

TAMMAN TITOE



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco Pharmaceutical Complex,
Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product
(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/ FG/341/24-25

Report Date: 23-10-2024

Name of the product : HP DOL Injection 1ml
Generic Name : Haloperidol Injection I.P
Batch No. : HP407
Batch Size : 155000
Mfg. Date. : OCT-2024
Exp. Date. : SEP -2027
Quantity of Sample : 100 Nos
Date of Sampling : 08-10-2024
Date of Commencement of analysis : 08-10-2024
Date of Completion of analysis : 22-10-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification:		
A.(By IR)	The infrared absorption spectrum of sample is concordant with infrared absorption spectrum of haloperidol RS.	Complies to IP specification
B.UV –Absorbance.	Assay shows an absorption Maximum onlyat about 245nm	Complies to IP specification
pH	2.8 to 3.6	3.17
Extractable Volume	NLT- 1.0ml / Ampoule	1.1 ml
Particulate matter	No visible particles	No visible particles
Related Substances(by T.L.C)	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with refrence solution(a)and not more than one such spot is morethan the spot in the chromatogram obtained with refrence solution.(b)	Complies to IP specification
Bacterial endotoxins	NMT 71.4 EU/ml of Haloperidol.	LT 71.4 EU/ml
Sterility	To comply as per IP	complies
Assay	4.5 mg to 5.5 mg	5.07mg
Each ml contains : Haloperidol I.P 5mg	(90.0 % - 110.%)	(101.40%)

OBSERVATION: In the opinion of the undersigned the sample referred to above is of **Standard Quality** / ~~Not Standard Quality~~ as in the act and the rules made there under for the reason give below.

REMARKS : COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIEDOUT.

Analysed By:
Date: 23/10/2024

Checked By:
Date: 23/10/2024

Person In Charge of Testing
Date: 23/10/24

