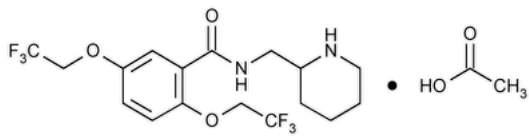


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Aug-2024
Document Type: USP Monographs
DocId: GUID-FAF372FC-DF54-456A-9FA9-57CD9659A990_7_en-US
DOI: https://doi.org/10.31003/USPNF_M33193_07_01
DOI Ref: ziqmf

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Flecainide Acetate



$C_{17}H_{20}F_6N_2O_3 \cdot C_2H_4O_2$ 474.39
Benzamide, *N*-(2-piperidinylmethyl)-2,5-bis(2,2,2-trifluoroethoxy)-, monoacetate;
N-(2-Piperidylmethyl)-2,5-bis(2,2,2-trifluoroethoxy)benzamide monoacetate CAS RN®: 54143-56-5; UNII: M8U465Q1WQ.

DEFINITION

Flecainide Acetate contains NLT 98.0% and NMT 102.0% of flecainide acetate ($C_{17}H_{20}F_6N_2O_3 \cdot C_2H_4O_2$), calculated on the dried basis.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy(197):** [NOTE—Methods described in (197K) or (197A) may be used.]
- B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy: 197U**
Solution: 130 µg/mL in alcohol
Analytical wavelength: 298 nm
Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.
- C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Solution A: 0.1 M [ammonium acetate](#) in [water](#). Adjust with [acetic acid](#) to a pH of 5.4.
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
7.0	45	55
12.0	45	55
12.1	75	25
15.0	75	25

Diluent: [Acetonitrile](#) and [water](#) (25:75)
Standard solution: 0.2 mg/mL of [USP Flecainide Acetate RS](#) in *Diluent*. Sonication may be needed for complete dissolution.
Sample solution: 0.2 mg/mL of Flecainide Acetate in *Diluent*. Sonication may be needed for complete dissolution.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)

Mode: LC
Detector: UV 300 nm
Column: 3.0-mm × 15-cm; 3-µm packing L1
Flow rate: 0.5 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*

Suitability requirements**Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of flecainide acetate ($C_{17}H_{20}F_6N_2O_3 \cdot C_2H_4O_2$) in the portion of Flecainide Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of flecainide from the *Sample solution* r_S = peak response of flecainide from the *Standard solution* C_S = concentration of [USP Flecainide Acetate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Flecainide Acetate in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**OTHER COMPONENTS****• CONTENT OF ACETATE****Sample solution:** Dissolve about 600 mg of Flecainide Acetate in about 100 mL of [dimethylformamide](#), and stir by mechanical means until dissolved.**Titrimetric system**(See [Titrimetry \(541\)](#).)**Mode:** Direct titration**Titrant:** [0.1 N tetrabutylammonium hydroxide VS](#)**Endpoint detection:** Potentiometric**Analysis:** Perform a blank determination and make any necessary correction. Each mL of 0.1 N tetrabutylammonium hydroxide is equivalent to 6.005 mg of acetic acid ($C_2H_4O_2$).**Acceptance criteria:** 12.4%–12.8% on the dried basis**IMPURITIES****• RESIDUE ON IGNITION (281):** NMT 0.2%**• ORGANIC IMPURITIES****Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system:** Proceed as directed in the Assay.**System suitability solution:** 0.25 mg/mL of [USP Flecainide Acetate RS](#) and 0.1 mg/mL of flecainide acid in *Diluent***Sensitivity solution:** 0.001 mg/mL of [USP Flecainide Acetate RS](#) in *Diluent***Standard solution:** 0.01 mg/mL each of [USP Flecainide Acetate RS](#) and [USP Flecainide Related Compound A RS](#) in *Diluent***Sample solution:** 2.0 mg/mL of Flecainide Acetate in *Diluent*. Sonication may be needed for complete dissolution.**System suitability****Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution*[NOTE—See [Table 2](#) for relative retention times.]**Suitability requirements****Resolution:** NLT 5.0 between flecainide acetate and flecainide acid, *System suitability solution***Relative standard deviation:** NMT 5.0%, *Standard solution***Signal-to-noise ratio:** NLT 50, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of flecainide related compound A in the portion of Flecainide Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of flecainide related compound A from the *Sample solution* r_S = peak response of flecainide related compound A from the *Standard solution* C_S = concentration of [USP Flecainide Related Compound A RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Flecainide Acetate in the *Sample solution* (mg/mL)

Calculate the percentage of each specified or unspecified impurity in the portion of Flecainide Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$