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## **Desoxycorticosterone Pivalate**

 $C_{26}H_{38}O_4$  414.58

Pregn-4-ene-3,20-dione, 21-(2,2-dimethyl-1-oxopropoxy)-.

11-Deoxycorticosterone pivalate CAS RN®: 808-48-0; UNII: 16665T4A2X.

» Desoxycorticosterone Pivalate contains not less than 97.0 percent and not more than 103.0 percent of C<sub>26</sub>H<sub>38</sub>O<sub>4</sub>, calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°. **Labeling**—Label it to indicate that it is for veterinary use only.

USP REFERENCE STANDARDS (11)-

USP Desoxycorticosterone Pivalate RS

Identification-

## Change to read:

A: 
Spectroscopic Identification Tests (197), Infrared Spectroscopy: 197K (CN 1-May-2020)

## Change to read:

B: <sup>≜</sup>Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U<sub>▲</sub> (CN 1-May-2020)

Solution: 20 µg per mL. *Medium:* methanol.

Absorptivities at 241 nm, calculated on the dried basis, do not differ by more than 3.0%.

MELTING RANGE (741): between 200° and 206°.

Specific rotation (781S): between +155° and +163°.

Test solution: 10 mg per mL, in dioxane.

Loss on DRYING (731)—Dry it at 105° for 2 hours: it loses not more than 0.5% of its weight.

## Assay-

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (4:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

Internal standard solution—Transfer about 100 mg of desoxycorticosterone acetate to a 50-mL volumetric flask, add methanol to volume, and mix.

Standard preparation—Transfer about 12.5 mg of <u>USP Desoxycorticosterone Pivalate RS</u>, accurately weighed, to a 25-mL volumetric flask, add 20 mL of methanol, and mix. Add 2.5 mL of *Internal standard solution*, dilute with methanol to volume, and mix to obtain a solution having a known concentration of about 0.5 mg of <u>USP Desoxycorticosterone Pivalate RS</u> per mL.

Assay preparation—Transfer about 50 mg of Desoxycorticosterone Pivalate, accurately weighed, to a 100-mL volumetric flask, add 80 mL of methanol, and mix. Add 10.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Chromatographic system (see <a href="Chromatography">Chromatographic System</a> (see <a href="Chromatography">Chromatographic System</a> (see <a href="Chromatography">Chromatographic System</a> (see <a href="Chromatography">Chromatographic Standard preparation</a>, and record the peak responses as directed for <a href="Procedure">Procedure</a>: the resolution, R, between the analyte and internal standard peaks is not less than 2.0; and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 25  $\mu$ L) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.5 for desoxycorticosterone acetate and 1.0 for desoxycorticosterone pivalate. Calculate the quantity, in mg, of  $C_{26}H_{38}O_4$  in the portion of

Desoxycorticosterone Pivalate taken by the formula:

in which C is the concentration, in mg per mL, of <u>USP Desoxycorticosterone Pivalate RS</u> in the *Standard preparation*; and  $R_U$  and  $R_S$  are the peak response ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
DESOXYCORTICOSTERONE PIVALATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 29(6)

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