



Certificate

EZETIMIBE SYSTEM SUITABILITY MIXTURE

(A mixture containing Ezetimibe, *o*-Fluorobenzene isomer and *R,R,S*-Ezetimibe)

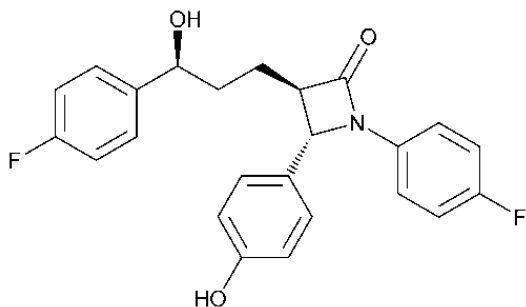
USP Catalog No.: 1269039

USP Lot No.: R167G0

Only compendial components as listed in the monograph are shown below

Component 1 (Ezetimibe)

((3*R*,4*S*)-1-(4-Fluorophenyl)-3-[(*S*)-3-(4-fluorophenyl)-3-hydroxypropyl]-4-(4-hydroxyphenyl)azetidin-2-one)



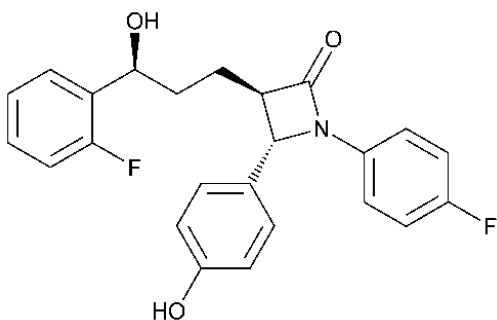
CAS No.: 163222-33-1

Molecular Formula: C₂₄H₂₁F₂NO₃

Molecular Weight: 409.43

Component 2 (*o*-Fluorobenzene isomer)

((3*R*,4*S*)-1-(4-Fluorophenyl)-3-[(*S*)-3-(2-fluorophenyl)-3-hydroxypropyl]-4-(4-hydroxyphenyl)azetidin-2-one)



CAS No.: 1798008-25-9

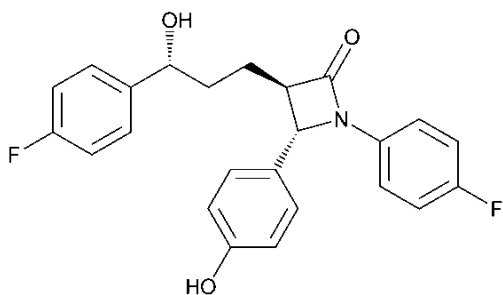
Molecular Formula: C₂₄H₂₁F₂NO₃

Molecular Weight: 409.43



Component 3 (*R,R,S*-Ezetimibe)

((3*R*,4*S*)-1-(4-Fluorophenyl)-3-[(*R*)-3-(4-fluorophenyl)-3-hydroxypropyl]-4-(4-hydroxyphenyl)azetidin-2-one)



CAS No.: 163380-16-3

Molecular Formula: C₂₄H₂₁F₂NO₃

Molecular Weight: 409.43

**LABEL TEXT**

For use with specified USP compendial tests.
Not for use as a drug. See SDS prior to use
at www.usp.org/cds.

**REFERENCE STANDARD****EZETIMIBE SYSTEM SUITABILITY MIXTURE 20 mg**

A mixture containing Ezetimibe, *o*-Fluorobenzene isomer and *R,R,S*-Ezetimibe. Labeled for qualitative use. Keep container tightly closed. Protect from light. Store in a refrigerator. Material is hygroscopic.

See certificate for any additional information.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
Cat. No. 1269039 Material mfd. in India

LOT: R167G0



Quality Assurance

Certificate Version History

Version Number	Date	Reasons for Change
00	26-OCT-2022	First issue

**Assigned Value**

Please refer to the USP Reference Standard label and/or USP Certificate for the assigned value of the specific lot. If an assigned value is not included on the label or Certificate, the lot was developed for qualitative USP compendial use and an assigned value will not be provided.

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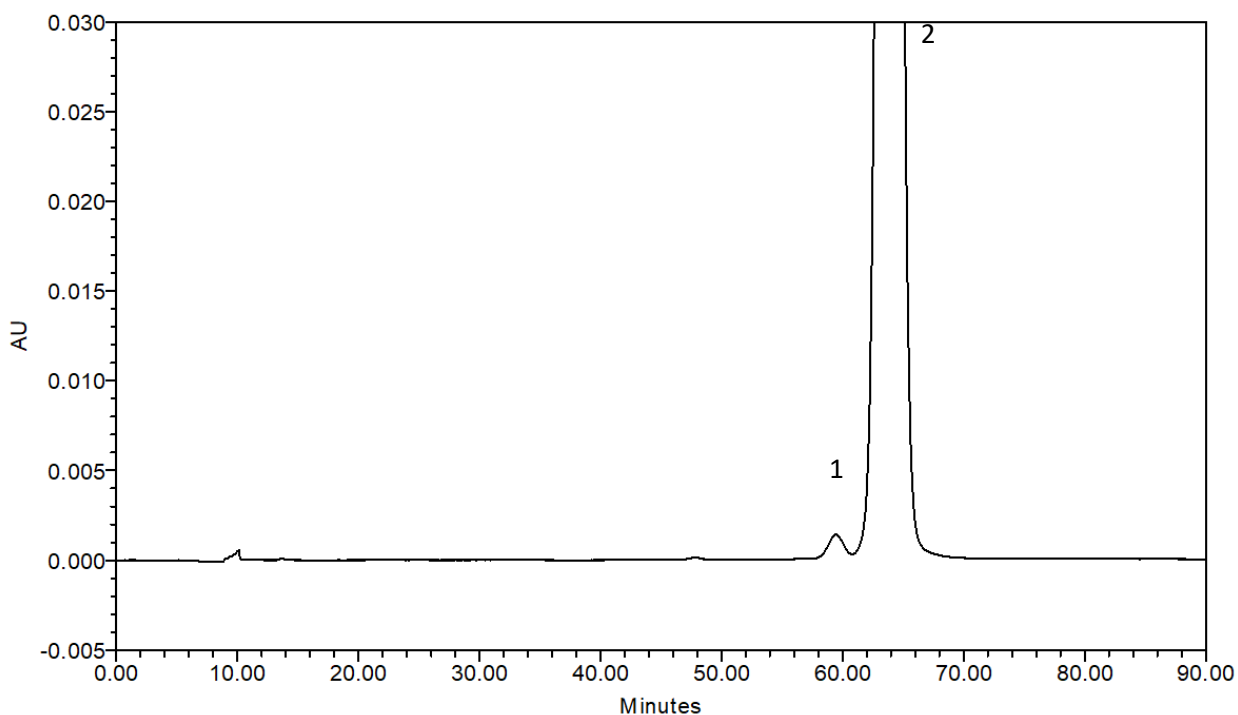
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Typical Chromatogram

USP Ezetimibe System Suitability Mixture RS

Catalog Number: 1269039
Lot: R167G0
Monograph: Ezetimibe
Publication: USP-NF 2022
Test: Organic Impurities, Procedure 2
Sample: System suitability solution



1. *R,R,S*-Ezetimibe
2. Ezetimibe

This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.