



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/380/24-25

Report Date: 10-11-2024

Name of the product :DELPHYLLIN Injection 2ml
Generic Name :Etofylline and Theophylline Injection
Batch No. : ET414
Batch Size : 155000
Mfg. Date. : OCT-2024
Exp. Date. : SEP-2027
Quantity of Sample :100 Nos
Date of Sampling :26-10-2024
Date of Commencement of analysis :26-10-2024
Date of Completion of analysis : 09-11-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A Clear,colourless to Greenish liquid.	A Clear,colourless liquid
Identification: A.For Etofylline B.For Theophylline	The Yellow-red colour of the residue changes to red-violet. A white crystalline precipitate is produced.	Complies to IP specification
pH	4.00 to 6.00 (As per I.H.S)	5.39
Extractable Volume	NLT - 2.0ml/ Ampoule	2.1ml
Particulate matter	No visible particles	No visible particles
Sterility Test	Should be absent	complies
Assay Each ml contains: Etofylline I.P 84.7mg Theophylline(Anhydrous) I.P 25.3mg	(90% to 110%) 84.70mg (76.23mg to 93.17mg) 25.30mg (22.77mg to 27.83mg)	85.27mg (100.67%) 25.37mg (100.28%)

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 LABEL CLAIM/ IHS WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By: *L. H. S.*
Date: 10/11/2024

Checked By: *S. S.*
Date: 10/11/2024

Person In Charge of Testing
Date: 11/11/24

