

भारत सरकार
केंद्रीय औषधि मानक नियंत्रण संगठन
राज्यीय स्तर
आयुर्वेद विभाग का महानिदेशालय
आयुर्वेद एवं परिवार कल्याण मंत्रालय
नियंत्रण, निरीक्षण एवं प्रमाणन विभाग
एन.ए. रोड, ग्वाज़िबाद-201002 (उ.प्र.)

Circulated to state
23 JUN 2014
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GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (NORTH ZONE)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
C.G.O. Building No.-1, Kamla Nehru Nagar,
Hapur Road, Ghaziabad-201002. (U.P.)

'E-mail/Speed Post/Fax'

Ref. No NZ/SMP/SKK/A-039/2013-14/ 45/2014

Dated: 16/06/2014
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To
All State Drugs Controllers of North Zone.

Uttar Pradesh Punjab Haryana Rajasthan,
NCT of Delhi, Himachal Pradesh, Chandigarh Admn.,
Jammu & Kashmir and Uttarakhand.

Subject -Test Report of Sample No. NZ/SMP/SKK/A-039/13-14 for Ondot 2 ml Injection (Ondansetron Injection U.S.P 2 ml). Batch No. OND-1015, D/M-09/2012, D/E-08/2014, manufactured by M/s Crystal Pharmaceuticals, 365, Model Town Ambala City-134 003 declared as **Not of Standard Quality**-regarding.

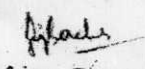
Sir
A sample of Ondot 2 ml Injection (Ondansetron Injection U.S.P 2 ml), Batch No. OND-1015, D/M-09/2012, D/E-08/2014, manufactured by M/s Crystal Pharmaceuticals, 365, Model Town, Ambala City-134 003 was drawn by the Drugs Inspector of this office from the premises of Zonal Hospital Drugs Store, Dharamshala, HP on 23/05/2013. The sample was forwarded to the Central Drugs Laboratory, Kolkata in Form-18 for test/analysis on 28/05/2013.

The subject sample has been declared as **Not of Standard Quality** by the Government Analyst of Central Drugs Laboratory, Kolkata vide report no. 32-1/2013-SS/DCA(N)-40/280, dated 30/05/2014 in Form-13 for the reason that the sample does not confirm to U.S.P with respect to the test of "**Assay of Ondansetron**". (A copy of the test report is enclosed herewith)

You are requested to direct your inspectorate staff to keep strict vigil over movement of the said products in the market.

Encl. As stated above.

Yours faithfully,


(Dr. Ajay Sachan)
Asstt. Drugs Controller (India)
For Deputy Drugs Controller (India)

46/14
Copy to: The Drugs Controller General (I) FDA Bhawan, Kotla Road, New Delhi.

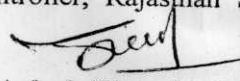
GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN,
TILAK MARG, JAIPUR

No. DC/D-1/General File/2014/359

Dated: 03/07/2014

Copy forwarded to following for information & needful action:-

1. Drugs Controller (II) Hqr. Jaipur
2. All Asstt. Drugs Controller of Rajasthan State.
3. All Drugs Control Officer of Rajasthan State.
4. Incharge Server Room Hqrs; with request to please upload this letter with its enclosures on Departmental website & E-mail to All Asst. Drugs Controller, Rajasthan State. (Enclose:- 01)


(Ashok Bhandari)
Drugs Controller
Rajasthan, Jaipur

फॉर्म संख्या - 13 / FORM NO - 13
के० ओ० प्र०-8 / CDL-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 जिससे प्राप्त हुआ
Name of the Inspector from whom received : Suresh K Kalwaniya, Drugs Inspector (India), CDSCO (North) Zone, C.G.O. Building 1st Floor, Kamala Nehru Nagar, Ghaziabad-201002 (U.P.)
2. निरीक्षक के ज्ञापन की क्रम संख्या व तारीख
Serial No. and date of Inspector's memorandum : NZ/SMP/SKK/A/13-14/646/2013 dt. 28-05-2013
3. नमूने की संख्या
Sample No. : NZ/SMP/SKK/A-039/13-14
4. प्राप्ति की तारीख
4. Date of receipt : 10-06-2013
5. उस औषध का नाम जो नमूने में मिलाई जाना है
Name of drug purporting to be contained in the sample : Ondot. (Ondansetron Injection U.S.P. 2 ml), Batch No : OND-1015, D/M -09/2012, D/E- 08/2014, M/s. Crystal Pharmaceuticals, 365, Model Town, Ambala City - 134 003.
6. पैकेट अथवा नमूने के हिस्से पर अथवा पात्र पर भूहर 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 परिक्षणों 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 तत्राधीन नियमों से द्रव्यापरिमाणित नामक कोठि 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:-
Date of testing : 01-08-2013 to 14-08-2013 & 11-03-2014

Method : U.S.P.

Description	: Clear colourless liquid supplied in sealed amber coloured glass ampoule.		
Particulate matter	: Passes the test.		
Identification	: Gives positive test for Ondansetron Hydrochloride.		
pH	: 3.42 (Limit : between 3.3 & 4.0)		
Extractable volume	: 2.0 ml/ampoule (Claim : 2.0 ml/ampoule)		
Sterility	: Passes the test.		
Bacterial Endotoxins	: Passes the test.		
Assay	Found / ml	Claim / ml	Limit
Ondansetron Hydrochloride equiv. to Ondansetron	1.6265 mg (= 81.325% of claim)	2.0 mg	95.0% to 105.0% of claim

Reason for declaring the sample as not of standard quality

Remarks : The sample does not conform to U.S.P. with respect to the "Assay of Ondansetron".

संख्या / No. 32-1/2013-SS/DCA(N) - 40/280
तारीख / Dated. 30-5-2014

(Sujit Kr. Mallik)

सरकारी विश्लेषक / Government Analyst
Central Drugs Laboratory

1. प्रतिलिपि, औषध नियंत्रक, भारत, स्वास्थ्य सेवा महामिर्देशालय, नई दिल्ली - 110 011 को सुचनार्थ प्रेषित।
Copy to the Drugs Controller General (I), Dte. General of Health Services, FDA Bhawan, Kolla Road, Near Mala Sundari College, I.T.O., New Delhi - 110 002, for information.

(Sujit Kr. Mallik)

सरकारी विश्लेषक / Government Analyst
Central Drugs Laboratory

