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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

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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](#)