Since 1949 Dipharma

Certificate of analysis

Manufacturing site
Dipharma Francis S.r.l.
Via Bissone 5
20021 Baranzate MI
Italy
+39 02 382281

QA Approved
11.04.2022

Code
500907

Ref. DDT.

Ref. Order

Batch Nr.	2202563
Mfg. date	25.01.2022
Retest date	24.01.2027
Analysis nr.	40000054250

Product

NIFEDIPINE MICRONIZED

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	Yellow crystalline powder. Is affected by exposure to light.	EP/USP	Conform to description
Identification : IR Spectrum	-	Conform	EP/USP	Conform
Identification : HPLC	-	Conform	USP	Conform
Loss on drying	%	max 0,5	EP/USP	0,0
Sulphated Ash	%	max 0,1	EP/USP	0,0
Chlorides (n.m.t. 0.02%)	-	Conform	USP	Conform
Sulphate (n.m.t. 0.05%)	-	Conform	USP	Conform
Impurity D and other impurities basic	%	max 0,14	EP/USP	0,01
Nitrophenylpyridine Analog (HPLC)	%	max 0,1	EP	< 0,0
Nitrosophenylpyridine Analog (HPLC)	%	max 0,1	EP	0,0
Each impurity (HPLC)	%	max 0,10	EP	0,02
Total impurities (HPLC)	%	max 0,3	EP	0,0
Assay (potentiometric)	%	98,0 - 102,0	EP	100,2
Assay (HPLC)	%	98,0 - 102,0	USP	100,1
Methanol (GC)	µg/g	max 1500	Company	< 30
Bulk density	g/ml	0,1 - 0,3	Company	0,2
Particle size Malvern D(90)	µm	max 30	Company	7

Elemental impurities: none of the elemental impurity reported in ICHQ3D is likely to be present

Name and Surname: MICHELA RAMPI
Title: Quality Control
Approved
Date: 05.04.2022 19:07:32

Name and Surname: MARTINA RUBES
Title: Quality Assurance
Approved
Date: 11.04.2022 10:00:50