

Status: Currently Official on 15-Feb-2025

Official Date: Official as of 01-Dec-2016

Document Type: USP Monographs

DocId: GUID-4B75A3C9-1BA6-44E6-868C-41FA0FCA93B9_1_en-US

DOI: https://doi.org/10.31003/USPNF_M3930_01_01

DOI Ref: 970gb

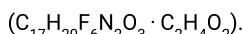
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Flecainide Acetate Compounded Oral Suspension

DEFINITION

Flecainide Acetate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of flecainide acetate



Prepare Flecainide Acetate Compounded Oral Suspension 20 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)):

Flecainide Acetate	2 g
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), <i>NF</i> , and Vehicle for Oral Suspension, <i>NF</i> , a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. If using tablets, place the required number in a suitable mortar, and comminute to a fine powder with a pestle, or use *Flecainide Acetate* powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a flecainide acetate liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the liquid *Vehicle* to bring to final volume, and mix well.

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and 0.06% phosphoric acid solution (40:60)

Standard stock solution: 1.0 mg/mL of [USP Flecainide Acetate RS](#) in *Mobile phase*

Standard solution: Transfer 2 mL of *Standard stock solution* to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution containing about 200 µg/mL of flecainide acetate.

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at -70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Pipet 1.0 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution having a nominal concentration of about 200 µg/mL.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flecainide acetate ($C_{17}H_{20}F_6N_2O_3 \cdot C_2H_4O_2$) in the portion of Oral Suspension 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 Flecainide Acetate RS](#) in the *Standard solution* ($\mu\text{g/mL}$) C_u = nominal concentration of flecainide acetate in the *Sample solution* ($\mu\text{g/mL}$)**Acceptance criteria:** 90.0%–110.0%**SPECIFIC TESTS**

- [pH \(791\)](#): 3.8–4.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.
- **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature or when stored in a refrigerator
- **LABELING:** Label it to indicate that it is to be well-shaken before use, protected from light, and to state the *Beyond-Use Date*.
- [USP Reference Standards \(11\)](#)
[USP Flecainide Acetate RS](#)

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

Topic/Question	Contact	Expert Committee
FLECAINIDE ACETATE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(5)

Current DocID: GUID-4B75A3C9-1BA6-44E6-868C-41FA0FCA93B9_1_en-US**DOI: https://doi.org/10.31003/USPNF_M3930_01_01****DOI ref: 97ogb**