

**Pace**

Add Pace To Health

**Pace Biotech**

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

Title

:

Certificate of Analysis Finished Product

|              |                                          |                 |              |
|--------------|------------------------------------------|-----------------|--------------|
| Product Name | DELPHYLLIN Injection                     | A.R. No.        | NL/FP/26/133 |
| Generic Name | Etophylline & Theophylline Injection 2ml | Sampled qty.    | 45 Ampoules  |
| Batch No.    | A26098A                                  | Sampled by      | Rakesh       |
| Batch Size   | 98,,480 Ampoules                         | Sampled on      | 16/07/2026   |
| Mfg. Date    | 06/2026                                  | Date of Testing | 17/07/2026   |
| Exp. Date    | 05/2028                                  | Date of Release | 31/07/2026   |

| 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                                                                                                                                                                                                     | 8.08                                                        |
| 6.     | Particulate Matter<br>(A.) Light Obscuration<br>Particle Count Test<br>(1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$<br>(B.) Visual Particle | NMT 6000/Ampoule<br>NMT 600/Ampoule<br>The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection. | 94/Ampoule<br>2/Ampoule<br>Complies                         |
| 7.     | Sterility                                                                                                                                                                 | No microbial growth should be observed.                                                                                                                                                                          | Complies                                                    |
| 8.     | Assay: (By HPLC)<br>Each ml contains:                                                                                                                                     |                                                                                                                                                                                                                  |                                                             |

| Ingredients                                      | Labelled Claim | Found       | % of labelled amount | Limits % of labelled amount |
|--------------------------------------------------|----------------|-------------|----------------------|-----------------------------|
| Etophylline                                      | 84.70 mg       | 85.71115 mg | 101.19%              | 90.0% to 110.0%             |
| Theophylline IP<br>Eq. to Anhydrous Theophylline | 25.30 mg       | 25.40267 mg | 100.41%              | 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.

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Qualification: M.Sc. Clinical Microbiology  
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