



# 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/26A0477
Generic Name	Etofylline and Theophylline Injection	Sample Quantity	65 Ampoules
Batch No.:	AA60121	Sample Received on	06/03/2026
Batch Size:	1.0 Lac	Analysis Date	06/03/2026
Mfg. Date.	01/2026	Release Date	20/03/2026
Exp. Date	12/2027	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	5.30		
4.	Extractable volume	Not less than 2.0 ml	2.02 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)	83.173 mg	98.20 %
	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)	25.007 mg	98.84 %
	Benzyl Alcohol IP	0.2%	Between 90.0 % to 110.0 % of stated amount. (Between 0.18 % to 0.22 %)	0.2106%	105.31 %

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	Ravleen Kumar	Komal Kant	Subhrajit Paul
Designation	Executive	Executive	Head QC
Signature			
Date	20/03/2026	20/03/2026	20/03/2026