



VELLINTON HEALTHCARE
Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product Name	: HPDOL DEPOT 50 Haloperidol Injection BP 50 mg/ml		
Batch No.	: GA25L-51A	Mfg. Date	: 12/2025
Batch Size	: 10116 Ampoules	Exp. Date	: 11/2027
Sample Qty.	: 75 Ampoules	Analytical Report No	: AFP20250763
Date of Receiving	: 22/12/2025	Date of Completion	: 05/01/2026
Spec No	: FP/HPD/SPC/001	STP No	: FP/HPD/STP/001

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 1 ml amber colour glass ampoule.	Clear colourless liquid solution filled in 1 ml amber colour glass ampoule.		
2.	Identification				
	By HPLC	The retention time of the major peak of the sample solution should be corresponds to that of the standard solution, as obtained in the Assay.	Complies		
	Uniformity of filled volume	Not less than nominal volume	Min: 1.0 ml Max: 1.1 ml		
4.	Average fill volume	Not less than 1 ml	1.05 ml		
5.	pH	Between (3.0 to 3.80)	3.35		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule		
7.	Sterility	Should be Sterile	Sterile		
8.	Bacterial Endotoxins	NMT 71.40 USP Eu/mg of haloperidol	Less than 71.40 USP Eu/mg		
9.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Haloperidol BP		50 mg	52.73 mg	105.46 %	90.0% to 110%

Remarks: In the opinion of the undersigned the sample submitted complies/~~does not~~ complies with the prescribed standard/ not standard of quality, as according to USP & IHS with respect to the above test only.

Name	Prepared By	Checked By	Approved By
Designation	Manisha Sr. Officer (QC)	Anuj Kumar Asst. Manager (QC)	Yashwant Singh Manager (QC)
Sign/ Date			

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