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Monensin Granulated

» Monensin Granulated contains Monensin mixed with suitable diluents, carriers, and inactive ingredients prepared in a granulated form that is free-flowing and free from aggregates. It may contain added Monensin Sodium. It contains not less than 140 mg of monensin per g.

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 Granulated under test by the formula:

$$100A/P$$

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

Assay—

Mobile phase, Neutralized methanol, Diluent, Derivatizing reagent, Standard preparation, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Monensin*.

Assay preparation—Transfer about 5 g of Monensin Granulated, 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.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Monensin*. Calculate the quantity, in mg, of monensin A in each g of the Monensin Granulated 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 Granulated 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 mg, of monensin B in each g of the Monensin Granulated 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 mg, of monensin C/D in each g of the Monensin Granulated 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 Granulated taken by the formula:

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

in which A is the quantity, in mg, of monensin A in each g of the Monensin Granulated taken, as calculated above, and B is the quantity, in mg,

of monensin B in each g of the Monensin Granulated taken, and *C/D* is the quantity, in mg, of monensin C/D in each g of Monensin Granulated taken, as calculated above.

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

Topic/Question	Contact	Expert Committee
MONENSIN GRANULATED	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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