

Certificate

DUTASTERIDE RESOLUTION MIXTURE

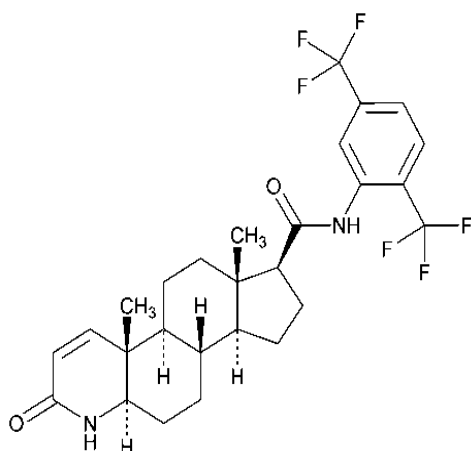
(Mixture of dutasteride, dutasteride 17 α -epimer, dutasteride α -dimer and dutasteride β -dimer)

USP Catalog No.: 1229931

USP Lot No.: F00840

Dutasteride

((5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide)



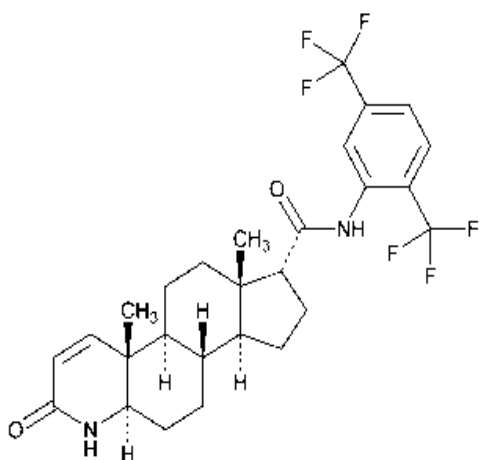
CAS No. 164656-23-9

Molecular Formula C₂₇H₃₀F₆N₂O₂

Molecular Weight 528.53

Dutasteride 17 α -epimer

((5 α ,17 α)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide)



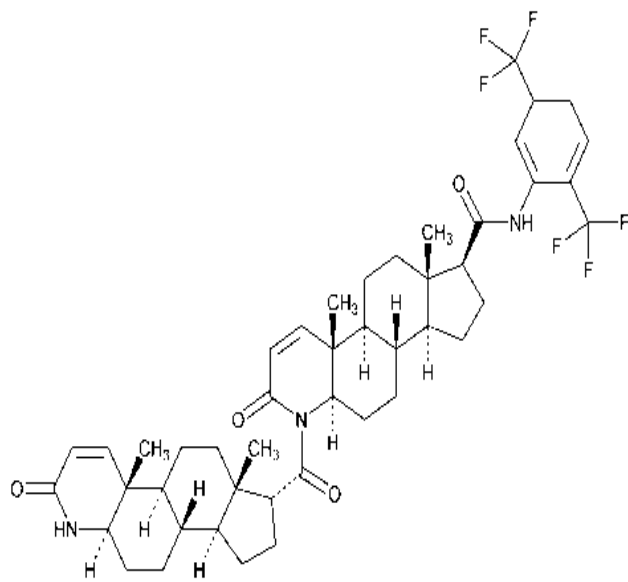
CAS No. N/A

Molecular Formula C₂₇H₃₀F₆N₂O₂

Molecular Weight 528.53

Dutasteride α -dimer

(((5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide]-4-yl){[(5 α ,17 α)-3-oxo-4-azaandrost-1-ene]-17-yl}methanone)



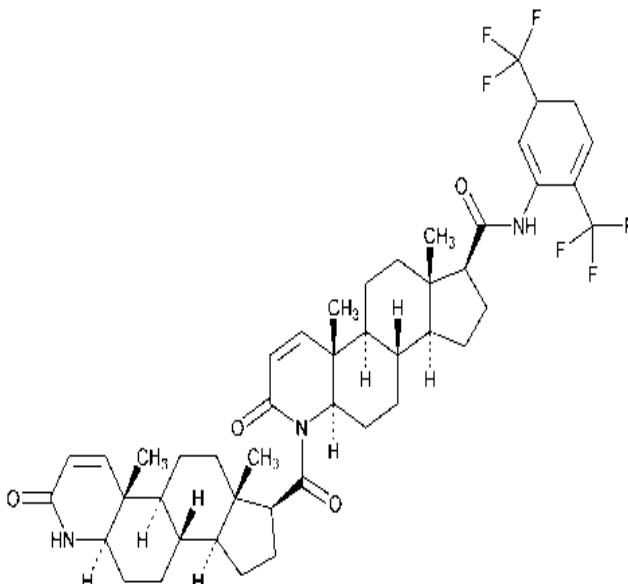
CAS No. N/A

Molecular Formula C₄₆H₅₅F₆N₃O₄

Molecular Weight 827.94

Dutasteride β -dimer

(((5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide]-4-yl){[(5 α ,17 β)-3-oxo-4-azaandrost-1-ene]-17-yl}methanone)



CAS No. N/A

Molecular Formula C₄₆H₅₅F₆N₃O₄

Molecular Weight 827.94

LABEL TEXT

← **USP REFERENCE STANDARD**



DUTASTERIDE RESOLUTION MIXTURE 20 mg



Danger! May damage fertility or the unborn child.

