

UNIQUE CHEMICALS

(A Division of J. B. Chemicals & Pharmaceuticals Ltd.)

Plot no.5, Phase IV, GIDC Industrial Area, Panoli-394116. (GUJARAT) INDIA.

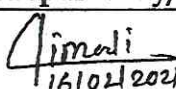
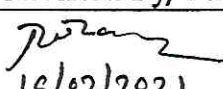
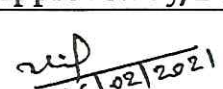
QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Name of the Product	: Nifedipine EP		
Name of the Manufacturer	: UNIQUE CHEMICALS, PANOLI.		
Batch No.	: PNFD100062	A.R.No.	: 09FP21000393
Date of manufacturing	: Oct-2020	Expiry Date	: Sep-2025
		Release Date	: 14/02/2021

TESTS	RESULTS	SPECIFICATION
Appearance	A yellow crystalline powder.	A 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 A: By Infrared spectrum	A: Infrared absorption maxima in the spectrum obtained with the substance corresponds in position and relative size to those in the spectrum obtained with the Nifedipine working standard.	A: Infrared absorption maxima in the spectrum obtained with the substance being examined correspond in position and relative size to those in the spectrum obtained with Nifedipine working standard.
Impurity D and other basic impurities	0.04 mL	Not more than 0.48 ml of 0.1M Perchloric acid is required for 4 g (0.14%)
Related substances (By HPLC): A: Impurity A B: Impurity B C: Any individual impurity D: Total impurities	0.01 % Below Detection Limit (LOD=0.001%) 0.01 % 0.02 %	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	0.17 % 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)	100.0 % w/w	98.0 % w/w to 102.0 %w/w
Additional tests		
Residual solvent : - Methanol (By GC-HSS) - Acetic acid (By Loss on drying)	413 ppm Complies	Not more than 3000 ppm Not more than 5000 ppm
Particle size (by Malvern Mastersizer 3000-wet method)	D(10) : 8.4 µm D(50) : 38.9 µm D(90) : 108 µm	D(10) : Not more than 20µm D(50) : 25 µm to 60 µm D(90) : 60 µm to 130 µm

Note: LOD= Limit of Detection.

OPINION: The above sample complies with the prescribed standard 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
 16/02/2021	 16/02/2021	 16/02/2021
Vimal Modi (Asst. Manager QC)	Rohan Rana (Manager QC)	Alpesh Patel (Head QC)