


TAMMAN TITOE 	Tamman Titoe Pharma Pvt Ltd 56-57, Sidco Pharmaceutical Complex, Alathur-603 110, Tamilnadu.
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QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No:TT/ FG/630/24-25

Report Date: 28-03-2025

Name of the product	:DELPHYLLIN Injection 2ml
Generic Name	:Etofylline and Theophylline Injection
Batch No.	: ET505
Batch Size	: 155000
Mfg. Date.	: MAR-2025
Exp. Date.	: FEB-2028
Quantity of Sample	:100 Nos
Date of Sampling	:12-03-2025
Date of Commencement of analysis	:12-03-2025
Date of Completion of analysis	: 27-03-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A Clear,colourless to Greenish liquid.	A Clear,colourless liquid
Identification: A.For Etofylline B.For Theophylline	TheYellow-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)	4.81
Extractable Volume	NLT - 2.0ml/ Ampoule	2.1ml
Particulate matter	No visible particles	Complies
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)	 87.28mg (103.05%) 25.39mg (100.36%)

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:

Date:

28/03/25

Checked By:

Date:

28/03/25

Person In Charge of Testing

Date:

28/03/25
