

फॉर्म संख्या - 13 / FORM NO. 13
कोओ 70-8 / CDL, B
(नियम 46 देखिये) / (See Rule 46)



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

1. निदेशक का नाम जिससे प्राप्त हुआ
Name of the Inspector from whom received : Bidya Sekhar Mishra, Drugs Inspector, CDSCO, East Zone, Nizam Palace, 1st MSO Building, 234/4, A.J.C. Bose Road, Kolkata - 700 020.
2. निदेशक के ज्ञापन की क्रम संख्या व तारीख
Serial No. and date of Inspector's memorandum : EZ/6-13/BGM/2017/2664 dt. 02-05-2017
3. नमूने की संख्या
- Sample No. : EZ/BSM/ACT/70/2017
4. प्राप्ति की तारीख
4. Date of receipt : 02-05-2017
5. उस औषध का नाम जो नमूने में मिली है
Name of drug purporting to be contained in the sample : Pantoprazole Tablets (I.P. 40 mg, Batch No : PRJT-1001, D/M: 11/2016, D/E: 10/2018, M/s. Wings Biotech, 43 & 44, HP SIDC, Industrial Area, Baddi - 173 205 (H.P.).
6. पैकेट अथवा नमूने के हिस्से पर अथवा भाग पर मुहर 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 प्रमाणिकता सहित
Result of test or analysis with protocols of tests applied :
मेरे हिसाब में उक्त नमूना निम्नलिखित कारणों से औषध अधिनियम, 1940 और तदधीन नियमों से यथापरिभाषित नामक कठि 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 : 12-06-2017, 18-07-2017, 25-07-2017, 28-07-2017

Method : I.P.

Description	: Brick red coloured biconvex round shaped tablets supplied in aluminium foil blister pack.		
Identification	: Gives positive test for Pantoprazole Sodium.		
Dissolution	: Does not comply with I.P.		
Acid Stage	: Average Drug Release - 22.63% of claim (Limit : Not more than 10.0% of claim);		
Buffer Stage	: Average Drugs Release - 85.10% (Limit : Not less than 75.0% of claim)		
Uniformity of weight	: Complies with I.P.		
Assay	Found / tab	Claim / tab	Limit
Pantoprazole Sodium equiv. to Pantoprazole	40.31 mg (= 100.78% of claim)	40 mg	90.0% to 110.0% of claim

Reason for declaring the sample as not of standard quality

Remarks : The sample does not conform to I.P. with respect to Dissolution test.

संख्या / No. 32-8/2017-SS/DCA (E) - 61 / 2973
तारीख / Dated: 22-09-2017

(Joljen Xalxo)
सरकारी विश्लेषक / Government Analyst

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

Central Drugs Laboratory
Government of India,

(Joljen Xalxo)
सरकारी विश्लेषक / Government Analyst
Central Drugs Laboratory

3, Kyd Street, Kolkata-16

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