



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	BIPERIDEN HYDROCHLORIDE USP 40	CAS No:	1235-82-1
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A White practically odorless crystalline powder	Complies
2	Solubility	Slightly soluble in water. in ether, alcohol and in chloroform, sparingly soluble in methanol	Complies
3	Identification by -IR	Matching with working standard.	Complies
4	Identification by -UV	Absorptivity at 257nm, calculated ODB do not differ by More than 3.0%	Complies
5	Identification by - Color of solution	Meets the requirement	Complies
6	Identification by - Chemical test	Meets the requirement	Complies
7	Identification by - Test for chlorides	It responds to the test of chlorides	Complies
8	Loss on Drying	NMT 0.50% w/w	0.20%
9	Ordinary impurities by TLC (%)	NMT 2.0%	BDL
10	Organic Volatile Impurities (Residual Solvents) Isopropyl alcohol	< 5000 ppm	85 ppm
11	Organic Volatile Impurities (Residual Solvents) Dichloromethane	< 600 ppm	Not Detected
12	Organic Volatile Impurities (Residual Solvents) N-Hexane	< 290 ppm	32 ppm
13	Organic Volatile Impurities (Residual Solvents) Tetrahydrofuran	< 720 ppm	Not Detected
14	Organic Volatile Impurities (Residual Solvents) 1,4 Dioxane	< 380 ppm	Not Detected
15	Organic Volatile Impurities (Residual Solvents) Toluene	< 890 ppm	Not Detected
16	Assay by Titration ODB (% w/w)	NLT 98.0% and NMT 101.0%	99.80% w/w

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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