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: 97ogb

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 ($C_{17}H_{20}F_6N_2O_3 \cdot C_2H_4O_2$).

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), *NF*, and Vehicle for Oral Suspension, *NF*, 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* (µg/mL)

C_U = nominal concentration of flecainide acetate in the *Sample solution* (µg/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