

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS001010-01)

Release Date: 24/07/2024

Re-test Date: 23/07/2027

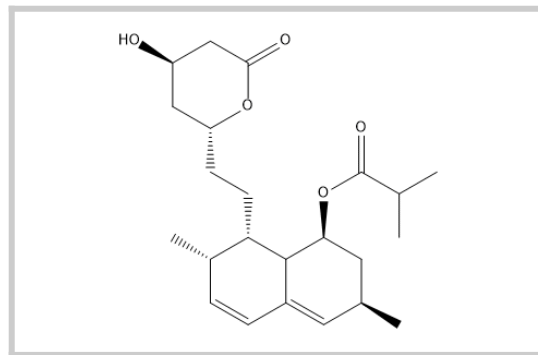
## Simvastatin EP Impurity I

### Identification

**Chemical Name :**

(1S,3R,7S,8S)-8-(2-((2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)ethyl)-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl isobutyrate

**Alt. Name** : 2  
**CAT No.** : KMS001010  
**CAS No.** : 79902-42-4  
**Molecular Formula** : C<sub>23</sub>H<sub>34</sub>O<sub>5</sub>  
**Molecular Weight** : 390.51



### Analytical Information

<b>Batch No.</b>	: SIM-IMP-EPI-019-119	<b>Solubility</b>	: ACN
<b>Description</b>	: Off White Semi Solid	<b>Mass</b>	: Confirm
<b>HPLC Purity</b>	: 97.63 %	<b>IR</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.93 %	<b><sup>1</sup>H NMR</b>	: Confirm
<b>% Potency</b>	: 96.72 %		

### Additional Information

**Long Term Storage** : Store at 2-8 deg. C for long term storage  
**Shipping Condition** : Product is stable to be shipped at room temperature  
**% Potency** = [100 - 0.93(Weight Loss By TGA)] x [97.63(HPLC Purity)]/100 = 96.72 %  
-Re-tested on 24.07.2024

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		24/07/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA