

Format No. T/QC/177-F1-R1

January 29, 2026

CERTIFICATE OF ANALYSIS
HALOPERIDOL USP

Batch No.	: HAL3002520	Date of Receipt	: 24.01.2026
Date of Mfg.	: DEC 2025	Date of Exp. / Retest	: NOV 2030
Analytical Ref. No.	: FP/HAL/26/0008	Specification No.	: RPG/T/1300569/R-5
Date of Release	: 29.01.2026	Grade	: USP
Batch Size	: 107.800 kg	Dispatch Quantity	: 30.000 kg

SR. NO.	TESTS	SPECIFICATIONS	OBSERVATIONS	REMARKS
1.	Description	White to faintly yellowish, amorphous or microcrystalline powder. Its saturated solution is neutral to litmus.	White, amorphous powder. Its saturated solution is neutral to litmus.	Complies
2.	Solubility	Practically insoluble in water, soluble in chloroform, sparingly soluble in alcohol and slightly soluble in ether.	Practically insoluble in water, soluble in chloroform, sparingly soluble in alcohol and slightly soluble in ether.	Complies
3.	Identification A. By IR	The Infra-red spectrum of test sample should conform to that of the working standard.	Complies	Complies
	B. By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the test for organic impurities.	Complies	Complies
4.	Loss on drying (% w/w) (Dry at 60°C under vacuum for 3 hours)	Not more than 0.50%	0.22%	Complies
5.	Residue on ignition (% w/w)	Not more than 0.10%	0.05%	Complies

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6.	Organic impurities (%w/w, on as is basis) (By HPLC) ➤ Haloperidol related compound A ➤ Haloperidol related compound B ➤ Any other impurity ➤ Total impurities	Not more than 0.20% Not more than 0.30% Not more than 0.10% Not more than 0.50%	BDL 0.10% BDL 0.10%	Complies Complies Complies Complies
7.	Assay (%w/w, on dried basis) (By HPLC)	Not less than 98.0% and not more than 102.0%	99.4%	Complies
8.	Residual solvents (ppm) (By HSGC) ➤ Methanol ➤ Dichloromethane ➤ Ethyl acetate ➤ Benzene ➤ Toluene	Not more than 100 ppm Not more than 100 ppm Not more than 800 ppm Not more than 2 ppm Not more than 400 ppm	2 ppm BDL 94 ppm BDL BDL	Complies Complies Complies Complies Complies
9.	Particle Size	D (10) For information only D (50) For information only D (90) For information only	D10 = 11.4 µm D50 = 79.1 µm D90 = 180 µm	For information only
10.	Melting range	150.0°C-153.0°C	151.0°C-151.2°C	Complies

BDL-BELOW DETECTION LIMIT

STORAGE : PRESERVE IN TIGHT, LIGHT RESISTANT CONTAINERS AND STORE AT TEMPERATURE BELOW 30°C.

Remarks: The material conforms / ~~does not conform~~ to above specifications.

Prepared By	Checked By	Approved By
		
Date : 29/01/2026	Date : 29/01/2026	Date : 29/01/2026
Mr. Chandrashekhar Chaurasia Sr. Executive- QC	Mr. Maruti Kamble Sr. Manager - QC	Mr. Kamlesh Kore Head Quality - API

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