

	<p>Tamman Titoe Pharma Pvt Ltd 56-57, Sidco Pharmaceutical Complex, Alathur-603 110, Tamilnadu.</p>
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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/190/24-25
Report Date: 22-07-2024

Name of the product	: DELPHYLLIN Injection 2ml
Generic Name	: Etofylline and Theophylline Injection
Batch No.	: ET410
Batch Size	: 100000
Mfg. Date.	: July-2024
Exp. Date.	: June-2027
Quantity of Sample	: 100 Nos
Date of Sampling	: 07-07-2024
Date of Commencement of analysis	: 07-07-2024
Date of Completion of analysis	: 21-07-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A Clear, colourless to Greenish liquid.	A Clear, colourless to Greenish 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)	5.08
Extractable Volume	NLT - 2.0ml/ Ampoule	2.1ml
Particulate matter	No visible particles	Complies
Sterility Test	Should be absent	Complies
Assay Each ml contains:	(90% to 110%)	
Etofylline I.P 84.7mg	84.70mg (76.23mg to 93.17mg)	85.31mg (100.72%)
Theophylline (Anhydrous) I.P 25.3mg	25.30mg (22.77mg to 27.83mg)	25.25mg (99.80%)

OBSERVATION: In the opinion of the undersigned the sample referred to above is of ~~Standard Quality~~ **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: *[Signature]*
 Date: 22/07/2024

Checked By: *[Signature]*
 Date: 22/07/2024

Person In Charge of Testing
 Date: 22/7/24
