



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/314/24-25

Report Date: 29-09-2024

Name of the product : SPASMOCAN Injection 1ml  
Generic Name : Hyoscine Butylbromide Injection I.P.  
Batch No. : HB407  
Batch Size : 104000  
Mfg. Date. : SEP-2024  
Exp. Date. : AUG-2027  
Quantity of Sample : 100 Nos  
Date of Sampling : 14-09-2024  
Date of Commencement of analysis : 14-09-2024  
Date of Completion of analysis : 28-09-2024

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 Hyoscine butylbromide IPRS.	Complies to IP specification
B.UV-Absorption:	Maxima at about 252nm, 257nm, 264nm	Complies to IP specification
C. Colour reaction.	A violet colour is produced.	Complies to IP specification
pH	3.7 to 5.5	5.14
Extractable Volume	NLT- 1.0ml/ Ampoule	1.1 ml
Particulate matter	No visible particles	Complies
Bacterial endotoxins	NMT 8.75 EU/mg of Hyoscine butyl bromide	LT8.75 EU/mg
Sterility Test	To comply as per IP	Complies
Assay		
Each ml contains: Hyoscine	18.5mg to 21.5 mg	20.27mg
Butylbromide I.P 20mg	(92.50 % - 107.50%)	(101.35%)

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 given below.

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

Analysed By: *BT*  
Date: 29/09/2024

Checked By: *SM*  
Date: 29/09/2024

Person In Charge of Testing  
Date: 29/09/24