

## Certificate of Analysis

0060224

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Name of Product: Clonidine Hydrochloride Ph.Eur.	
Product Code: 30000360	Quantity / Batch size: 44.6 kg
Batch No: 2302034445	Insp. Lot No./A.R.No.: FP/A1/23/2272
S.O.No.: 22026868	Stage: API
Mfg. Date: 27/10/2023	Release date: 04/11/2023
Retest Date: 25/10/2028	

No.	Test	Result	Specification
1	Appearance	White crystalline powder	White or almost white, crystalline powder
2	Solubility	Soluble in water and in anhydrous ethanol	Soluble in water and in anhydrous ethanol
3	Identification A. IR  B. Chloride Test	IR absorption spectrum of test sample is 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	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 (At 105°C for 3 hours)	0.19 % w/w	NMT 0.50% w/w
5	Sulfated Ash	0.08 % w/w	NMT 0.10% w/w

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CIN-L24230GJ2010PLC061123

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No.	Test	Result	Specification
6	Appearance of solution	Solution S is clear and less intensely coloured than reference solution Y7	Solution S should be clear and not more intensely coloured than reference solution Y7
7	pH	4.37	4.0 to 5.0
8	Related Substances (By HPLC ) Unspecified Impurities Total Impurities	BQL (LOQ 0.021 %)  Below quantification limit	NMT 0.10% w/w  NMT 0.20% w/w
9	Assay (By Chemical)	100.4 % w/w	98.5% w/w to 101.0% w/w (on dried basis)
10	Residual Solvent Dichloromethane  Methanol  Isopropyl alcohol	BQL ( LOQ 16 ppm )  BQL ( LOQ 48 ppm )  89 ppm	NMT 300 ppm  NMT 2000 ppm  NMT 2000 ppm

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No.	Test	Result	Specification
11	Ethylene Diamine (By HPLC)	BQL (LOQ 6 ppm)	NMT 250 ppm

**Remark:** Batch complies as per Specification No.-A1\SPC\API\00099-1.0

**Note:** Storage Conditions: Keep the container tightly closed (Drug substance does not require any special storage condition).

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