Ipca Laboratories Limited

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur
Batch No. : 20022NFD1RA
Mfg Date : SEP.2020
Re-Test Date : AUG.2023
Batch Size : 437.900 Kg
Qty.for Dispatch : 5.00 Kg

Control No. : NFD1-R/QA/052/20
Date of Analysis : 26/09/2020
Analysed As per : Ph.Eur
Specification No : TS/BPC/NFD/CS/COS
Date of Report : 10/05/2022

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	Not detected	Not more than 0.10%
	Impurity B	<0.01%	Not more than 0.10%
	Impurity C	Not detected	Not more than 0.10%
	Any Unspecified impurity	0.02%	Not more than 0.10%
	Total impurities	0.05%	Not more than 0.30%
5.	Loss on drying (at 105°C for 2 h)	0.23 %w/w	Not more than 0.5% w/w
6.	Sulphated Ash	0.07 % w/w	Not more than 0.1% w/w
7	Assay	100.1 % w/w	98.0% to 102.0% of $C_{17}H_{18}N_2O_6$ (On dried substance)
8	Residual Solvent Methanol	579 ppm	Not more than 3000 ppm
9	2-Nitrobenzaldehyde content	3.0 ppm	Not more than 8 ppm

Remarks: Conforms to Ph.Eur Specification TS/BPC/NFD/CS/COS

Analyst 10/05/2022

Approved by
Pinal Shah
Manager Q.C. 10/05/2022

Reviewed By QA
Sign / Date 10/05/2022

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