

Hetero Labs Limited (Unit-I)



Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Sangareddy District Telangana, INDIA

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CERTIFICATE OF ANALYSIS

Product	: HYDRALAZINE HYDROCHLORIDE	Reference STP No.	: HH-005-07
Batch No.	: HH18030045	Reference	: Ph.Eur
Dt. of Manufacture	: March, 2018	Batch Qty	: 102.98 Kg
Retest Date	: February, 2023	Dt. of Analysis	: 12/04/2018
Analytical Report No.	: HL01FP18000806	Status	: Initial Certification

S.No.	Test	Specifications	Results	Reference
1.0	Description	A white or almost white crystalline powder.	Almost white crystalline powder	Visual inspection
2.0	Solubility	Soluble in Water, Slightly soluble in alcohol.	Complies	Visual inspection Ph.Eur 1.4
3.0	**Melting temperature	Between 265.0°C and 275.0°C.	273.2°C	Ph.Eur 2.2.14
4.0	Identification by	The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Hydralazine Hydrochloride Working Standard.	Matches with Working Standard	Ph.Eur 2.2.24
	4.1) Infrared absorption			
	4.2) Test for Chlorides	It gives reaction of chlorides.	Complies	Ph.Eur 2.3.1
5.0	Appearance of solution	The solution is clear and not more intensely coloured than reference solution GY ₆ .	Complies	Ph.Eur 2.2.1 Ph.Eur 2.2.2 (Method II)
6.0	pH(2% w/v solution in water)	Between 3.5 and 4.2	3.6	Ph.Eur 2.2.3
7.0	Related substances by HPLC	1-Phthalazinone : Not more than 0.15% (LOQ:0.01%) # Impurity-01 1-Chlorophthalazine : Not more than 0.15% (LOQ:0.01%) # Impurity-02 2- Formylbenzoic acid : Not more than 0.15% (LOQ:0.01%) # Impurity-03 Phthalazine : Not more than 0.15% (LOQ:0.01%) Maximum Single Unknown impurity : Not more than 0.10% (LOQ:0.01%) Total impurities : Not more than 1.0%	Not detected Not detected Not detected Not detected 0.05% 0.10%	Ph.Eur 2.2.29 (In-House)

* No potential for any Class 1 solvents as specified by ICH to be present in the Hydralazine Hydrochloride, as they are not used in the manufacturing process. The material, if tested for these impurities, will comply with the established standards.

In-House Impurities ** In-House test

The product CONFORMS to above specifications.

Compiled by : *[Signature]* Checked by : *[Signature]* Authorised Signatory : *[Signature]*

Date : 12/04/18 Date : 12/04/18 Date : 12/04/18