

G. AMPHRAY LABORATORIES

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CERTIFICATE OF ANALYSIS

Product	: PYRAZINAMIDE BP / USP / EP	A. R. No.	: PZ/045/2008
Batch No.	: PZ / 20080144	Exp. Date	: December, 2012
Date of Mfg.	: January, 2008		
Batch Size	: 600 KGS		

RESULTS OF ANALYSIS

TEST	OBSERVATIONS	STANDARDS
Characters : Description	White Crystalline Powder.	White Crystalline Powder.
Solubility	Complies.	Sparingly soluble in water, slightly soluble in alcohol and methylene chloride, very slightly soluble in ether.
Identification : C. IR Spectrum	Complies.	Concordant with reference standard spectra.
Other Tests : Appearance of Solution Acidity & Alkalinity Related Substances Heavy Metals Water Sulphated Ash Assay (On Anhydrous Basis)	Complies Complies No Secondary spot is observed. Less than 10 ppm. 0.05 % 0.05 % 99.80 %	Solution S is clear & colourless. Final Solution is red. Not More Than 0.2 % Not More Than 10 ppm. Not More Than 0.5 % Not More Than 0.1 % 99.1 % & 100.5 %
Additional Tests : Sieve retention on 200 μ Sieve retention on 1000 μ	0.16 % NIL	Not more than 3.0 %. Not more than 0.5 %.
Bulk Density	0.63 gm/ml	Not less than 0.4 & not more than 0.72 gm/ml

NO SOLVENT MENTIONED UNDER ICH Q 3C GUIDELINES ARE USED. WATER IS THE ONLY SOLVENT USED FOR MANUFACTURING PYRAZINAMIDE.

REMARK: MATERIAL COMPLIES AS PER BP 2004, U.S.P. 28 & EP – 2005.

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AUTHORISED SIGNATORY