



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. : BMS0550213 Mfg. Date : February - 2013
Batch Size : 2002.25 kg Exp. Date : January - 2018
Qty. Supplied : 2000.00 kg Date of Sampling : March 26, 2013
Qty. Sampled : 100 g Date of analysis : March 27, 2013
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	223°C	222 °C to 226 °C
	B. IR Spectrum	Concordant	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.
	D. Colour test	Complies	A pink colour should develop
	E. Chlorides	Positive	Should be positive
04.	Appearance of solution (10% solution in water)	Solution is clear and colourless	Should be clear and colourless
05.	Related substances (by HPLC)		
	a) Impurity A (Cyanoguanidine)	0.002%	Not more than 0.02%
	b) Other impurity	0.042%	Not more than 0.1%
	c) Total impurities	0.069%	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	0.20%	Not more than 0.5%
08.	Sulphated ash	0.03%	Not more than 0.1%
09.	Assay (% on dry basis)	99.6%	98.5% - 101.0%
10.	Additional Test		
	Residual Solvent		
	Methanol	278 ppm	NMT 1000 ppm
	Xylene	Not detected	NMT 600 ppm

Remarks: Product Complies with B.P-2011 / PhEur -7th Edition /USP-33/Customer Specifications/COS NO.: RI-CEP 1998-079-Rev. 04

Declaration: Product is free from animal derived materials and is manufactured from synthetic sources only.

Analysed By:

Checked By :

Approved By:

S. K. Dalvi
28.03.13
S. K. Dalvi
Analyst

K. V. Gunjal
28.03.13
K. V. Gunjal
Asst. Manager QC

A. D. Gailwad
28/03/2013
A. D. Gailwad
Asst. Manager QA/QC