



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/643/23-24  
Report Date: 20-02-2024

Name of the product :HP DOL Injection 1ml  
Generic Name : Haloperidol injection IP  
Batch No. : HP402  
Batch Size : 104000  
Mfg. Date. : Feb-2024  
Exp. Date. : Jan-2027  
Quantity of Sample :100 Nos  
Date of Sampling :05-02-2024  
Date of Commencement of analysis :05-02-2024  
Date of Completion of analysis : 19-02-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification: A.(By IR ) B.UV –Absorbance.	The infrared absorption spectrum of sample is concordant with infrared absorption spectrum of haloperidol RS. Assay shows an absorption Maximum onlyat about 245nm	Complies to IP specification Complies to IP specification
pH	2.8 to 3.6	3.28
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	Complies to IP specification
Sterility	To comply as per IP	Comply as per IP
Assay Each ml contains : Haloperidol I.P 5mg	4.5 mg to 5.5 mg (90.0 % - 110.%)	4.956mg (99.12 % )

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: *L. H. S.*  
Date: 20/02/2024

Checked By: *V. B.*  
Date: 20.2.24

Person In Charge of Testing  
Date: *20/2/24*