

**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/225/24-25**  
**Report Date: 12-08-2024**

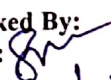
Name of the product : SPASMOCAN Injection 1ml  
Generic Name : Hyoscine Butylbromide Injection I.P.  
Batch No. : HB406  
Batch Size : 100000  
Mfg. Date. : JULY-2024  
Exp. Date. : JUN-2027  
Quantity of Sample :100 Nos  
Date of Sampling :29-07-2024  
Date of Commencement of analysis :29-07-2024  
Date of Completion of analysis :12-08-2024

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	4.96
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	20.04mg
Butylbromide I.P 20mg	(92.50 % - 107.50%)	(100.20%)


**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 CARRIEDOUT.

Analysed By:   
Date: 12/08/2024

Checked By:   
Date: 12/08/2024



Person In Charge of Testing:   
Date: 12/8/24