



CERTIFICATE OF ANALYSIS

NAME OF PRODUCT : HALOPERIDOL-EP

BATCH NO. : HP-0170824 (NM)

Mfg Date : 08/2024

BATCH SIZE : 120.100 Kg

Exp Date : 07/2029

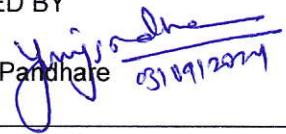
A.R.NUMBER : AR/FP/HP/021/24

Mfg Lic. No. : PD/29

Sr. No.	TEST	OBSERVATION	SPECIFICATION
01.	Appearance	A white powder.	White or almost white powder.
02.	Solubility	Complies	Practically insoluble in water, slightly soluble in ethanol (96 per cent) in methanol and in methylene chloride.
03.	Identification by		
	A) Melting point	152.4	150°C to 153°C
	B) I.R.	Complies	The Infrared absorption spectrum of the sample should be concordant with the IR spectrum obtained from Haloperidol WS.
	C) TLC	Complies	Should comply as per EP
	D) Colour Test	Complies	A violet colour is produced and becomes brownish-red after 20 min.
	E) Chloride Test	Complies	The solution gives reaction (a) of chlorides
04.	Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution Y ₇ .
05.	Related substances by HPLC	0.11 0.03 Not detected Not detected 0.04 0.29	Impurity D: Not more than 0.5 % Impurity B: Not more than 0.3 % Impurity G: Not more than 0.15 % Impurity H: Not more than 0.15 % Unspecified impurities: Not more than 0.10% Total : Not more than: 1.0 %
06.	Loss on drying	0.21	Maximum 0.5 %
07.	Sulfated ash	0.02	Maximum 0.1 %
08.	Assay by chemical	100.0	99.0 % to 101.0 % (dried substances)
09.	Residual Solvents by GCHS	803 Not detected Not detected	Méthanol : NMT 3000 ppm Toluene : NMT 890 ppm Methylene dichloride : NMT 600 ppm

STORAGE: Store in well closed container and Protected from light.

RESULT : The above product result complies as per EP 11.0 specification.

PREPARED BY Date: Mr. Sandeep Upase Dy. Manager-QC	 03/09/2024	CHECKED BY Date: Mr. C.N.Watare GM-QC	 03/09/2024	APPROVED BY Date: Mr. Yuvraj Pandhare GM-QA	 03/09/2024
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