Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-49E0C86E-7102-4678-B2F4-BF1D9E4581EA_1_en-US
DOI: https://doi.org/10.31003/USPNF_M25830_01_01
DOI Ref: l0dzk

Diflorasone Diacetate Cream

» Diflorasone Diacetate Cream contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{26}H_{32}F_2O_7$.

Packaging and storage—Preserve in collapsible tubes, preferably at controlled room temperature.

USP Reference standards ⟨11⟩—

USP Diflorasone Diacetate RS

Identification—The chromatogram of the *Assay preparation* exhibits a major peak for diflorasone diacetate at a retention time that corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained in the *Assay*.

Microbial enumeration tests ⟨61⟩ and Tests for specified microorganisms ⟨62⟩—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩—meets the requirements.

Assay—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Diflorasone Diacetate*.

Assay preparation—Transfer an accurately weighed amount of Cream, equivalent to about 1 mg of diflorasone diacetate, to a suitable container. Add 30.0 mL of *Internal standard solution*, and shake for about 30 minutes. Centrifuge the solution, and remove and discard the top (excipient) layer. Use the lower, clear chloroform layer.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Diflorasone Diacetate*. Calculate the quantity, in mg, of diflorasone diacetate ($C_{26}H_{32}F_2O_7$) in the portion of Cream taken by the formula:

$$0.03C(R_U/R_S)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
DIFLORASONE DIACETATE CREAM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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