Lot 8080714 - 1,000 Kg.

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WANBURY

Certificate of Analysis

Product	**: Metformin Hydrochloride BP/ PhEur /USP**		
Batch No.	: ME01370614	**Mfg. Date**	: June – 2014
Qty. Supplied	: 1000 kg	**Exp. Date**	: May – 2019
Customer Name	: R2 PHARMA	**Mfg.Lic.No.**	: KD-242

Sr. No.	Tests	Observations	Specifications
01.	Appearance	White Crystals	White Crystals
	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
02.	Identification		
	B. IR Spectrum	Concordant	Infrared absorption spectrum of sample should concordant with that of Metformin hydrochloride working standard.
	E. Chloride	Positive	Should be positive
03.	Appearance of solution (10% solution in water)	Solution is clear and colourless	Should be clear and colourless
04.	Impurity F	0.044%	Not more than 0.05% w/w
05.	Related substances (by HPLC) a) Impurity A b) Impurity B c) Unspecified impurities d) Total other impurities	 BQL 0.017% 0.010% 0.043%	 Not more than 0.02% w/w Not more than 0.05% w/w Not more than 0.05% w/w Not more than 0.2%
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	0.03%	Not more than 0.1 %
09.	Assay (% on dry basis)	99.4%	98.5% - 101.0% w/w
10.	Residual solvent a) Methanol b) Xylene	 364 ppm BDL	 Not more than 1000 ppm Not more than 500 ppm
11.	Bulk Density	0.74 g/ml	0.7 g/ml to 0.8 g/ml

Remarks: Product Complies with B.P-2011 / PhEur –8th Edition /USP-35/Customer Specifications/COS NO.: R1-CEP 1998-079-Rev. 06

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

Prepared By:	Checked By:	Approved By:
Executive / Officer Date: 27-06-2014	Manager QC Date: 27/06/14	Asst. Manager QA Date: 27-06-2014