

Lot: 00909,4 - 500 kg.

# Wanbury Limited

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## Certificate of Analysis

Product	: Metformin Hydrochloride BP/ PhEur /USP		
Batch No.	: ME01380614		
Qty. Supplied	: 1000 kg	Mfg. Date	: June - 2014
Customer Name	: R2 PHARMA	Exp. Date	: May - 2019
		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	0.038%	
05.	Related substances (by HPLC)		Not more than 0.05% w/w
	a) Impurity A	BQL	
	b) Impurity B	0.017%	Not more than 0.02% w/w
	c) Unspecified impurities	BQL	Not more than 0.05% w/w
	d) Total other impurities	0.043%	Not more than 0.05% w/w
06.	Heavy metals	Less than 10 ppm	Not more than 0.2%
07.	Loss on drying at 105°C for 5 hours	0.21%	Not more than 10 ppm
08.	Sulphated ash	0.04%	Not more than 0.5 %
09.	Assay (% on dry basis)	99.6%	Not more than 0.1 %
10.	Residual solvent		98.5% - 101.0% w/w
	a) Methanol	277 ppm	
	b) Xylene	BDL	Not more than 1000 ppm
11.	Bulk Density	0.73 g/ml	Not more than 500 ppm
			0.7 g/ml to 0.8 g/ml

Remarks: Product Complies with B.P-2011 / PhEur -8<sup>th</sup> 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:  Executive / Officer Date: 27-06-2014	Checked By:  Manager QC Date: 27/06/14	Approved By:  Asst. Manager QA Date: 27-06-2014
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