SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel:+ 91 4023191337
URL: http//www.symedlabs.com, CIN: U24231TG1998PLC029961

Quality Assurance * Symed Labs Ltd. Unit-II * 01/06/21

Certificate of Analysis

Product	: **HYDROXYZINE HYDROCHLORIDE**	Reference	: USP
Batch No.	: 2HH0110521	Batch Quantity	: 252.90 Kg
Date of Manufacture	: May'- 2021	Date of analysis	: 01/06/2021
Expiry date	: Apr'- 2026	A.R. No.	: 02FP21000818
Storage conditions	: Preserve in tight containers, Store at Controlled room temperature. Protect from light.		

S.No.	Test	Specifications	Results
*1.	Description	A white odorless powder.	A white odorless powder
*2.	Solubility	Very soluble in water, soluble in chloroform, slightly soluble in acetone and practically insoluble in ether.	Complies
**3.	Melting Range	Between 199.0°C and 205.0° C with decomposition.	Decomposition at 203.1°C
4.	Identification by	A)IR : The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wave numbers as that of a similar preparation of Hydroxyzine Hydrochloride working standard.	Matches with the spectrum of standard
		*B) UV: Absorptivities at 230 nm calculated on anhydrous basis should not differ by more than 3.0% between working standard and test sample.	Complies
		C) Test for chlorides: Positive test for chlorides.	Complies
		D) UHPLC: The retention time of the major peak in the chromatogram of test solution corresponds to that in the chromatogram of the standard solution as obtained in the Assay.	Matches with the retention time of standard
5.	Water content	Not more than 5.0 %w/w	1.4%w/w
**6.	Residue on ignition	Not more than 0.50 %w/w	0.03%w/w
7.	Organic impurities by UHPLC	Decloxizine :Not more than 0.30%	Not detected (LOQ=0.0305%)
		Hydroxyzine Related Compound-A:Not more than 0.30%	Not detected (LOQ=0.0112%)
		4-Chlorobenzophenone :Not more than 0.20%	Not detected (LOQ=0.0038%)
		Any individual unspecified impurity: Not more than 0.20%	Not detected
		Total impurities: Not more than 0.75%	Nil

Corp. Office: 8-2-293/174/3,Beside BN Reddy colony, Road No.14, Banjara Hills, Hyderabad-34 Telangana, INDIA.Tel: +91 40 23635000,Fax: +91 40 23549428

SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel:+ 91 4023191337
URL: http//www.symedlabs.com, CIN: U24231TG1998PLC029961

Certificate of Analysis

Product	:	HYDROXYZINE HYDROCHLORIDE	Reference	:	USP
Batch No.	:	2HH0110521	Batch Quantity	:	252.90 Kg
Date of Manufacture	:	May'- 2021	Date of analysis	:	01/06/2021
Expiry date	:	Apr'- 2026	A.R. No.	:	02FP21000818
Storage conditions	:	Preserve in tight containers, Store at Controlled room temperature. Protect from light.			

S.No.	Test	Specifications	Results
8.	Assay by UHPLC (on anhydrous basis)	Between 98.0% w/w and 102.0% w/w	99.6%w/w
*9.	Residual solvents by GC	Methanol - Not more than 500 ppm	Not detected (LOQ=150 ppm)
		Acetone - Not more than 500 ppm	Not detected (LOQ=33 ppm)
		Isopropyl alcohol - Not more than 500 ppm	Not detected (LOQ=63 ppm)
		Toluene - Not more than 100 ppm	Not detected (LOQ=36 ppm
*10.	Particle Size	Not more than 10% of the material should retain on 40 mesh	0.2%
*11.	Bulk density and Tapped density	Bulk Density : Between 0.20 and 0.40 g/mL	0.26 g/mL
		Tapped Density : Between 0.40 and 0.70 g/mL	0.48 g/mL
#12.	AMC content by LC-MS	Not more than 3.75 ppm	Not tested

The product **conforms** to the above specifications.
*In House tests.
**In House specifications.
LOQ = Limit of Quantitation.
#Test should be performed for every 10th batch or 1st batch per year, whichever is more frequent.

Approved Signatory (QC)
Name : V.Mukesh
Designation: Sr.Chemist
Date 02.06.21

Authorized signatory (QA)
Name : A.Koushik Kumar
Designation: Sr.Supervisor
Date 02/06/2021

Corp. Office: 8-2-293/174/3,Beside BN Reddy colony, Road No.14, Banjara Hills, Hyderabad-34 Telangana, INDIA.Tel: +91 40 23635000,Fax: +91 40 23549428