



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/26A0745
Generic Name	Etofylline and Theophylline Injection	Sample Quantity	65 Ampoules
Batch No.:	AA60408	Sample Received on	16/04/2026
Batch Size:	1.0 Lac	Analysis Date	16/04/2026
Mfg. Date.	04/2026	Release Date	01/05/2026
Exp. Date	03/2028	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	5.32		
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.	Bacterial Endotoxins Tests	Not more than 0.5 EU/mg	Less than 0.5 EU/mg		
8.	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)	85.478 mg	100.92 %
	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)	25.681 mg	101.51 %
	Benzyl Alcohol IP	0.2%	Between 90.0 % to 110.0 % of stated amount. (Between 0.18 % to 0.22 %)	0.2016%	100.80 %

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	Komal Kant	Subash Kumar
Designation	Executive	Executive	Head Qc
Signature			
Date	01/05/2026	01/05/2026	01/05/2026