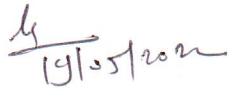

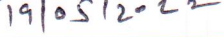


# Ipca Laboratories Limited

## QUALITY ASSURANCE DEPARTMENT

### CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur		Control No. : FP/00119/21	
Batch No. : 21019NFD1RA		Date of Analysis : 31/07/2021	
Mfg Date : JUL.2021		Analysed As per : Ph.Eur	
Re-Test Date : JUN.2024		Specification No : TS/BPC/NFD/CS/COS	
Batch Size : 457.000 Kg		Date of Report : 19/05/2022	
Qty.for Dispatch : 2.000 Kg			
Sr.No	TEST	RESULTS	LIMITS
1.	Description Appearance	Yellow crystalline powder	Yellow crystalline powder.
	Solubility	Complies	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol
2.	Identification		
	By IR Spectrum	Complies	Infrared Absorption spectrum of sample and standard are concordant.
3.	Impurity D and other basic impurities	0.08-ml	Not more than 0.48 ml of 0.1 M Perchloric acid is required (0.14%)
4.	Related substances (by HPLC)		
	Impurity A	ND	Not more than 0.10%
	Impurity B	ND	Not more than 0.10%
	Impurity C	Not detected	Not more than 0.10%
	Any Unspecified impurity	0.01 %	Not more than 0.10%
	Total impurities	0.04 %	Not more than 0.30%
5.	Loss on drying ( at 105°C for 2 h)	0.20 %w/w	Not more than 0.5% w/w
6.	Sulphated Ash	0.06 % w/w	Not more than 0.1% w/w
7.	Assay	99.3 % w/w	98.0% to 102.0% of C <sub>17</sub> H <sub>18</sub> N <sub>2</sub> O <sub>6</sub> ( On dried substance)
8.	Residual Solvent Methanol	1042 ppm	Not more than 3000 ppm
9.	2-Nitrobenzaldehyde content	< 2.1 ppm	Not more than 8 ppm
Remarks: Conforms to Ph.Eur Specification TS/BPC/NFD/CS/COS			
Analyst 		Approved by  Pinal Shah Manager Q.C. 	

Reviewed By QA

Sign / Date.....

Ipca Laboratories Ltd.

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