

Lot: 0100113

Wanbury Limited

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Certificate of Analysis

Product : Metformin Hydrochloride BP/ PhEur/USP
Batch No. : BMS1210911
Batch Size : 2002.28 kg
Qty. Supplied : 2000 kg
Qty. Sampled : 100 g
Mfg. Date : September-2011
Exp. Date : August -2016
Date of Sampling : September 19, 2011
Date of analysis : September 21, 2011
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.
	D. Colour test E. Chlorides	Complies Positive	A pink colour should develop 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) b) Other impurity c) Total impurities	0.005% 0.044% 0.086%	Not more than 0.02% Not more than 0.1% 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	0.04%	Not more than 0.1 %
09.	Assay (% on dry basis)	99.6%	98.5% - 101.0%
10.	Additional Test Residual Solvent Methanol Xylene	249 ppm Not detected	NMT 1000 ppm NMT 500 ppm

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

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

Analysed By:

Checked By:

Approved By:

S. K. Dalvi
Analyst

A.D. Gaikwad
Asst. Manager QA/QC

M. G. Narayan
DGM-QA/QC

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