

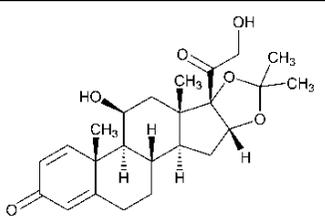
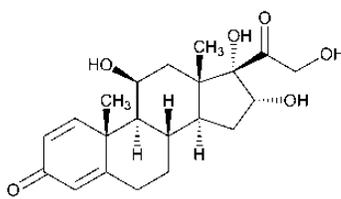
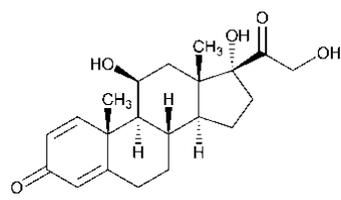
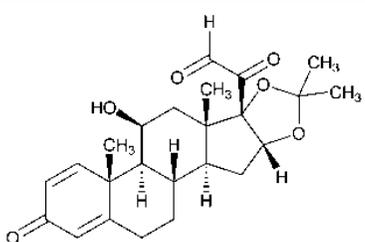
Certificate

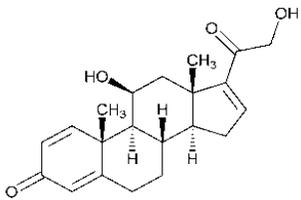
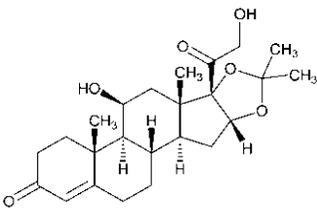
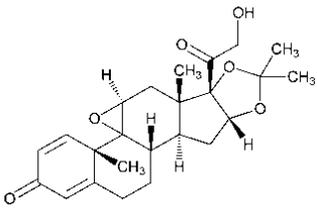
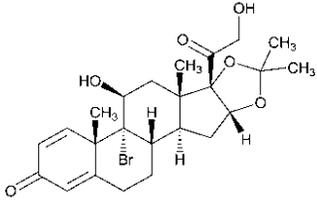
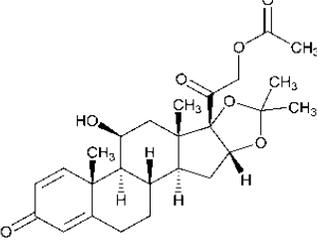
DESONIDE IMPURITIES MIXTURE

(A mixture containing Desonide and about 1% each of 16 α -Hydroxyprednisolone, Prednisolone, Desonide Glyoxal, Deoxyprednisolone-16-ene, Dihydrodesonide, Epoxydesonide, Bromodesonide, and Acetyldesonide)

USP Catalog No.: 1173315

USP Lot No.: F00340

<u>Desonide</u> (Pregna-1,4-diene-3,20-dione, 11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11 β ,16 α)-)	
	CAS No.: 638-94-8
	Molecular Formula: C ₂₄ H ₃₂ O ₆
	Molecular Weight: 416.51
<u>16α-Hydroxyprednisolone</u> (11 β ,16 α ,17,21-Tetrahydroxy-3,20-dioxopregna-1,4-diene)	
	CAS No.: 13951-70-7
	Molecular Formula: C ₂₁ H ₂₈ O ₆
	Molecular Weight: 376.44
<u>Prednisolone</u> (11 β ,17,21-Trihydroxy-3,20-dioxopregna-1,4-diene)	
	CAS No.: 50-24-8
	Molecular Formula: C ₂₁ H ₂₈ O ₅
	Molecular Weight: 360.44
<u>Desonide Glyoxal</u> (11 β -Hydroxy-16 α ,17-[(1-methylethylidene)bis(oxy)]-3,20-dioxopregna-1,4-dien-21-al)	
	CAS No.: 57171-18-3
	Molecular Formula: C ₂₄ H ₃₀ O ₆
	Molecular Weight: 414.49

Deoxyprednisolone-16-ene <i>(11β,21-Dihydroxypregna-1,4,16-triene-3,20-dione)</i>	
	CAS No.: 3103-17-1
	Molecular Formula: C ₂₁ H ₂₆ O ₄
	Molecular Weight: 342.43
Dihydrodesonide <i>(11β,21-Dihydroxy-16α,17-[(1-methylethylidene)bis(oxy)]pregn-4-ene-3,20-dione)</i>	
	CAS No.: 638-93-7
	Molecular Formula: C ₂₄ H ₃₄ O ₆
	Molecular Weight: 418.52
Epoxydesonide <i>(9,11β-Epoxy-21-hydroxy-16α,17-(1-methylethylidenedioxy)pregna-1,4-diene-3,20-dione)</i>	
	CAS No.: 39672-75-8
	Molecular Formula: C ₂₄ H ₃₀ O ₆
	Molecular Weight: 414.49
Bromodesonide <i>(9α-Bromo-11β,21-dihydroxy-16α,17-[(1-methylethylidene)bis(oxy)]pregna-1,4-diene-3,20-dione)</i>	
	CAS No.: 39672-77-0
	Molecular Formula: C ₂₄ H ₃₁ BrO ₆
	Molecular Weight: 495.40
Acetyldesonide <i>(11β-Hydroxy-16α,17-[(1-methylethylidene)bis(oxy)]-3,20-dioxopregna-1,4-dien-21-yl acetate)</i>	
	CAS No.: 25092-25-5
	Molecular Formula: C ₂₆ H ₃₄ O ₇
	Molecular Weight: 458.54

