

# Certificate

## DUTASTERIDE RESOLUTION MIXTURE

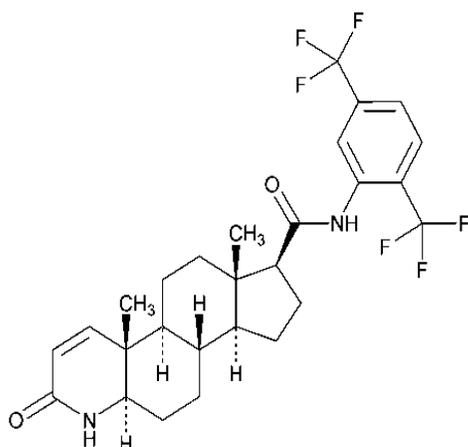
(Mixture of dutasteride, dutasteride 17 $\alpha$ -epimer, dutasteride  $\alpha$ -dimer and dutasteride  $\beta$ -dimer)

USP Catalog No.: 1229931

USP Lot No.: F00840

### Dutasteride

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



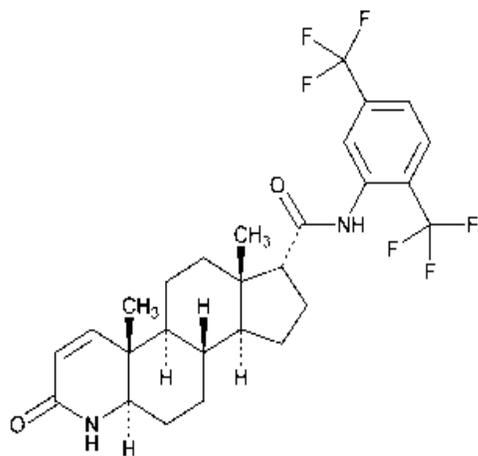
CAS No. 164656-23-9

Molecular Formula C<sub>27</sub>H<sub>30</sub>F<sub>6</sub>N<sub>2</sub>O<sub>2</sub>

Molecular Weight 528.53

### Dutasteride 17 $\alpha$ -epimer

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



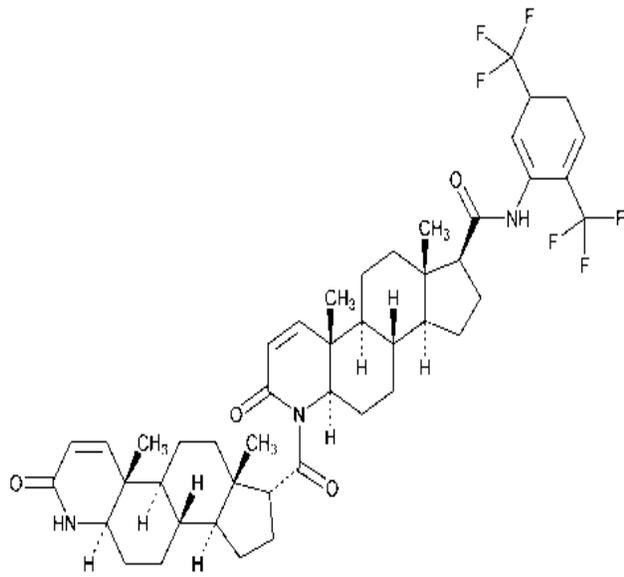
CAS No. N/A

Molecular Formula C<sub>27</sub>H<sub>30</sub>F<sub>6</sub>N<sub>2</sub>O<sub>2</sub>

Molecular Weight 528.53

**Dutasteride  $\alpha$ -dimer**

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



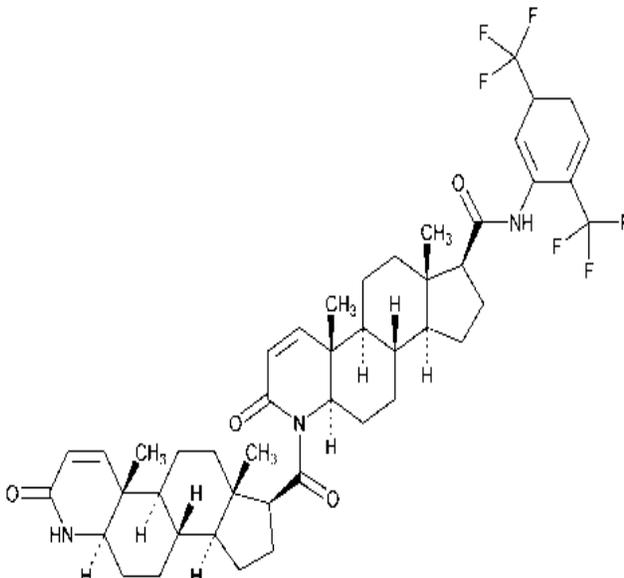
CAS No. N/A

Molecular Formula C<sub>46</sub>H<sub>55</sub>F<sub>6</sub>N<sub>3</sub>O<sub>4</sub>

