

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

June 17, 2021

**CERTIFICATE OF ANALYSIS**

**Lt: 0090721**

**HALOPERIDOL Pharm Eur.**

Batch No.	:	HAL3002112	Date of Receipt	:	14.05.2021
Date of Mfg.	:	MAY 2021	Date of Exp. / Retest	:	APR 2026
Analytical Ref. no.	:	FP/HAL/21/0042	Specification No.	:	RPG/T/1300019/CEP-1/R-5
Date of Release	:	25.05.2021	Grade	:	Pharm Eur.
Batch Size	:	107.700 kg	Dispatch Quantity	:	1.000 kg

SR.NO.	TESTS	SPECIFICATIONS	OBSERVATION	REMARKS
1.	Description	White or almost white powder.	White powder.	Complies
2.	Solubility	Practically insoluble in water, slightly soluble in ethanol (96%), in methanol and in methylene chloride.	Practically insoluble in water, slightly soluble in ethanol (96%), in methanol and in methylene chloride.	Complies
3.	Identification	A. Melting range 150.0°C-153.0°C B. Infra-red spectrum concordant with standard reference spectra. C. The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a). D. A violet colour is produced and becomes brownish-red after 20min. E. Reaction of chloride positive.	150.8°C-152.2°C Complies Complies Complies	Complies Complies Complies
4.	Appearance of solution (1% w/v solution in 1% v/v lactic acid)	The solution is clear and not more Intensely coloured than reference solution Y <sub>7</sub> .	A clear solution and less intense coloured than reference solution Y <sub>7</sub> .	Complies

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SR.NO.	TESTS	SPECIFICATIONS	OBSERVATION	REMARKS
5.	Related substances by HPLC (% w/w)			
	Impurity B	Not more than 0.30%	0.08%	Complies
	Impurity D	Not more than 0.50%	BDL	Complies
	Impurity G	Not more than 0.15 %	BDL	Complies
	Impurity H	Not more than 0.15 %	BDL	Complies
	Unspecified impurity	Not more than 0.10 %	BDL	Complies
	Total impurities	Not more than 1.00%	0.08%	Complies
6.	Loss on drying at 105°C (% w/w)	Not more than 0.50%	0.24%	Complies
7.	Sulphated ash (% w/w)	Not more than 0.10%	0.04%	Complies
8.	Assay (Titrimetry) (% w/w)	99.0% to 101.0% on dried basis.	99.9%	Complies
<b>ADDITIONAL TESTS</b>				
9.	Residual solvents (By GC)			
	➤ Ethyl acetate	Not more than 800 ppm	172 ppm	Complies
	➤ Methanol	Not more than 100 ppm	2 ppm	Complies
	➤ Dichloromethane	Not more than 100 ppm	BDL	Complies
	➤ Toluene	Not more than 400 ppm	BDL	Complies
	➤ Benzene	Not more than 2 ppm	BDL	Complies

BDL-Below Detection Limit

**STORAGE:** STORE PROTECTED FROM LIGHT AND STORE AT TEMPERATURE BELOW 30°C.

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

Prepared By	Checked By	Approved By
<i>ASA</i> Date : 17/06/2024	<i>[Signature]</i> Date : 17/06/2024	<i>[Signature]</i> Date : 17/06/2024
Mrs. Ashwini Abhyankar Executive- QC	Mr. Maruti Kamble Manager - QC	Mr. Kamlesh Kore Head Quality-API

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