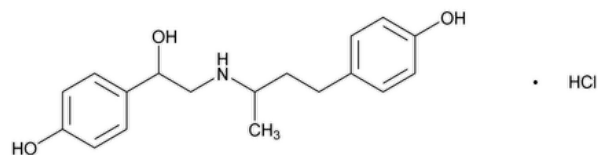


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## Ractopamine Hydrochloride Suspension



$C_{18}H_{23}NO_3 \cdot HCl$  337.84

Benzenemethanol, 4-hydroxy- $\alpha$ -[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]methyl]-, hydrochloride;

( $\pm$ )-all-*rac*-*p*-Hydroxy- $\alpha$ -[[[3-(*p*-hydroxyphenyl)-1-methylpropyl]amino]methyl]benzyl alcohol, hydrochloride CAS RN<sup>®</sup>: 90274-24-1; UNII: 309G9J93TP.

### DEFINITION

Ractopamine Hydrochloride Suspension contains NLT 10% and NMT 20%, by weight, of ractopamine hydrochloride ( $C_{18}H_{23}NO_3 \cdot HCl$ ) in water.

[NOTE—The material partially precipitates out at room temperature to form a slurry, and redissolves when heated to 50°–60°.]

### IDENTIFICATION

#### Change to read:

- [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

**Sample:** Dry a portion of Ractopamine Hydrochloride Suspension under vacuum for 3 h at 60°.

### ASSAY

#### • Procedure

**Solution A:** 5.75 mg/mL solution of monobasic ammonium phosphate adjusted with 10% phosphoric acid to a pH of  $4.0 \pm 0.1$

**Solution B:** 1.1 mg/mL solution of 1-heptanesulfonic acid sodium salt in *Solution A*

**Mobile phase:** Stabilizer-free tetrahydrofuran and *Solution B* (3:17)

**Diluent:** Stabilizer-free tetrahydrofuran and water (3:17). [NOTE—The *Standard solutions* and *System suitability solution* are stable for up to 72 h at room temperature. The *Sample solution* is stable for up to 90 h at room temperature.]

**System suitability solution:** 100 µg/mL of [USP Ractopamine Hydrochloride RS](#) and 10 µg/mL of [USP Raspberry Alcohol RS](#) in *Diluent*

**Standard solution A:** 0.08 mg/mL of [USP Ractopamine Hydrochloride RS](#) in *Diluent*

**Standard solution B:** 0.1 mg/mL of [USP Ractopamine Hydrochloride RS](#) in *Diluent*

**Standard solution C:** 0.12 mg/mL of [USP Ractopamine Hydrochloride RS](#) in *Diluent*

**Sample stock solution:** Stir Ractopamine Hydrochloride Suspension in a 60° water bath for up to 1 h, to ensure complete dissolution. While hot, transfer 700 mg of the Ractopamine Hydrochloride Suspension dropwise to a 100-mL volumetric flask, and dilute with *Diluent* to volume.

**Sample solution:** Dilute a portion of the *Sample stock solution* with *Diluent* (1:10).

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 226 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Flow rate:** 1 mL/min

**Injection size:** 20 µL

#### System suitability

**Samples:** *System suitability solution* and *Standard solution B*

#### Suitability requirements

**Resolution:** NLT 1.5 between raspberry alcohol and ractopamine, *System suitability solution*

**Tailing factor:** NLT 0.7 and NMT 2.0 for the ractopamine peak, *Standard solution B*

**Relative standard deviation:** NMT 2.0% for three replicate injections, *Standard solution B*

## Analysis

**Samples:** *Standard solutions* and *Sample solution*

Prepare a calibration curve using the three ractopamine peak responses from *Standard solutions A, B, and C* and their corresponding concentrations. From the graph determine the concentration, *C*, in mg/mL, of ractopamine hydrochloride in the *Sample solution*.

Calculate the percentage (w/w) of  $C_{18}H_{23}NO_3 \cdot HCl$  in the portion of Ractopamine Hydrochloride Suspension taken:

$$\text{Result} = (V/W) \times C_s \times D \times 100$$

*V* = volume of the *Sample stock solution*, 100 mL

*W* = weight of Ractopamine Hydrochloride Suspension taken (mg)

*C<sub>s</sub>* = concentration of ractopamine hydrochloride from the *Sample solution*

*D* = dilution factor to prepare the *Sample solution*, 10

**Acceptance criteria:** 10%–20% of  $C_{18}H_{23}NO_3 \cdot HCl$

## IMPURITIES

### ORGANIC IMPURITIES

#### PROCEDURE

**Solution A:** 5.75 mg/mL of monobasic ammonium phosphate in water; pH NLT 4.4

**Solution B:** 1.1 mg/mL of 1-heptanesulfonic acid sodium salt in *Solution A*

**Solution C:** Acetonitrile and *Solution B* (1:9)

**Solution D:** Acetonitrile and *Solution B* (17:33)

**Mobile phase:** See the gradient table below.

| Time<br>(min) | Solution C<br>(%) | Solution D<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 100               | 0                 |
| 22            | 0                 | 100               |
| 32            | 0                 | 100               |
| 37            | 100               | 0                 |
| 55            | 100               | 0                 |

**Diluent:** Acetonitrile and water (1:4)

**System suitability solution:** 9 µg/mL each of [USP Raspberry Ketone RS](#) and [USP Ractopamine Hydrochloride RS](#) in *Diluent*

**Blank:** *Diluent*

**Sample solution A:** Stir Ractopamine Hydrochloride Suspension in a 60° water bath for up to 1 h, to ensure complete dissolution. While hot, transfer 200 mg of the Ractopamine Hydrochloride Suspension dropwise into a 50-mL volumetric flask, and dilute with *Diluent* to volume.

**Sample solution B:** Dilute a portion of *Sample solution A* with *Diluent* (1:100). [NOTE—The *Sample solutions* are stable for up to 48 h if stored at 5°.]

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 226 nm

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

**Flow rate:** 1 mL/min

**Injection size:** 20 µL

### System suitability

**Sample:** *System suitability solution*

**Suitability requirements**