



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/482/24-25

Report Date: 30-12-2024

Name of the product : SPASMOCAN Injection 1ml
Generic Name : Hyoscine Butylbromide Injection I.P.
Batch No. : HB408
Batch Size : 155000
Mfg. Date. : DEC-2024
Exp. Date. : NOV-2027
Quantity of Sample : 100 Nos
Date of Sampling : 14-12-2024
Date of Commencement of analysis : 14-12-2024
Date of Completion of analysis : 29-12-2024

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	4.92
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	20.37mg
Butylbromide I.P 20mg	(92.50 % - 107.50%)	(101.85%)

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: 30/12/2024

Checked By:
Date: 30/12/2024

Person In Charge of Testing
Date: 30/12/2024

