvt. Ltd., C1, 306/5, Kerala GIDC, Kerala Ta Bavla Road, Dist. Ahmedabad.	AA- 246	02/20 15	01/20 18	The sample does not comply to the IP Standards with respect to the tests for "Dissolution".
16	32-8/2017- SS/DCA(E)-110/1016 dated 12/06/2017 issued by the Govt. Analyst, CDL, Kolkata.	Tetracet -500 (Tetracycline Capsules IP)	M/s Alco Formulation (India), 14/5, Mathura Road, Faridabad - 121003	TTC 19	03/20 16	02/20 18	The sample does not comply with respect to the tests for "Dissolution".
17	32-10/2017- SS/DCA(S)-47/1088 dated 16/06/2017 issued by the Govt. Analyst, CDL, Kolkata.	Gentamicin Sulphate Injection IP 2 ml	M/s Tannan Tivie Pharma Pvt. Ltd., 56-57, SIDCO Pharmaceutical Complex, Alathur, Tamilnadu	GS630	08/20 16	07/20 18	The sample does not comply to the IP Standards with respect to the tests for "Description & Particulate Matter".
18	32-10/2017- SS/DCA(S)-122/1089 dated 16/06/2017 issued by the Govt. Analyst, CDL, Kolkata.	Amikacin Sulphate Injection IP 100mg -2ml	M/s Nandani Medical Laboratories Pvt. Ltd., 221/5, Bicholi Hapsi, kanadla road, Indore	AK 1663	12/20 16	11/20 18	The sample does not comply to the IP Standards with respect to the tests for "Description & Particulate Matter and Sterility".
19	CDTL-M/FORM- 18/2016-17/365 dated 15/06/2017 issued by the Govt. Analyst, CDTL, Mumbai	Kalcical -500 (Tablets of Vitamin D3 with Elemental calcium)	M/s Viniochem Pharmaceuticals, Indl. Area, maxi Road, Ujjain (M.P.)	1508	01/20 16	06/20 17	The sample does not comply with respect to the tests for "Assay".

Therefore, you are requested to alert the machinery and Inspector of Drugs under your control on the movement of
the movement of further sale/ distribution and take necessary action if required under intimation to this

रत सरकार



GOVERNMENT OF INDIA

The Drug Controller

Diary No. 1608-A

Dated 31/8/17

E mail : cdskobaddi@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

Dated:

मेल : cdskobaddi@gmail.com

रत सरकार

न्द्रीय औषध मानक नियन्त्रण

संगठन (बद्दी)

(स्वास्थ्य सेवाओं का महानिदेशालय)

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

कंटेनर कॉर्पोरेशन ऑफ इंडिया बिल्डिंग

गाँव शीतलपुर, तहसील बद्दी

जिलासोलन(एच।पी.)- 173205

Phone no. 01795-247112

Ref No. NZ/BD-SZO/LEGL/AK/NSQ-02/2017-18

2377-2380

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 CEFKUS- 200 (Cefixime Tablets), Batch No.: TN-8826, M/D: Apr/2017, D/E: Mar/2019, M/s Neptune Life Sciences Pvt Ltd, 100-B, EPIP, Phase II, Baddi, Distt Solan, Himachal Pradesh-173205. -regarding

Reference:- Test report no LSD/RDTL/0309/17-18 dated: 26.07.2017 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/0309/17-18 dated: 26.07.2017 for the reason that the sample does not conform to claim as per Patent & Proprietary in respect to the "Dissolution Test" and "Assay of Cefixime Trihydrate".

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. LSD/RDTL/0309/17-18 dated: 26.07.2017.

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.**