

Analysis Date: 01-09-2025

Re-test Date: 01-09-2028

## EZETIMIBE IMPURITY 1

### Identification

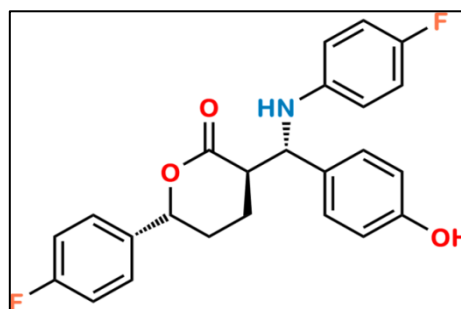
**Chemical Name** : (3R,6R)-6-(4-Fluorophenyl)-3-((S)-((4-fluorophenyl)amino)(4-hydroxyphenyl)methyl)tetrahydro-2H-pyran-2-one

**CAT No** : ALL-E03825

**CAS No** : N.A.

**Molecular Formula** : C<sub>24</sub>H<sub>21</sub>F<sub>2</sub>NO<sub>3</sub>

**Molecular Weight** : 409.4



### Analytical Information

<b>Batch Code</b>	: ALL-E03825	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 97.87%
<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>	: 0.024%	<b><sup>1</sup>H NMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.108%		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (0.024+0.108) × 98.00]/100 = 97.87%

**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