

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	HPDOL Injection	A.R. No.	NL/FP/25/146
Generic Name	Haloperidol Injection IP 1ml	Sampled qty.	45 Ampoules
Batch No.	A25146A	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	31/07/2025
Mfg. Date	07/2025	Date of Testing	31/07/2025
Exp. Date	06/2027	Date of Release	16/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber colour glass ampoule.	A clear colourless solution filled in amber colour glass ampoule.
2.	Identification by IR By UV	A. Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with haloperidol IPRS or with the reference spectrum of haloperidol. B. When examined in the range 230nm to 360nm, the final solution obtained in the Assay shows an absorption maximum only at about 245nm.	Complies 0.349
3.	Nominal fill volume	NLT 1ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	2.8 to 3.6	3.12
6.	Related Substance	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution (a) and not more than one such spot is more intense than the spot in the chromatogram obtained with reference solution (b).	Complies
7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can see with naked eye.	7/Ampoule 0/Ampoule Complies
8.	Bacterial Endotoxins	NMT 71.4 EU/mg of Haloperidol.	Less than 71.4 EU/mg of Haloperidol

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: NIKHIL SHARMA

Approved by

NAME: MRS. SWATIDHAWAN

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9.	Sterility	No microbial growth should be observed.	Complies		
10.	Assay: (By UV) Each ml contains:				
Ingredients		Labeled claim	Found	% of labeled amount	Limits % of labeled amount
Haloperidol IP		5 mg	5.134 mg	102.68%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/BP/USP/IHS.

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NAME: MRS. SWATI DHAWAN

