

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-53E6CF59-E406-400E-853B-42CE7DE13022_4_en-US
DOI: https://doi.org/10.31003/USPNF_M42815_04_01
DOI Ref: 0g66u

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Isoflupredone Acetate Injectable Suspension

» Isoflupredone Acetate Injectable Suspension contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of isoflupredone acetate ($C_{23}H_{29}FO_6$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

Labeling—Label it to indicate that it is intended for veterinary use only.

USP REFERENCE STANDARDS (11)—

[USP Isoflupredone Acetate RS](#)
[USP Prednisolone Acetate RS](#)

Change to read:

▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy:197M](#) ▲ (CN 1-May-2020) •

Test specimen—Transfer about 25 mg of Injectable Suspension to a centrifuge tube, add 20 mL of water, and shake well. Centrifuge, and discard the liquid layer. Repeat this washing step with three additional 20-mL portions of water. Dry the material so obtained at 105° for 3 hours.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 125 USP Endotoxin Units per mg of isoflupredone acetate.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH (791): between 5.0 and 7.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Mobile phase, Diluent, Internal standard solution, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under [Isoflupredone Acetate](#).

Assay preparation—Transfer an accurately measured volume of Injectable Suspension, equivalent to about 4 mg of isoflupredone acetate, to a suitable container. Add 8.0 mL of *Internal standard solution* and 32.0 mL of *Diluent*, and swirl to dissolve.

Procedure—Proceed as directed for *Procedure* in the Assay under [Isoflupredone Acetate](#). Calculate the quantity, in mg, of isoflupredone acetate ($C_{23}H_{29}FO_6$) in each mL of Injectable Suspension taken by the formula:

$$(W_s/V)(R_d/R_s)$$

in which *V* is the volume, in mL, of Injectable Suspension taken to prepare the *Assay preparation*; and the other terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ISOFLUPREDONE ACETATE INJECTABLE SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 27(4)

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