

# G. AMPHRAY LABORATORIES

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## CERTIFICATE OF ANALYSIS

Product	: SIMVASTATIN EP [COS Material]	A. R. No	: FP 288/2004
Batch No.	: SV288/12/2004	Date of receipt	: 20.12.2004
Date of Mfg.	: December, 2004.	Date Analysis	: 20.12.2004
Date of Expiry	: November, 2007.	Quantity	: 50.00 KGS

## RESULTS OF ANALYSIS

TEST	RESULT	SPECIFICATION
Description	A white crystalline powder.	A white or almost white crystalline powder.
Solubility	Practically insoluble in water, very soluble in methylene chloride, freely soluble in alcohol.	Practically insoluble in water, very soluble in methylene chloride, freely soluble in alcohol.
Identification A. Specific Optical Rotation B. Infrared Absorption	Complies. Complies.	Complies for test of specific optical rotation. IR spectra concordant with spectrum obtained with Simvastatin CRS.
Appearance of solution	1 % solution in methanol is clear and not more intensely colour than BY <sub>7</sub> standard.	1 % solution in methanol is clear and not more intensely colour than BY <sub>7</sub> standard.
Specific Optical Rotation	+ 291 °	From + 285 ° to 300 ° on dry basis.
Heavy Metal	< 20 ppm	Maximum 20 ppm
Loss on Drying ( at 60 ° C for 3 Hrs. ) under vacuum	0.23 %	Not more than 0.5 %
Sulphated Ash	0.01 %	Not more than 0.1 %
Related Substances ( By HPLC ) A. Hydroxy Acid B. Acetate Ester C. AnhydroSimvastatin D. Dimer E. Lovastatin & F. Epilovastatin Sum of all the area of all peaks apart from principle peak and peak due to Lovastatin & Epilovastatin.	0.10 % 0.19 % NIL 0.05 % 0.18 % 0.43 %	Not more than 0.4 % Not more than 0.4 % Not more than 0.4 % Not more than 0.4 % Not more than 1.0 % Not more than 1.0 %
Assay of Simvastatin , C <sub>25</sub> H <sub>38</sub> O <sub>5</sub>	99.10 %	Contains not less than 97.0 % and not more than 102.0 % of Simvastatin, C <sub>25</sub> H <sub>38</sub> O <sub>5</sub>
Residual Solvents A. Methanol B. THF C. Hexane D. Toluene	62 ppm 70 ppm 25 ppm NIL	As per ICH Guideline. 3000 ppm 720 ppm 290 ppm 890 ppm
Particle Size A. ≤ 10 % B. ≥ 90 %	4.5 µm 18.5 µm	As per In-house specification Not more than 5 µm Not more than 20 µm
BHT Content ( By HPLC )	0.007 %	Between 0.005 % & 0.015 %

REMARK: THE ABOVE SAMPLE COMPLIES AS PER THE SPECIFICATION OF E.P. 5.0

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AUTHORISED SIGNATORY