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Narasin Type A Medicated Article

(Title for this monograph not to change until December 1, 2017)

(Prior to December 1, 2017, the current practice of labeling the article of commerce with the name Narasin Premix may be continued. Use of the name Narasin Type A Medicated Article will be permitted as of June 1, 2017; however, the use of this name will not be mandatory until December 1, 2017.)

DEFINITION

Narasin Type A Medicated Article contains Narasin Granular mixed with suitable diluents and inactive ingredients. It contains NLT 90% and NMT 110% of the labeled amount of narasin.

IDENTIFICATION

• **A.** The retention time of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Methanol, water, and glacial acetic acid (94:6:0.1)

Diluent: Methanol and water (9:1)

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

Derivatizing reagent: 30 g of vanillin in a mixture of methanol and sulfuric acid (950:20), in a container protected from light. [**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 the vanillin. Do not filter.]

System suitability solution: Prepare a solution containing 3 mg/mL of USP Narasin RS and 1 mg/mL of USP Monensin Sodium RS in *Neutralized methanol*. Dilute 2.0 mL of this solution with *Diluent* to 200 mL.

Standard stock solution: 1 mg/mL of USP Narasin RS in *Neutralized methanol*

Standard solution A: 5 µg/mL of USP Narasin RS from *Standard stock solution*, in *Diluent*

Standard solution B: 20 µg/mL of USP Narasin RS from *Standard stock solution*, in *Diluent*

Standard solution C: 40 µg/mL of USP Narasin RS from *Standard stock solution*, in *Diluent*

Sample solution: Transfer 5 g of Narasin Type A Medicated Article to a suitable container, add 200.0 mL of *Diluent*, and shake by mechanical means for 1 h. Allow the solids to settle, and quantitatively dilute a volume of the supernatant with *Diluent* to obtain a solution with a nominal concentration of 20 µg/mL of narasin. Pass a portion of this solution through a filter of 0.5-µm or finer pore size, and use the filtrate.

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 the *Mobile phase* and the *Derivatizing reagent*

Injection volume: 200 µL

System suitability

Samples: *System suitability solution*, *Standard solution A*, *Standard solution B*, and *Standard solution C*

[Note—The relative retention times for monensin B, monensin A, narasin A, and narasin D+I are 0.7, 0.75, 1.0, and 1.1, respectively.]

Suitability requirements

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

Tailing factor: NMT 1.4 for the narasin A peak, *Standard solution A*, *Standard solution B*, and *Standard solution C*, when calculated:

$$\text{Result} = W_{0.1}/2f$$

$W_{0.1}$ = width of the peak at 10% of peak height

f = distance from the peak maximum to the leading edge of the peak, the distance being measured at a point on the baseline at which 10% peak height is reached

Relative standard deviation: NMT 10.0%, *Standard solution A*, *Standard solution B*, and *Standard solution C*

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

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

[NOTE—Narasin D and narasin I will coelute under this chromatographic system.]

Plot the three narasin peak responses from the *Standard solutions* versus the concentration (µg/mL) of narasin A, and draw the straight line best fitting the three plotted points. From the graph and the narasin A peak response from the *Sample solution*, determine the concentration, C_A, in µg/mL, of narasin A in the *Sample solution.* From the same graph and the narasin D+I peak response from the *Sample solution,* determine the concentration, C_{D+I}, in µg/mL, of narasin D+I in the *Sample solution*.

Calculate the biopotency conversion factor, F_{D+I}, for narasin D+I:

$$\text{Result} = [(F_D \times D) + (F_I \times I)]/(D + I)$$

F_D = biopotency conversion factor for narasin D, 1.510

D = specified percentage of narasin D in USP Narasin RS

F_I = biopotency conversion factor for narasin I, 0.012

I = specified percentage of narasin I in USP Narasin RS

Calculate the biopotency, in mg/g, in the portion of Narasin Type A Medicated Article taken:

$$\text{Result} = 0.001 \times [(C_A \times F_A) + (C_{D+I} \times F_{D+I})] \times (V \times E/M)$$

C_A = concentration of narasin A in the *Sample solution* (µg/mL)

F_A = biopotency conversion factor for narasin A, 1.077

C_{D+I} = concentration of narasin D+I in the *Sample solution* (µg/mL)

F_{D+I} = biopotency conversion factor for narasin D+I, calculated previously

V = extraction volume (mL)

E = dilution factor to prepare the final estimated *Sample solution* concentration of 20 µg/mL

M = weight of Narasin Type A Medicated Article taken to prepare the *Sample solution* (g)

Acceptance criteria: 90%–110%

SPECIFIC TESTS

- **LOSS ON DRYING ⟨731⟩**

Analysis: Dry under vacuum at 60° for 3 h.

Acceptance criteria: NMT 12%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Avoid moisture and excessive heat.
- **LABELING:** Label it to indicate that it is for animal 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
NARASIN TYPE A MEDICATED ARTICLE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

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