



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Delphyllin	A.R. No.	FG/G/25A2138
Generic Name	Etofylline and Theophylline Injection	Sample Quantity	65 Ampoules
Batch No.:	AA51113	Sample Received on	07/12/2025
Batch Size:	1.0 Lac	Analysis Date	07/12/2025
Mfg. Date.	11/2025	Release Date	22/12/2025
Exp. Date	10/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A clear colourless liquid filled in 2 ml amber colour glass ampoule with blue dot.	A clear colourless liquid filled in 2 ml amber colour glass ampoule with blue dot.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	pH	Between 5.0 to 6.0	5.40		
4.	Extractable volume	Not less than 2.0 ml	2.05 ml		
5.	Particulate Matter	The Solution should be clear, and free from any visible particle.	The Solution is clear, and free from any visible particle.		
6.	Sterility	Should be sterile	Sterile		
7.	Assay:				
	Each ml contains:	Claim	Limit	mg	%
	Etofylline IP	84.7 mg	Between 90.0 % to 110.0 % of stated amount. (Between 76.23 mg to 93.17 mg)	83.740 mg	98.87 %
	Theophylline anhydrous IP eq. to Theophylline hydrate IP	25.3 mg	Between 90.0 % to 110.0 % of stated amount. (Between 22.77 mg to 27.83 mg)	24.680 mg	97.55 %
	Benzyl Alcohol IP	0.2%	Between 90.0 % to 110.0 % of stated amount. (Between 0.18 % to 0.22 %)	0.1933%	96.63 %

Remarks: The above test parameters are complies/ not complies-as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kant	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	22/12/2025	22/12/2025	22/12/2025