

Pace

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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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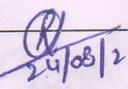
Certificate of Analysis Finished Product

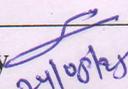
Product Name	Delphyllin Injection	A.R. No.	NL/FP/25/156
Generic Name	Etophylline & Theophylline Injection 2ml	Sampled qty.	45 Ampoules
Batch No.	A25093A	Sampled by	Rakesh
Batch Size	99,200 Ampoules	Sampled on	09/08/2025
Mfg. Date	06/2025	Date of Testing	09/08/2025
Exp. Date	05/2027	Date of Release	24/08/2025

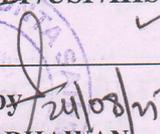
S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber colour ampoule.	A clear colourless solution filled in amber colour ampoule.
2.	Identification	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	Complies
3.	Nominal fill volume	NLT 2ml	2.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	7.50 to 8.50	8.39
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	48/Ampoule 2/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Etophylline	84.7 mg	81.8677 mg	96.66%	90.0% to 110.0%
Theophylline IP Eq. to Anhydrous Theophylline	25.3 mg	25.3006 mg	100.00%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not complies~~ as per IP/BP/USP/IHS.

Analysis by 
NAME: RAMANJEET SINGH

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN