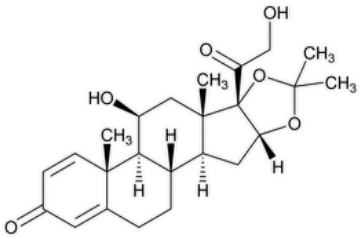


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-CFBCCA7C-1547-4CAA-BCE8-7B03F4441ABB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M22970_02_01
DOI Ref: l27af

Desonide



$C_{24}H_{32}O_6$ 416.51

Pregna-1,4-diene-3,20-dione, 11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11β,16α)-;

11β,16α,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone CAS RN®: 638-94-8; UNII: J280872D1O.

DEFINITION

Desonide contains NLT 98.0% and NMT 102.0% of the labeled amount of desonide ($C_{24}H_{32}O_6$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Use low-actinic glassware for all solutions containing desonide.

Solution A: 0.1% Phosphoric acid in water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
4	68	32
5	68	32
9	65	35
13	30	70
16	30	70

Diluent: *Solution A* and acetonitrile (60:40)

System suitability solution: 0.7 mg/mL of USP Desonide Impurities Mixture RS in *Diluent*

Standard solution: 0.7 mg/mL of USP Desonide RS in *Diluent*

Sample solution: 0.7 mg/mL of Desonide in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 2.6-µm packing L7

Temperatures

Column: 20° (15°–22° was shown to be acceptable)

Autosampler: 20°

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between desonide glyoxal and deoxyprednisolone-16-ene; NLT 2.0 between desonide and dihydrodesonide, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of desonide ($C_{24}H_{32}O_6$) in the portion of Desonide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Desonide RS in the *Standard solution* (mg/mL)

C_U = concentration of Desonide in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.10%
- **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.28 µg/mL of USP Desonide RS in *Diluent* from the *Standard solution*

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.0 between desonide glyoxal and deoxyprednisolone-16-ene; NLT 2.0 between desonide and dihydrodesonide, *System suitability solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Desonide taken:

$$\text{Result} = (r_U/r_T) \times (1/F) \times 100$$

r_U = peak area of each impurity from the *Sample solution*

r_T = total peak area from the *Sample solution*

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

[Note—Disregard peaks that are less than 0.04% of the desonide peak from the *Standard solution*.]

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
16α-Hydroxyprednisolone[a]	0.31	1.0	0.15
Prednisolone[b]	0.48	1.0	0.15
Desonide glyoxal[c]	0.76	1.0	0.50
Deoxyprednisolone-16-ene[d]	0.82	1.7	0.50
Sum of desonide glyoxal and deoxyprednisolone-16-ene	—	—	0.50
Desonide	1.00	—	—
Dihydrodesonide[e]	1.07	0.84	0.50
Epoxydesonide[f]	1.18	1.0	0.50
Sum of dihydrodesonide and epoxydesonide	—	—	0.50
Bromodesonide[g]	1.43	0.68	0.15
Acetyldesonide[h]	1.74	0.82	0.15
Any other impurity	—	1.0	0.10
Total impurities	—	—	1.0

[a] 11β,16α,17,21-Tetrahydroxy-3,20-dioxopregna-1,4-diene.

[b] 11β,17,21-Trihydroxy-3,20-dioxopregna-1,4-diene.

[c] 11β-Hydroxy-16α,17-[(1-methylethylidene)bis(oxy)]-3,20-dioxopregna-1,4-dien-21-al.

[d] 11β,21-Dihydroxypregna-1,4,16-triene-3,20-dione.

[e] 11β,21-Dihydroxy-16α,17-[(1-methylethylidene)bis(oxy)]pregn-4-ene-3,20-dione.

[f] 9,11β-Epoxy-21-hydroxy-16α,17-(1-methylethylidenedioxy)pregna-1,4-diene-3,20-dione.

[g] 9α-Bromo-11β,21-dihydroxy-16α,17-[(1-methylethylidene)bis(oxy)]pregna-1,4-diene-3,20-dione.

[h] 11β-Hydroxy-16α,17-[(1-methylethylidene)bis(oxy)]-3,20-dioxopregna-1,4-dien-21-yl acetate.

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩**

  Sample: 1.0 g

  Analysis: Dry at 105° for 3 h.

  Acceptance criteria: NMT 0.5%

- **Optical Rotation, *Specific Rotation* ⟨781S⟩**

  Sample: 10 mg/mL in dioxane

  Acceptance criteria: +104.0° to +110.0°, calculated on the dried basis

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature. Protect from light.
- **USP Reference Standards ⟨11⟩**

  USP Desonide RS

USP Desonide Impurities Mixture RS

This is a mixture that contains desonide and may contain about 1% each of 16α-hydroxyprednisolone, prednisolone, desonide glyoxal, deoxyprednisolone-16-ene, dihydrodesonide, epoxydesonide, bromodesonide, and acetyldesonide.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DESONIDE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-CFBCCA7C-1547-4CAA-BCE8-7B03F4441ABB_2_en-US

DOI: https://doi.org/10.31003/USPNF_M22970_02_01

DOI ref: l27af