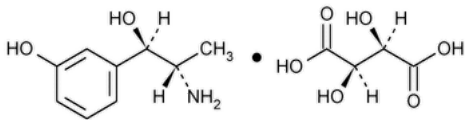


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Metaraminol Bitartrate



$C_9H_{13}NO_2 \cdot C_4H_6O_6$ 317.29
Benzenemethanol, α -(1-aminoethyl)-3-hydroxy-, [*R*-(*R**,*S**)]-, [*R*-(*R**,*R**)]-2,3-dihydroxybutanedioate (1:1) (salt);
(-)- α -(1-Aminoethyl)-*m*-hydroxybenzyl alcohol tartrate (1:1) (salt) CAS RN®: 33402-03-8; UNII: ZC4202M9P3.

DEFINITION

Metaraminol Bitartrate contains NLT 98.0% and NMT 102.0% of metaraminol bitartrate ($C_9H_{13}NO_2 \cdot C_4H_6O_6$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197K
- **B.** 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: Dissolve 3.24 g of anhydrous [octanesulphonic acid sodium salt](#) in 1 L of water.

Solution B: [Acetonitrile](#) and [water](#) (90:10)

Diluent: [Acetonitrile](#) and [water](#) (20:80)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
5	80	20
20	5	95
30	5	95
30.1	80	20
40	80	20

Standard solution: 0.75 mg/mL of [USP Metaraminol Bitartrate RS](#) in *Diluent*

Sample solution: 0.75 mg/mL of Metaraminol Bitartrate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 3-μm packing L1

Column temperature: 35°

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 metaraminol bitartrate ($C_9H_{13}NO_2 \cdot C_4H_6O_6$) in the portion of Metaraminol Bitartrate taken:

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

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

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

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

C_U = concentration of Metaraminol Bitartrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Solution A, Solution B, Diluent, Mobile phase, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Peak identification solution: 0.1 mg/mL each of [USP Metaraminol Bitartrate RS](#), [USP Metaraminol Related Compound A RS](#), and [USP Metaraminol Related Compound B RS](#) in *Diluent*

Sensitivity solution: 0.76 µg/mL of [USP Metaraminol Bitartrate RS](#) in *Diluent* from the *Standard solution*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Signal-to-noise ratio: NLT 15, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of metaraminol related compound A and any unspecified impurity in the portion of Metaraminol Bitartrate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of metaraminol related compound A or any unspecified impurity from the *Sample solution*

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria: See [Table 2](#). Disregard peaks due to tartaric acid and metaraminol related compound B.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tartaric acid	0.13 and 0.14	—
Metaraminol	1.00	—
Metaraminol related compound B	1.52	—
Metaraminol related compound A	1.82	0.15
Any unspecified impurity	—	0.10
Total impurities	—	1.0

• LIMIT OF METARAMINOL RELATED COMPOUND B

Solution A: Dissolve 1.88 g of anhydrous [1-hexane sulfonic acid sodium salt](#) and 1.36 g of [monobasic potassium phosphate](#) in 1 L of [water](#).

Adjust with dilute [phosphoric acid](#) to a pH of 2.6.