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Monensin Type A Medicated Article

DEFINITION

Monensin Type A Medicated Article contains Monensin Granulated mixed with suitable diluents and inactive ingredients. It contains the equivalent of NLT 85.0% and NMT 115.0% of the labeled amount of monensin.

IDENTIFICATION

• **A.** The retention times of the major peak for monensin A and minor peak for monensin B of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Methanol, glacial acetic acid, and water (940:1:60)

Neutralized methanol: Add 1 g of sodium bicarbonate to 4 L of methanol, mix, and filter.

Diluent: Methanol and water (9:1)

Derivatizing reagent: Dissolve 3 g of vanillin in a mixture of 95 mL of methanol and 2 mL of sulfuric acid. [**Caution—**To avoid splattering, add the sulfuric acid carefully and slowly with a pipet; do not pour. Allow the mixture of methanol and sulfuric acid to cool before adding vanillin.]

System suitability solution: 1 mg/mL of USP Monensin Sodium RS and 3 mg/mL of USP Narasin RS in *Neutralized methanol*. Dilute 2 mL of this solution with *Diluent* to 200 mL.

Standard stock solution: 1000 µg/mL of monensin from USP Monensin Sodium RS in methanol

Standard solution: 20 µg/mL of monensin from *Standard stock solution* in *Diluent*

Sample stock solution: Dilute 5 g of Monensin Type A Medicated Article in 200.0 mL of *Diluent*, and shake by mechanical means for 1 h. Allow the solids to settle.

Sample solution: Nominally 20 µg/mL of monensin, from the clear supernatant of the *Sample stock solution*, in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 520 nm

Column: 4.6-mm × 25-cm; packing L1. The column outlet is attached to a tee, the opposing arm is attached to a tube from which is pumped the *Derivatizing reagent,* and the outlet is connected to a 2-mL postcolumn reaction coil maintained at 98°. The outlet of the reaction coil is connected to the *Detector*.

Flow rate: 0.7 mL/min for *Mobile phase* and *Derivatizing reagent*

Injection volume: 200 µL

System suitability

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

[Note—The relative retention times for monensin B, monensin A, narasin A, and narasin I are about 0.9, 1.0, 1.3, and 1.5, respectively.]

Suitability requirements

Resolution: NLT 1.25 between the monensin B and the monensin A peaks; NLT 3.5 between the monensin A and the narasin A peaks, *System suitability solution*

Tailing factor: NMT 1.4, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

[Note—After use, flush the system with methanol.]

Analysis

Samples: *Standard solution* and *Sample solution*

[Note—Use peak areas where peak responses are indicated.]

Measure the responses for the major peaks, including a peak for monensin C/D, if present, at a retention time of 1.1 relative to that of the main monensin A peak in the chromatogram from the *Sample solution*.

Calculate the quantity, in mg, of monensin A, monensin B, and monensin C/D in each g of Monensin Type A Medicated Article taken:

$$\text{Result} = (r_U/r_S) \times (C_S \times F \times D)/(100{,}000 \times W)$$

r_U = peak response of monensin A, monensin B, or monensin C/D from the *Sample solution*

r_S = peak response of monensin A from the *Standard solution*

C_S = concentration of monensin activity in the *Standard solution*, based on the quantity of USP Monensin Sodium RS taken, its designated potency (µg/mg) and extent of dilution (µg/mL)

F = designated percentage of monensin A in USP Monensin Sodium RS

D = dilution factor used in preparing the *Sample solution*

W = quantity of Monensin Type A Medicated Article taken to prepare the *Sample solution* (g)

Calculate the potency, in mg, of monensin in each g of Monensin Type A Medicated Article taken:

$$\text{Result} = (A \times F_A) + (B \times F_B) + (C/D \times F_{C/D})$$

A = quantity of monensin A in each g of Monensin Type A Medicated Article taken, as calculated previously (mg)

F_A = biopotency conversion factor for monensin A, 1.00

B = quantity of monensin B in each g of Monensin Type A Medicated Article taken, as calculated previously (mg)

F_B = biopotency conversion factor for monensin B, 0.28

C/D = quantity of monensin C/D in each g of Monensin Type A Medicated Article taken, as calculated previously (mg)

$F_{C/D}$ = biopotency conversion factor for monensin C/D, 1.50

Acceptance criteria: 85.0%–115.0%

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩**

Analysis: Dry under vacuum at 60° for 2 h.

Acceptance criteria: NMT 10%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Avoid moisture and excessive heat.
- **Labeling:** Label it to indicate that it is for veterinary use only. The label bears the statement “Do not feed undiluted”.
- **USP Reference Standards ⟨11⟩**

USP Monensin Sodium RS
USP Narasin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MONENSIN TYPE A MEDICATED ARTICLE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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