

July 20, 2024

CERTIFICATE OF ANALYSIS

HALOPERIDOL Pharm Eur.

Batch No.	:	HAL3002417	Date of Receipt	:	13.07.2024
Date of Mfg.	:	JUL 2024	Date of Exp. / Retest	:	JUN 2029
Analytical Ref. no.	:	FP/HAL/24/0061	Specification No.	:	RPG/T/1300019/CEP-1/R-5
Date of Release	:	20.07.2024	Grade	:	Pharm Eur.
Batch Size	:	107.600 kg	Dispatch Quantity	:	1.000 kg

SR.NO.	TESTS	SPECIFICATIONS	OBSERVATION	REMARKS
1.	Appearance	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	150.8°C-151.9°C	Complies
		B. Infra-red spectrum concordant with standard reference spectra.	Complies	Complies
		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).	Complies	Complies
		D. A violet colour is produced and becomes brownish-red after 20min.	Complies	Complies
		E. Reaction of chloride positive.	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 ₇ .	A clear solution and less intense coloured than reference solution Y ₇ .	Complies

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


Grade : Pharm Eur.

SR.NO.	TESTS	SPECIFICATIONS	OBSERVATION	REMARKS
5.	Related substances by HPLC (% w/w)			
	Impurity B	Not more than 0.30%	0.06%	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%	0.06%	Complies
6.	Loss on drying at 105°C (% w/w)	Not more than 0.50%	0.20%	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.	99.7%	Complies
ADDITIONAL TESTS				
9.	Residual solvents (By GC)			
	➤ Ethyl acetate	Not more than 800 ppm	70 ppm	Complies
	➤ Methanol	Not more than 100 ppm	BDL	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
 Date : 20/07/2024	 Date : 20/07/2024	 Date : 20/07/2024
Mrs. Kumudini Varma Executive- QC	Mr. Maruti Kamble Sr. Manager - QC	Mr. Kamlesh Kore Head Quality-API

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