Molecular Weight 827.94

**Dutasteride  $\beta$ -dimer**

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

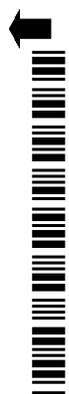


CAS No. N/A

Molecular Formula C<sub>46</sub>H<sub>55</sub>F<sub>6</sub>N<sub>3</sub>O<sub>4</sub>

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 $\alpha$ -epimer, dutasteride  $\alpha$ -dimer and dutasteride  $\beta$ -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](http://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](http://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.

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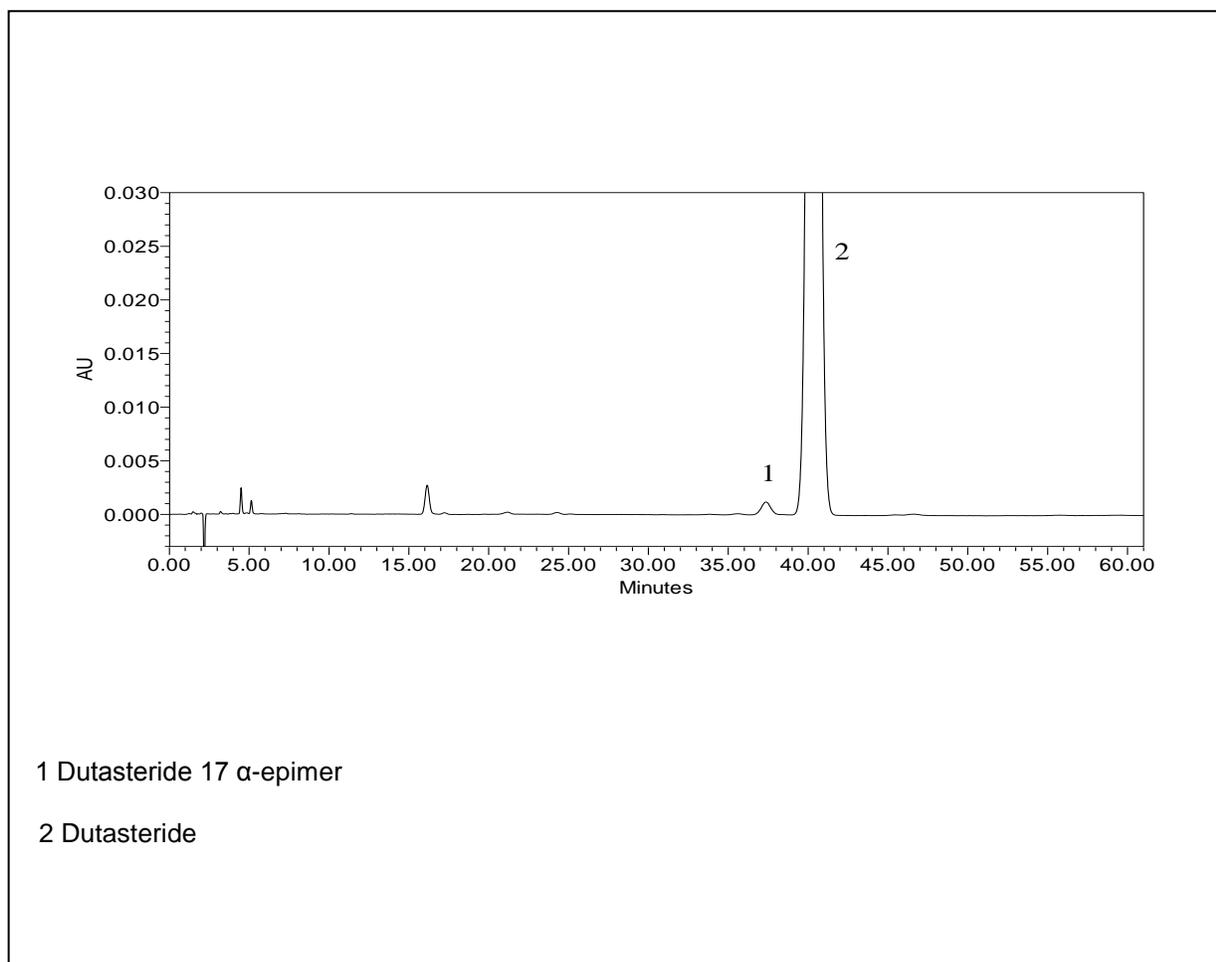
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# Typical Chromatogram

