



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252306

Product:	SIMVASTATIN
Lot:	252306
Expiry date:	29/03/2029
Reference:	Cumple PhEur11.8
Synonyms:	
Formule:	C ₂₅ H ₃₈ O ₅
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	+289	(+285) - (+300)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,18 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	97,8 %	97,0-102,0%	
Impurity E	0,08 %	<= 0,5 %	
Impurity F	0,11 %	<= 0,5 %	
Impurity D	< 0,05 %	<= 0,4 %	
Impurity K	0,02 %	<= 0,4 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	0,14 %	<= 0,3 %	
Impurity G	< 0,05 %	<= 0,2 %	
Impurity J	< 0,05 %	<= 0,2 %	
Impurities A + I	0,08 %	<= 0,4 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,47 %	<= 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: 19/12/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01059 Henan Topfond Sci-Tech Co.

Manufacturer batch: 250304001

Produit	Nom	Capacité	Lot
1100305	SIMVASTATINA	10 g	252306-F-10
1100305	SIMVASTATINA	10 g	252306-F-2
1100305	SIMVASTATINA	10 g	252306-F-3
1100305	SIMVASTATINA	10 g	252306-F-4
1100305	SIMVASTATINA	10 g	252306-F-9
1100306	SIMVASTATINA	100 g	252306-J-2
1100306	SIMVASTATINA	100 g	252306-J-3
1100306	SIMVASTATINA	100 g	252306-J-5
1100307	SIMVASTATINA	250 g	252306-N-2
1100307	SIMVASTATINA	250 g	252306-N-3
1370090	SIMVASTATINA (FLB)	10 g	252306-F-1
1370090	SIMVASTATINA (FLB)	10 g	252306-F-5
1370090	SIMVASTATINA (FLB)	10 g	252306-F-6
1370090	SIMVASTATINA (FLB)	10 g	252306-F-7
1370090	SIMVASTATINA (FLB)	10 g	252306-F-8
1370256	SIMVASTATINA (FLB)	100 g	252306-J-1
1370256	SIMVASTATINA (FLB)	100 g	252306-J-4
1370278	SIMVASTATINA (FLB)	250 g	252306-N-1

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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