This material is a mixture of dutasteride, dutasteride 17 α -epimer, dutasteride α -dimer and dutasteride β -dimer. Do not dry. Keep container tightly closed. Protect from light. Store in the refrigerator.

See accompanying typical chromatogram.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1229931 Material mfd. in United Kingdom

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

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
If exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth

Quality Assurance

Calculation Value

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in the compendial applications for which the use of this Reference Standard is intended. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

LEGAL NOTICE

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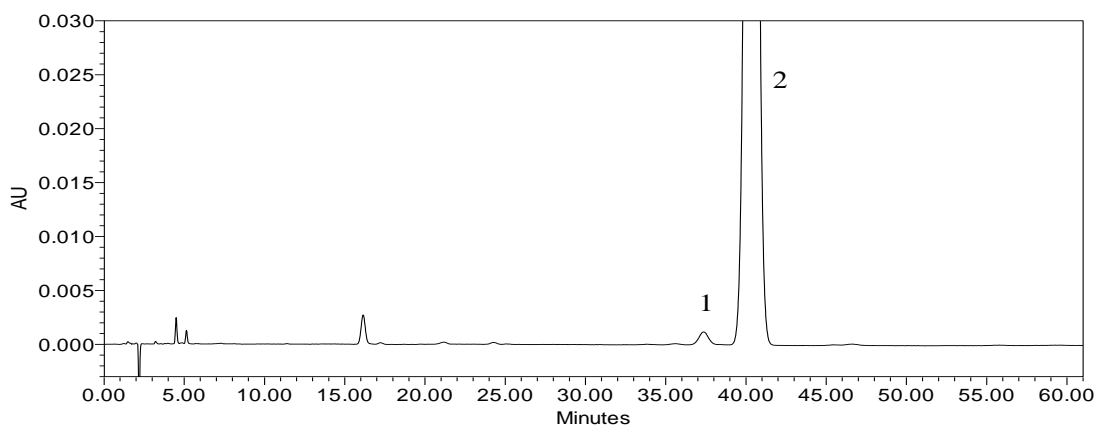
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Typical Chromatogram

USP Standard Name RS

Catalog Number: 1229931
Lot: F00840
Monograph: Dutasteride Organic Impurities— Procedure 1
Publication: PF 39(2)
Test: Organic Impurities
Sample: System suitability solution



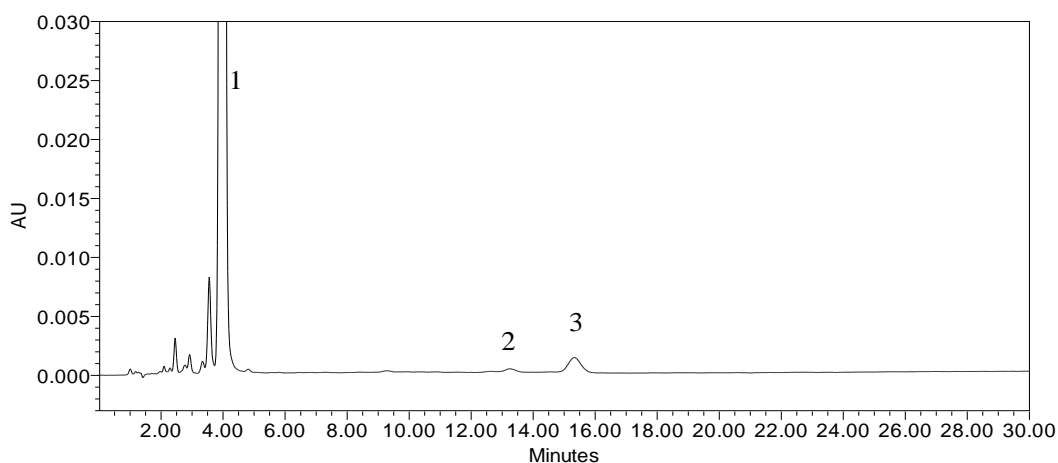
1 Dutasteride 17 α -epimer

2 Dutasteride

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

USP Standard Name RS

Catalog Number: 1229931
Lot: F00840
Monograph: Dutasteride Organic Impurities
Publication: PF 39(2)
Test: Organic Impurities— Procedure 2
Sample: System suitability solution



1 Dutasteride

2 Dutasteride α -dimer

3 Dutasteride β -dimer

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