Since 1949
Dipharma

DIPHARMA FRANCIS S.r.l.

Certificate of analysis

Manufacturing site
DIPHARMA FRANCIS S.r.l.
Via Bissone 5
20021 Baranzate MI
Italy

Issued
16.11.2010

Code
500317

Ref. DDT.

Ref. Order

Batch Nr. 0910458
Mfg. date 21.09.2009
Release date 25.09.2009
Retest date 20.09.2014
Analysis nr. 40000030171

Buyer

End User

Product

NIFEDIPINE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Appearance	-	Yellow crystalline powder Is affected by exposure to light.	EP/USP	Conform to description
Identification: melting range	-	Positive	EP	Positive
Identification : IR Spectrum	-	Positive	EP/USP	Positive
Identification by HPLC	-	Positive	USP	Positive
Heavy Metals	%	max 0,001	USP	< 0,001
Loss on drying	%	max 0,5	EP/USP	0,0
Sulphated Ash	%	max 0,1	EP/USP	0,0
Melting range (lower limit)	°C	min 171	EP/USP	174
Melting range (upper limit)	°C	max 175	EP/USP	175
Chlorides (n.m.t. 0.02%)	-	Conform	USP	Conform
Sulphate (n.m.t. 0.05%)	-	Conform	USP	Conform
Impurity D and other basic impurities	%	max 0,14	EP/USP	0,01
Nitrophenylpyridine Analog (HPLC)	%	max 0,1	EP	0,1
Nitrosophenylpyridine Analog (HPLC)	%	max 0,1	EP	0,0
Each impurity (HPLC)	%	max 0,10	EP	0,03
Total Impurities (HPLC)	%	max 0,3	EP	0,1
Assay (potentiometric)	%	98,0 - 102,0	EP	99,9
Assay (HPLC)	%	98,0 - 102,0	USP	99,0
Methanol (GC)	µg/g	max 1500	Company	677