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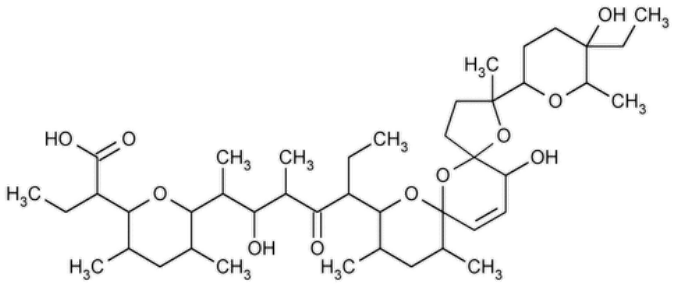
# Narasin Granular



$C_{43}H_{72}O_{11}$ (narasin A) 765.03
$C_{43}H_{70}O_{11}$ (narasin B) 763.01
$C_{44}H_{74}O_{11}$ (narasin D) 779.05
$C_{44}H_{74}O_{11}$ (narasin I) 779.05

Narasin.

2*H*-Pyran-2-acetic acid, α-ethyl-6-[5-[2-(5-ethyltetrahydro-5-hydroxy-6-methyl-2*H*-pyran-2-yl)-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5.3]pentadec-13-en-9-yl]-2-hydroxy-1,3-dimethyl-4-oxoheptyl]tet rahydro-3,5-dimethyl-.

α-Ethyl-6-[5-[2-(5-ethyltetrahydro-5-hydroxy-6-methyl-2*H*-pyran-2-yl)-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5.3]pentadec-13-en-9-yl]-2-hydroxy-1,3-dimethyl-4-oxoheptyl]tetrahydro-3,5-dimethyl-2*H*-pyran-2-acetic acid CAS RN®: 55134-13-9; UNII: DZY9VU539P.

» Narasin Granular contains narasin mixed with suitable carriers and inactive ingredients prepared in a granular form that is free-flowing and free of aggregates. It contains not less than 100 mg and not more than 160 mg of narasin per g.

**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. Label it also to indicate that it is for manufacturing, processing, or repackaging.

**USP Reference standards** ⟨11⟩—

USP Monensin Sodium RS
USP Narasin RS

**Identification**—The retention time of the major peak for narasin A in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

**Loss on drying** ⟨731⟩—Dry it in vacuum at 60° for 3 hours: it loses not more than 10% of its weight.

**Powder fineness** ⟨811⟩—Not less than 99% passes a No. 30 sieve, and not more than 15% passes a No. 140 sieve.

**Content of narasin A**—Using the chromatogram of the *Assay preparation* obtained as directed in the *Assay*, calculate the percentage of narasin A by the formula:

$$100A/[A + (D + I)]$$

in which *A* is the narasin A biopotency and *D* + *I* is the narasin *D* + *I* biopotency. Not less than 85% of narasin A is found.

**Assay**—

*Diluent*—Prepare a mixture of methanol and water (9:1).

*Mobile phase*—Prepare a degassed mixture of methanol, water, and glacial acetic acid (94:6:0.1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

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

*Derivatizing reagent*—Dissolve 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.

*Resolution solution*—Prepare a solution in *Neutralized methanol* containing about 3 mg of USP Narasin RS and 1 mg of USP Monensin Sodium RS per mL. Transfer 2 mL of this solution to a 200-mL volumetric flask, dilute with *Diluent* to volume, and mix.

*Standard preparations*—Dissolve an accurately weighed quantity of USP Narasin RS in *Neutralized methanol* to obtain a solution having a known concentration of about 1 mg per mL. Transfer 1.0 mL of this stock solution to a 200-mL volumetric flask, and transfer 2.0 mL and 4.0 mL of the stock solution to two separate 100-mL volumetric flasks, dilute each with *Diluent* to volume, and mix. These solutions contain about 5, 20, and 40 µg of USP Narasin RS per mL. Using the designated percentage of narasin A in the USP Narasin RS, calculate the exact narasin A concentration, in µg per mL, in each of the *Standard preparations*.

*Assay preparation*—Transfer about 5 g of Narasin Granular, accurately weighed, to a suitable container, add 200.0 mL of *Diluent,* and shake by mechanical means for 1 hour. Allow the solids to settle, and quantitatively dilute an accurately measured volume of the supernatant with *Diluent* to obtain a solution containing about 20 µg of narasin per mL. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity, and use the filtrate as the *Assay preparation*.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 4.6-mm × 25-cm column that contains 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 a detector set at 520 nm. The *Mobile phase* and the *Derivatizing reagent* flow at the rate of about 0.7 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.7 for monensin B, 0.75 for monensin A, 1.0 for narasin A, and 1.1 for narasin D + I; and the resolution, *R,* between the monensin B peak and the monensin A peak is not less than 1.25, and between the monensin A peak and the narasin A peak not less than 3.5. Chromatograph the *Standard preparations,* and record the peak responses as directed for *Procedure:* the tailing factor for the narasin A peak is not more than 1.4 when calculated by the formula:

$$W_{0.1}/2f$$

in which $W_{0.1}$ is the width of the peak at 10% of peak height; and $f$ is the 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. The relative standard deviation for replicate injections is not more than 10%. [Note—After use, flush the system with methanol.]

*Procedure*—Separately inject equal volumes (about 200 µL) of the *Standard preparations* and the *Assay preparation* into the chromatograph, and measure the areas of the peak responses for the narasin A and narasin D + I peaks [Note—Narasin D and narasin I will co-elute under this chromatographic system.]

Plot the three narasin peak responses in the chromatograms obtained from the *Standard preparations* versus the concentration, in µg per mL, of narasin A, and draw the straight line best fitting the three plotted points. From the graph so obtained, and the narasin A peak response in the chromatogram obtained from the *Assay preparation,* determine the concentration, $C_A$, in µg per mL, of narasin A in the *Assay preparation.* From the same graph and the narasin D + I peak response in the chromatogram obtained from the *Assay preparation,* determine the concentration, $C_{D+I}$, in µg per mL, of narasin D + I in the *Assay preparation.* Calculate the biopotency, in mg per g, in the portion of Narasin Granular taken by the formula:

$$(0.001)(C_A F_A + C_{D+I} F_{D+I})(VE/M)$$

in which $F_A$ is 1.077 representing the biopotency conversion factor for narasin A; $F_{D+I}$ is the biopotency conversion factor for narasin D + I; $V$ is the extraction volume, in mL; $E$ is the dilution factor used in diluting the extract to the final estimated concentration of 20 µg per mL; and $M$ is the weight, in g, of Narasin Granular taken to prepare the *Assay preparation.* Calculate the bioconversion factor, $F_{D+I}$, for narasin D + I by the formula:

$$(1.510D + 0.012I)/(D + I)$$

in which $D$ and $I$ are the specified percentages of narasin D and narasin I, respectively, in USP Narasin RS; 1.510 is the factor for converting narasin D to narasin D biopotency; and 0.012 is the factor for converting narasin I to narasin I biopotency.



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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| NARASIN GRANULAR | Documentary Standards Support | SM32020 Small Molecules 3 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM32020 Small Molecules 3 |

**Chromatographic Database Information:** Chromatographic Database

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