

Lot: 0121219



CERTIFICATE OF ANALYSIS

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Product: CLONIDINE HYCDROCHLORIDE Ph.Eur	
Batch No. : 1902010738	Insp. Lot No. : 890000025986
Mfg. Date : 07.10.2019	Retest Date : 06.10.2023
Batch Size : 4.460 KG	Release Date : 02.11.2019

No.	TEST	OBSERVATION	SPECIFICATION
1	Appearance	White crystalline powder	White or almost white, crystalline powder
2	Solubility	Complies	Soluble in water and in anhydrous ethanol
3	Identification IR Chloride test	Comparable Complies	IR absorption spectrum of test sample should be concordant with that of Clonidine hydrochloride standard. A curdy white precipitate is formed which is insoluble in nitric acid but is soluble in a slight excess of 6N Ammonium hydroxide
4	Loss on Drying	0.23 %W/W	Not more than 0.50% w/w
5	Sulphated ash	0.05 %W/W	Not more than 0.10% w/w
6	Appearance of solution	Complies	Solution should be clear and not more intensely colored than reference solution Y7
7	pH	4.72	4.0 to 5.0
8	Related Substances (By HPLC) Unspecified Impurities Total Impurities	Below disregard limit Below disregard limit	Not more than 0.10% w/w Not more than 0.20% w/w
9	Assay by chemical(On dried basis)	100.6 %W/W	98.5% w/w to 101.0% w/w

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ALEMBIC PHARMACEUTICALS LIMITED API UNIT-I, PANELAV

CIN No. : L24230GJ2010PLC061123

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No.	TEST	OBSERVATION	SPECIFICATION
10	Residual solvents(By GC) Dichloromethane Methanol Isopropyl alcohol	BQL(<16ppm) 59 ppm 43 ppm	Not more than 300ppm Not more than 2000ppm Not more than 2000ppm
11	Ethylene Diamine content by HPLC	BQL(<6ppm)	Not more than 250ppm

Additional Notes:

S.O.No.: 22014670

Storage Conditions:

Keep the container tightly closed (Drug substance does not require any special storage condition).

Remarks - The Batch Complies as per Specification No. - API/30000360/EU

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