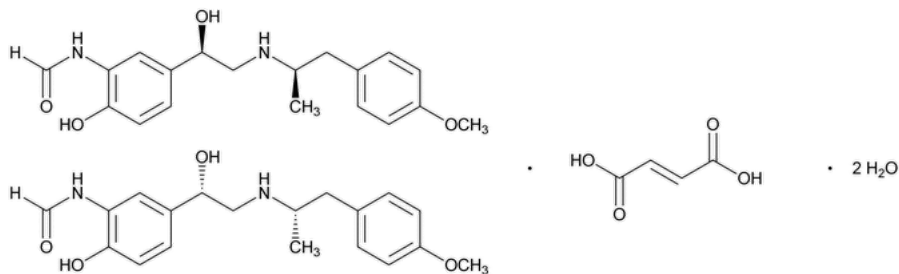


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2022
Document Type: USP Monographs
DocId: GUID-A2F3416E-7E0B-4A7D-B73C-B9659A609461_6_en-US
DOI: https://doi.org/10.31003/USPNF_M34302_06_01
DOI Ref: nz6gv

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Formoterol Fumarate



$(C_{19}H_{24}N_2O_4)_2 \cdot C_4H_4O_4 \cdot 2H_2O$ 840.92
Formamide, N-[2-hydroxy-5-[1-hydroxy-2-[[1-(4-methoxyphenyl)propan-2-yl]amino]ethyl]phenyl], (*R*,R**)-, fumarate (2:1) (salt), dihydrate;
(±)-2'-Hydroxy-5'-[(*R**)-1-hydroxy-2-[[(*R**)-*p*-methoxy- α -methylphenethyl]amino]ethyl]formanilide fumarate (2:1) (salt), dihydrate CAS RN®: 183814-30-4; UNII: W34SHF8J2K.
Anhydrous
 $(C_{19}H_{24}N_2O_4)_2 \cdot C_4H_4O_4$ 804.89 CAS RN®: 43229-80-7.

DEFINITION
Formoterol Fumarate contains NLT 98.5% and NMT 101.5% of formoterol fumarate [$(C_{19}H_{24}N_2O_4)_2 \cdot C_4H_4O_4$], calculated on the anhydrous basis.

- IDENTIFICATION**
- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
 - B.** The retention time of the formoterol peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Protect solutions of formoterol fumarate from light.

Buffer: 6.1 g/L of [monobasic sodium phosphate](#) and 1.0 g/L of [dibasic sodium phosphate dihydrate](#) in [water](#). [NOTE—The pH is 6.0 ± 0.1.]

Solution A: 3.7 g/L of [monobasic sodium phosphate](#) and 0.35 g/L of [phosphoric acid](#) in [water](#). [NOTE—The pH is 3.1 ± 0.1.]

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	84	16
10	84	16
12.7	30	70
12.8	84	16
18	84	16

Diluent: [Acetonitrile](#) and *Buffer* (16:84)

Standard solution: 0.2 mg/mL of [USP Formoterol Fumarate RS](#) in *Diluent*

Sample solution: 0.2 mg/mL of Formoterol Fumarate in *Diluent*

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Flow rate: 1 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 formoterol fumarate $[(C_{19}H_{24}N_2O_4)_2 \cdot C_4H_4O_4]$ in the portion of Formoterol Fumarate taken:

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

r_U = peak response of formoterol from the *Sample solution*

r_S = peak response of formoterol from the *Standard solution*

C_S = concentration of [USP Formoterol Fumarate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Formoterol Fumarate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.5% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#).

Sample: 1 g

Acceptance criteria: NMT 0.1%

Change to read:

- **ORGANIC IMPURITIES**

Protect solutions of formoterol fumarate from light.

Buffer, Solution A, Solution B, and Diluent: Prepare as directed in the Assay.

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	84	16
10	84	16
37	30	70
40	84	16
55	84	16

System suitability solution: 0.2 mg/mL of [USP Formoterol Fumarate RS](#) and 2 μg/mL each of [USP Formoterol Related Compound A RS](#), [USP Formoterol Related Compound C RS](#), and [USP Formoterol Related Compound D RS](#) in *Diluent*. Sonicate to dissolve prior to final dilution.

Sensitivity solution: 0.1 μg/mL of [USP Formoterol Fumarate RS](#) in *Diluent*

Sample solution: 0.2 mg/mL of Formoterol Fumarate in *Diluent*. Sonicate to dissolve before final dilution.

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 15-cm; packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

[NOTE—The relative retention times for the peaks are given in [Table 3](#).]

Suitability requirements