

Lot: 002054



Wanbury Limited

A-15, MIDC Industrial Area,
Patalganga, Dist. Raigad - 410 220.
Maharashtra, INDIA
Tel. : +91-2192-660200/660222/660229
Fax : +91-2192-660228
Website : www.wanbury.com

Certificate of Analysis

Product : **Metformin Hydrochloride BP/ PhEur /USP**
Batch No. : **MS02410312**
Batch size : 1205.20 kg
Qty. Supplied : 1000 kg
Qty. sampled : 100 g

Mfg. Date : **March-2012**
Exp. Date : **February -2017**
Date of sampling : **March 22, 2012**
Date of analysis : **March 23, 2012**
Mfg.Lic.No. : **KD-242**

Sr. No.	Tests	Observations	Specifications
01.	Appearance	White Crystals	White Crystals
02.	Solubility	Freely soluble in water, slightly soluble in alcohol	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride
03.	Identification A. Melting point B. IR Spectrum	223°C Concordant	222 °C to 226 °C Infrared absorption spectrum of sample should concordant with that of Metformin hydrochloride working standard.
	C. By TLC	Conforms	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution. A pink colour should develop Should be positive
	D. Colour test E. Chloride	Complies Positive	Should be clear and colourless
04.	Appearance of solution (10% solution in water)	Solution is clear and colourless	
05.	Related substances (by HPLC) a) Impurity A (Cyanoguanidine) b) Other impurity c) Total impurities	0.002% 0.036% 0.071%	Not more than 0.02% Not more than 0.10% Not more than 0.3%
06.	Heavy metals	Less than 10 ppm	Not more than 10 ppm
07.	Loss on drying at 105°C for 5 hours	0.18%	Not more than 0.5%
08.	Sulphated ash	0.04%	Not more than 0.1 %
09.	Assay (% on dry basis)	99.6%	98.5% - 101.0%
10.	Residual solvent Methanol Xylene	436 ppm Not detected	Not more than 1000 ppm Not more than 500 ppm
11.	Bulk Density	0.71 g/ml	0.7 g/ml to 0.8 g/ml

Remarks: The product complies with B.P-2011 / PhEur -7th Edition /USP-34/Customer Specification/CEP NO.: R1-CEP 1998-079-Rev. 04
Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Analysed By:

S. K. Dalvi
Analyst

Checked By:

A.D. Gaiwad
Asst. Manager QA/QC

Approved By:

M. G. Narayan
DGM-QA/QC