LABEL TEXT

USP REFERENCE STANDARD

DESONIDE IMPURITIES MIXTURE 25 mg

Danger! Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Do not dry. Keep container tightly closed. Protect from light. Store in a refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1173315 Material mfd in Italy



Lot: F00340



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. Wash thoroughly after handling. 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

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. 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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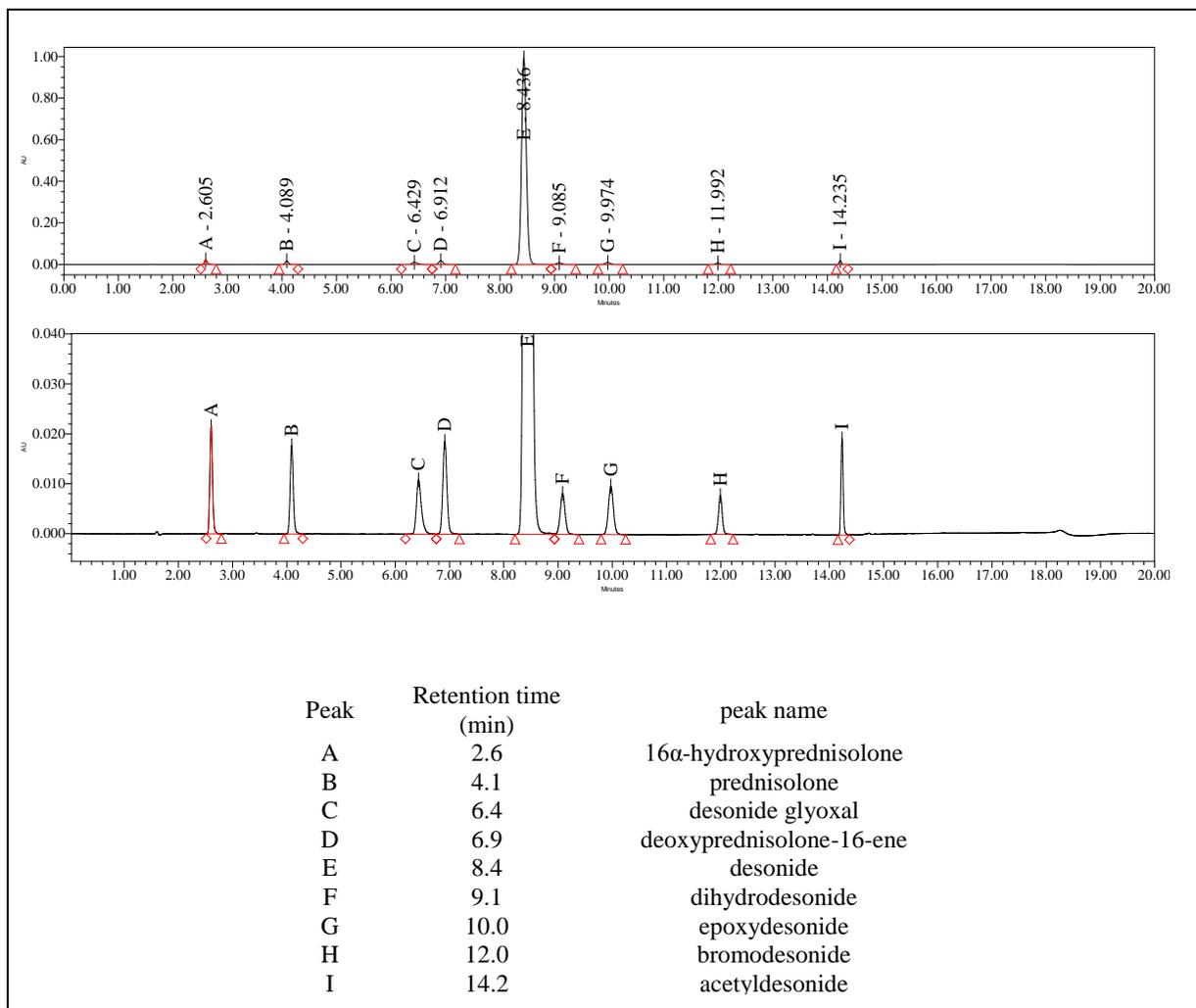
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Typical Chromatogram

USP DESONIDE IMPURITIES MIXTURE RS

Catalog Number: 1173315
Lot: F00340
Monograph: Desonide
Publication: USP 38-NF 33
Test: Organic Impurities
Sample: System suitability solution, as per monograph



This chromatogram was obtained with a Phenomenex Kinetex L7, 15 cm x 4.6 mm (i.d.), 2.6 μ m particle size HPLC column and is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.