## USP Standard Name RS

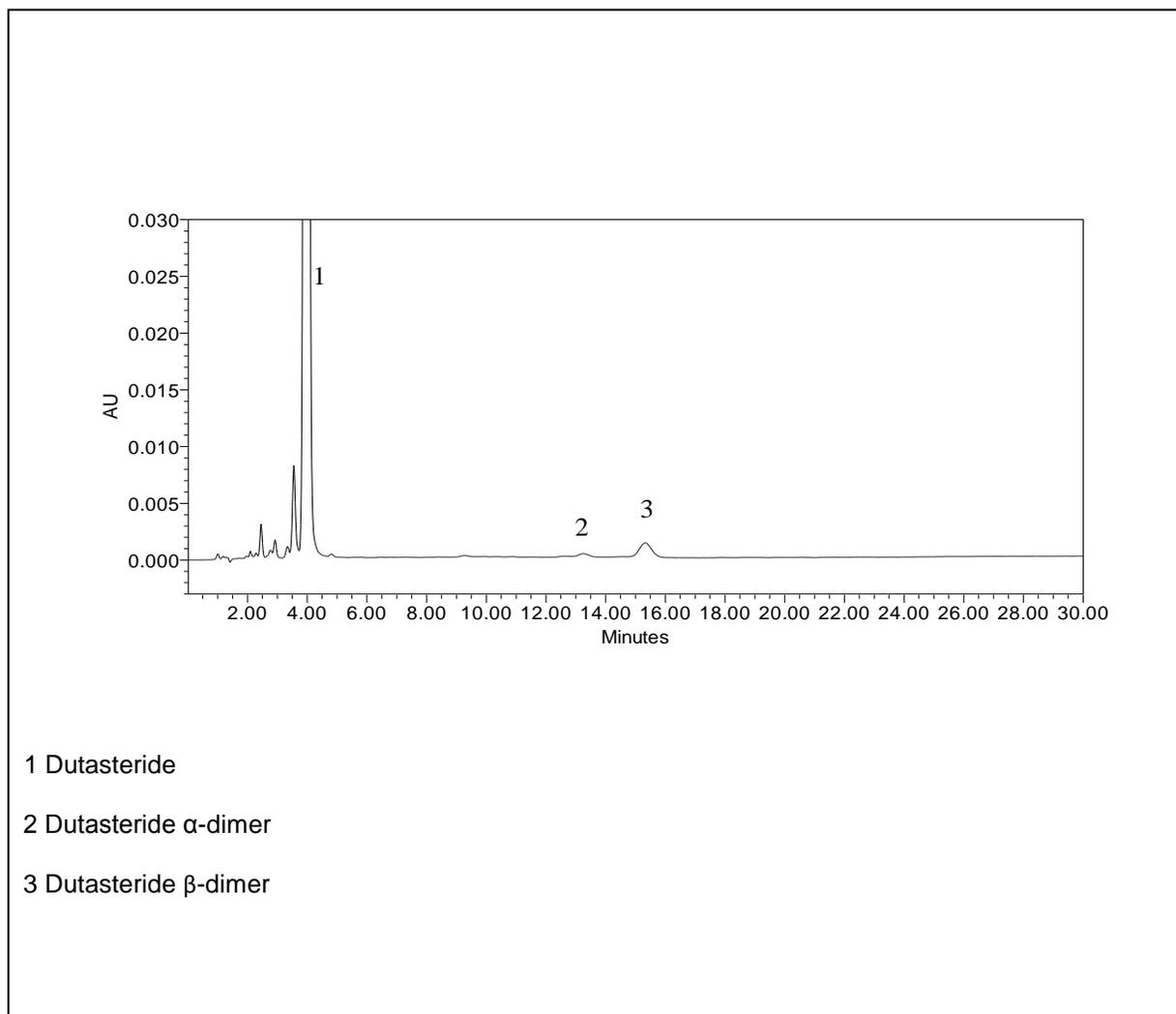
<b>Catalog Number:</b> 1229931
<b>Lot:</b> F00840
<b>Monograph:</b> Dutasteride Organic Impurities— Procedure 1
<b>Publication:</b> PF 39(2)
<b>Test:</b> Organic Impurities
<b>Sample:</b> System suitability solution



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

## USP Standard Name RS

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



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