



**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

Product Name : HPDOL DEPOT 50 Haloperidol Injection BP 50 mg/ml	
Batch No. : GA26B-79A	Mfg. Date : 02/2026
Batch Size : 10003 Ampoules	Exp. Date : 01/2028
Sample Qty. : 75 Ampoules	Analytical Report No : AFP20260117
Date of Receiving : 27/02/2026	Date of Completion : 13/03/2026
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		
3.	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 BP Eu/mg of haloperidol	Less than 71.40 BP Eu/mg		
9.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Haloperidol BP		50 mg	49.34 mg	98.68 %	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 BP & IHS with respect to the above test only.

	Prepared By Manisha	Checked By Anuj Kumar	Approved By Yashwant Singh
Name	Sr. Officer (QC)	Asst. Manager (QC)	Head QC
Designation			Kala Amb
Sign/ Date	<i>[Signature]</i> 13/03/2026	<i>[Signature]</i> 13/03/2026	<i>[Signature]</i> 13/03/2026

