

# G. AMPHRAY LABORATORIES

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## CERTIFICATE OF ANALYSIS

Product	: METFORMIN HYDROCHLORIDE BP/EP (Fine Powder)		
Batch No.	: MJ-1280308	A.R. No.	: MTF/148/2008
Date of Mfg.	: March, 2008.	Batch Size	: 1000 KGS
Exp. Date	: February, 2013.	Date of Analysis	: 07.03.2008

### RESULTS OF ANALYSIS

TESTS	OBSERVATIONS	SPECIFICATIONS
Characters	White Fine Powder.	White Fine Powder.
Solubility	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.	Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
Identification		
A. Melting Point	224 ° C	222 ° C to 226 ° C.
B. IR	Positive	Concordant with ref. Spectrum obtained with Metformin HCL CRS.
C. By TLC	Conforms	Conforms to standard.
D. Colouration with $\alpha$ - naphthol	Complies	Pink Colouration.
E. Reaction of Chlorides	Positive	Positive.
Appearance of Solution	Solution S is clear and colourless.	Solution S ( 2 g in 20 ml water ) should be clear and colourless.
Related Substances ( By HPLC )		
A. Cyanoguanidine	0.004 %	Not more than 0.02 %.
B. Other Impurity	0.039 %	Not more than 0.10 %.
Heavy Metals	Less than 10 ppm.	Not more than 10 ppm.
Loss on Drying	0.22 %	Not more than 0.5 %.
Sulphated Ash	0.05 %	Not more than 0.1 %.
Assay on dry basis	99.42 %	Between 98.5 % and 101 % of C <sub>4</sub> H <sub>12</sub> CIN <sub>5</sub> .
Additional Test		
Particle Size	98.61 % passing through 100 mesh.	Not less than 95 % passing through 100 mesh.

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

REPORT: THE PRODUCT COMPLIES AS PER B.P.-2004 / E.P. 2005 SPECIFICATIONS.

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AUTHORISED SIGNATORY