UNIQUE CHEMICALS

(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot no.5, Phase IV, GIDC Industrial Estate, PANOLI (GUJARAT) INDIA.

CERTIFICATE OF ANALYSIS

QUALITY CONTROL DEPARTMENT

Name of the Product	: **Nifedipine EP**		
Name of Manufacturer	: Unique Chemicals, Panoli		
Batch No.	: **PNFD120033**	A.R. No.	: 09FP12001089
Manufacturing Date	: Jun-2012	Expiry Date	: May-2017
		Release Date	: 11/09/2012

TESTS	RESULTS	STANDARD
Appearance	Yellow crystalline powder.	Yellow crystalline powder.
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol.	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol.
Identification: By Infrared spectrum	The Infrared Spectrum of sample is concordant with the spectrum obtained from Nifedipine working standard.	The Infrared Spectrum of sample should concordant with the spectrum obtained from Nifedipine working standard.
Impurity D and other basic Impurities	0.07 mL	Not more than 0.48 mL of 0.1 M Perchloric acid is required for 4 gm (0.14 %).
Related substances (By HPLC): A: Impurity A B: Impurity B C: Any other Individual impurity D: Total impurities	 0.01% 0.01% 0.02% 0.05%	 A: Not more than 0.1 % B: Not more than 0.1 % C: Not more than 0.10 % D: Not more than 0.3 %
Loss on drying	0.15% w/w	Not more than 0.5 % w/w
Sulphated Ash	0.07% w/w	Not more than 0.1 % w/w
Assay (On dried basis)	99.8% w/w	98.0 %w/w to 102.0 % w/w
Additional tests:		
Residual solvent : - Methanol (By GC-HSS) -Acetic acid (By LOD)	 463 ppm Complies	 Not more than 3000 ppm Not more than 5000 ppm
Particle size (Sympatec dry powder)	100 % < 55.0 µm	100 % < 180 µm

OPINION: The above sample complies with prescribed standards of quality as per EP & the requirements of certificate of suitability number R1-CEP 2000-096-Rev 04.

Prepared By / Date	Checked By / Date	Approved By / Date
14-09-12	14.09.12	14/9/12