

Pace

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Pace Biotech

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

Title

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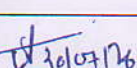
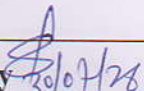
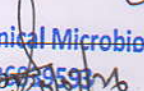
Certificate of Analysis Finished Product

Product Name	DELPHYLLIN Injection	A.R. No.	NL/FP/26/132
Generic Name	Etophylline & Theophylline Injection 2ml	Sampled qty.	45 Ampoules
Batch No.	A26097A	Sampled by	Rakesh
Batch Size	98,690 Ampoules	Sampled on	15/07/2026
Mfg. Date	06/2026	Date of Testing	16/07/2026
Exp. Date	05/2028	Date of Release	30/07/2026

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	8.16
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.	37/Ampoule 0/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	84.70 mg	86.21978 mg	101.79%	90.0% to 110.0%
Theophylline IP Eq. to Anhydrous Theophylline	25.30 mg	25.55126 mg	100.99%	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: FIROJ KHAN	Checked by  NAME: SURJEET KAUR	Approved by  NAME: MRS. SWATI DHAWAN
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