



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

:

Certificate of Analysis Finished Product

Product Name	HPDOL Injection	A.R. No.	ARN/FP/25/103
Generic Name	Haloperidol Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2597A	Sampled by	Aakash
Batch Size	2,00,000 Ampoules	Sampled on	07/03/2026
Mfg. Date	01/2026	Date of Testing	08/03/2026
Exp. Date	12/2027	Date of Release	22/03/2026

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 Complies
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	3.32
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 is free from particles of foreign matter particles that can be observed on visual inspection.	0/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: SHAHRUKH KHAN

Checked by

NAME: SUFIYAN ANSARI

Qualification : M.Sc. Clinical Microbiology

Registra Approved by

NAME: MRS. SWATI DHAWAN

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9.	Sterility	No microbial growth should be observed.			Complies
10.	Assay: Each ml contains:				
Ingredients		Labeled claim	Found	% of labeled amount	Limits % of labeled amount
Haloperidol	IP	5.00 mg	4.85938 mg	97.19%	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/HS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. 835593

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