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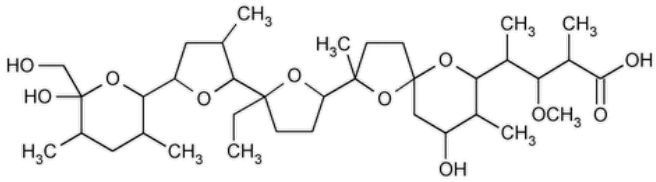
Monensin



$C_{36}H_{62}O_{11}$ (monensin A) 670.87
$C_{35}H_{60}O_{11}$ (monensin B) 656.84
$C_{37}H_{64}O_{11}$ (monensin C) 684.90

Monensin.

Stereoisomer of 2-[2-ethyloctahydro-3'-methyl-5'-[tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethyl-2*H*-pyran-2-yl][2,2'-bifuran-5-yl]]-9-hydroxy-β-methoxy-α,γ,2,8-tetramethyl-1,6-dioxaspiro[4.5]decan-7-butanoic acid CAS RN®: 17090-79-8; UNII: 906O0YJ6ZP.

» Monensin is a mixture of antibiotic substances produced by the growth of *Streptomyces cinnamonensis.* It has a potency of not less than 110 µg of monensin per mg.

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

USP Reference standards ⟨11⟩—

USP Monensin Sodium RS
USP Narasin RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for monensin A and a minor peak for monensin B, the retention times of which correspond to those exhibited in the chromatogram of the *Standard preparation*, obtained as directed in the *Assay*.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 2 hours: it loses not more than 10% of its weight.

Content of monensin A and B activity—Using the results of the calculations in the *Assay*, calculate the percentage of monensin A activity in the Monensin under test by the formula:

$$100A/P$$

in which *A* is the potency, in µg per mg, of monensin A in the Monensin under test, as determined in the *Assay*, and *P* is the potency, in µg of monensin, in each mg of the Monensin under test, as determined in the *Assay:* not less than 90% is found. Calculate the percentage of monensin A activity plus monensin B activity in the Monensin under test by the formula:

$$100(A + B)/P$$

in which *B* is the potency, in µg per mg, of monensin B in the Monensin under test, as determined in the *Assay*, and the other terms are as defined above: not less than 95% is found.

Assay—

Mobile phase—Prepare a filtered and 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 liters of methanol, mix, and filter.

Diluent—Prepare a mixture of 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.*]

Standard preparation—Dissolve an accurately weighed quantity of USP Monensin Sodium RS quantitatively in methanol to obtain a solution containing the equivalent of 1000 µg of monensin per mL. Dilute an accurately measured volume of this stock solution quantitatively with *Diluent* to obtain a solution containing 20.0 µg of monensin per mL.

Assay preparation—Transfer about 500 mg of Monensin, accurately weighed, to a 250-mL flask, add 200.0 mL of *Diluent*, and shake by mechanical means for 1 hour. Allow the solids to settle, and dilute an accurately measured volume of the supernatant quantitatively with *Diluent* to obtain a solution containing about 20 µg of monensin per mL.

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

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 4.6-mm × 25-cm column that contains packing L1 and the outlet of which is attached to a tee, the opposing arm of which is attached to a tube from which is pumped the *Derivatizing reagent*, and the outlet of which 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 under *Procedure:* the relative retention times are about 0.9 for monensin B, 1.0 for monensin A, 1.3 for narasin A, and 1.5 for narasin I, 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 is not less than 3.5. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the tailing factor is not more than 1.4, and the relative standard deviation for replicate injections is not more than 2.0%. [NOTE—After use, flush the system with methanol.]

Procedure—[NOTE—Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 200 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks, including a peak for monensin C/D, if present, at a retention time of about 1.1 relative to that of the main monensin A peak in the chromatogram obtained from the *Assay preparation*. Calculate the quantity, in µg, of monensin A in each mg of the Monensin taken by the formula:

$$(CFD/100{,}000W)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of monensin activity in the *Standard preparation*, based on the quantity of USP Monensin Sodium RS taken, its designated potency, in µg per mg, and the extent of dilution, F is the designated percentage of monensin A in USP Monensin Sodium RS, D is the dilution factor used in preparing the *Assay preparation*, W is the quantity, in g, of Monensin taken to prepare the *Assay preparation*, and r_U and r_S are the monensin A peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively. Calculate the quantity, in µg, of monensin B in each mg of the Monensin taken by the same formula, except that r_U is the monensin B peak response obtained from the *Assay preparation* and r_S is the monensin A peak response obtained from the *Standard preparation*. Calculate the quantity, in µg, of monensin C/D in each mg of the Monensin taken by the same formula, except that r_U is the monensin C/D peak response obtained from the *Assay preparation*. Calculate the potency, in µg of monensin, in each mg of the Monensin taken by the formula:

$$A + 0.28B + 1.5C/D$$

in which A is the quantity, in µg, of monensin A in each mg of the Monensin taken, as calculated above, and B is the quantity, in µg, of monensin B in each mg of the Monensin taken, and C/D is the quantity, in µg, of monensin C/D in each mg of Monensin taken, as calculated above.

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

Topic/Question	Contact	Expert Committee
MONENSIN	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

Most Recently Appeared In:
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