acofarma

ANALYSIS CERTIFICATE

Lot/Analysis/Analysis Nº: 260494

Product:	SIMVASTATIN
Lot:	260494
Expiry date:	26/06/2029
Reference:	Cumple PhEur12.2
Synonyms:	
Formule:	C25H38O5
Poids moléculaire:	418,6 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform		
Appearance of solution	Conform	Test PhEur	
Specific rotation	+ 295	(+285) - (+300)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,02 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	99,0 %	97,0-102,0%	
Impurity E	0,10 %	<= 0,5 %	
Impurity F	0,12 %	<= 0,5 %	
Impurity D	< 0,05 %	<= 0,4 %	
Impurity K	0,05 %	<= 0,4 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	0,13 %	<= 0,3 %	
Impurity G	< 0,05 %	<= 0,2 %	
Impurity J	< 0,05 %	<= 0,2 %	
Impurities A + I	0,07 %	<= 0,4 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,53 %	<= 3,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#
Residual solvent: tert-butyl methyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: Cyclohexane	< 3880 ppm	<= 3880 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Pract. insoluble in water, very soluble in methylene chloride, freely soluble ethanol 96%.

Conservation: In airtight containers. Protect from light. Readily oxidable.

Date of analysis: 28/04/2026

Judgement: APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01059 Henan Topfond Sci-Tech Co.

Manufacturer batch: 250604011

Produit	Nom	Capacité	Lot

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date d'édition: 14/05/2026