



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 252306**

|                   |  |
|-------------------|--|
| Product:          | SIMVASTATIN                                    |
| Lot:              | 252306   |
| Expiry date:      | 29/03/2029                                     |
| Reference:        | Cumple PhEur11.8                               |
| 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                         | +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

| Product | Name               | Capacity | Batch       |
|---------|--------------------|----------|-------------|
| 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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