



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 242044**

Product:	SIMVASTATIN
Lot:	242044
Expiry date:	15/08/2027
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C <sub>25</sub> H <sub>38</sub> O <sub>5</sub>
Molecular weight:	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	+293	(+285) - (+300)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,13 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,1%	
Assay (HPLC)	98,9 %	97,0-102,0%	
Impurity E	< 0,05 %	<= 0,5 %	
Impurity F	0,05 %	<= 0,5 %	
Impurity D	0,09 %	<= 0,4 %	
Impurity K	0,03 %	<= 0,4 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity G	< 0,05 %	<= 0,2 %	
Impurity J	< 0,05 %	<= 0,2 %	
Impurities A + I	< 0,05 %	<= 0,4 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,17 %	<= 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	#

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.

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Date of analysis: 30/10/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00286 ZHEJIANG JIANGBEI PHARMACEUTICAL CO. LTD

Manufacturer batch: 101-002-240846

Product	Name	Capacity	Batch
1100305	SIMVASTATINA	10 g	242044-F-2
1100305	SIMVASTATINA	10 g	242044-F-3
1100305	SIMVASTATINA	10 g	242044-F-4
1100305	SIMVASTATINA	10 g	242044-F-5
1100305	SIMVASTATINA	10 g	242044-F-7
1100306	SIMVASTATINA	100 g	242044-J-1
1100306	SIMVASTATINA	100 g	242044-J-2
1100306	SIMVASTATINA	100 g	242044-J-3
1100306	SIMVASTATINA	100 g	242044-J-4
1100307	SIMVASTATINA	250 g	242044-N-1
1100307	SIMVASTATINA	250 g	242044-N-2
1100307	SIMVASTATINA	250 g	242044-N-3
1100307	SIMVASTATINA	250 g	242044-N-4
1370090	SIMVASTATINA (FLB)	10 g	242044-F-1
1370090	SIMVASTATINA (FLB)	10 g	242044-F-6
1370090	SIMVASTATINA (FLB)	10 g	242044-F-8

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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