

TAMMAN TITOE

PREVENTION AND CURE

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/116/24-25
Report Date: 08-06-2024


Name of the product : SPASMOCAN Injection 1ml
Generic Name : Hyoscine Butylbromide Injection I.P.
Batch No. : HB404
Batch Size : 104000
Mfg. Date. : May-2024
Exp. Date. : Apr-2027
Quantity of Sample : 100 Nos
Date of Sampling : 24-05-2024
Date of Commencement of analysis : 24-05-2024
Date of Completion of analysis : 07-06-2024

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:	Maximam 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	5.05
Extractable Volume	NLT- 1.0ml/ Ampoule	1.1 ml
Particulate matter	No visible particles	No visible particles
Bacterial endotoxins	NMT 8.75 Eu/mg of Hyoscine butyl bromide	Complies to IP specification
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 CARRIEDOUT.

Analysed By: 
Date: 08/06/24

Checked By: 
Date: 8/6/24

Person In Charge of Testing
Date: 8/6/24

