

Analysis Date: 20-09-2025

Re-test Date: 20-09-2028

## SIMVASTATIN EP IMPURITY H

### Identification

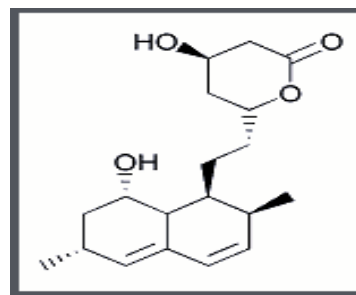
**Chemical Name** : 6(R)-[2-(8(S)-Hydroxy)-2(S),6(R)-dimethyl-1,2,6,7,8,8a(R)-hexahydro-1(S)-naphthyl]ethyl-4(R)-hydroxy-3,4,5,6-tetrahydro-2H-pyran-2-one

**CAT No** : ALL-S04930

**CAS No** : 79952-42-4

**Molecular Formula** : C<sub>19</sub>H<sub>28</sub>O<sub>4</sub>

**Molecular Weight** : 320.42



### Analytical Information

<b>Batch Code</b>	: ALL-S04930	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 95.87%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 1.145%	<b><sup>1</sup>HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 1.025%		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (1.145+1.025) × 98.00]/100 = 95.87%

**Recommendation** : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr.Vipul khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

**Attachment** : HPLC, Mass, <sup>1</sup>H NMR, IR, TGA

**Shipping Condition** : All Product are stable to be shipped at room temperature, unless otherwise specified

#### Corporate Office