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Ivermectin Injection

» Ivermectin Injection is a sterile solution of Ivermectin in a suitable vehicle. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of ivermectin, calculated as the sum of component H_2B_{1a} ($C_{48}H_{74}O_{14}$) plus component H_2B_{1b} ($C_{47}H_{72}O_{14}$). The ratio of the contents, $H_2B_{1a}/(H_2B_{1a}+H_2B_{1b})$, is not less than 90.0 percent.

Packaging and storage—Preserve in single-dose or in multi-dose containers, preferably of Type I glass or plastic. Store at a temperature of not more than 30°.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Ivermectin RS

Identification—

A: Thin-Layer Chromatographic Identification Test ⟨201⟩—

Test solution—Dissolve a volume of the Injection in methanol, dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution containing 0.5 mg per mL of ivermectin, and filter.

Injection volume: 2 µL.

Developing solvent system: unsaturated chamber, consisting of a freshly prepared and equilibrated mixture of methylene chloride, methanol, and ammonium hydroxide (90:9:1).

Procedure—Remove the plate, allow to air dry, and examine under short- and long-wavelength UV light: the retardation factor, R_F, of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution*.

B: The retention times of the two principal component peaks of ivermectin in the chromatogram of the *Assay preparation* corresponds to that of the two principal component peaks of ivermectin in the chromatogram of the *Standard preparation,* obtained as directed in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.016 USP Endotoxin Unit per µg of ivermectin.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Chromatographic purity—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay*.

Standard solution—Dissolve an accurately weighed quantity of USP Ivermectin RS in methanol and dilute quantitatively, and stepwise if necessary, with methanol to obtain a 0.004 mg per mL solution.

Test solution—Dissolve a volume of the Injection in methanol and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution containing 0.4 mg of ivermectin per mL of solution, based on the label claim.

Procedure—Inject equal volumes (about 20 µL) of the *Test solution* and the *Standard solution* into the chromatograph, record the chromatograms, and measure all of the peak responses. Calculate the percentage of each impurity in the portion of Injection taken by the formula:

$$100(C_S/C_T)(r_i/r_S)$$

in which C_S is the concentration, in mg per mL, of ivermectin in the *Standard solution;* C_T is the concentration, in mg per mL, of ivermectin in the *Test solution;* r_i is the peak response for each individual peak obtained from the *Test solution;* and r_S is the ivermectin peak response obtained from the *Standard solution*. Not more than 2.7% of the peak with a relative retention time of about 1.3 to 1.5 to that of the principal peak is found; not more than 1.0% of any other impurity is found; and not more than 6.0% of total impurities is found. Disregard any peak below 0.05%.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, methanol, and water (106:55:39). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Ivermectin RS in methanol and dilute quantitatively, and stepwise if necessary, with methanol to obtain a 0.4 mg per mL solution.

Assay preparation—Dilute a volume of Injection in methanol and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution containing 0.4 mg of ivermectin per mL of solution, based on the label claim.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with 245-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between the first peak (component H_2B_{1b}) and the second peak (component H_2B_{1a}) is not less than 3.0; and the relative standard deviation for replicate injections is not more than 2.0%, determined from the component H_2B_{1a} peak.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the component H_2B_{1a} plus component H_2B_{1b}. Calculate the percentage of label claim of ivermectin (H_2B_{1a} + H_2B_{1b}) in the portion of Injection taken by the formula:

$$100(C_S/C_U)(r_U/r_S)$$

in which C_S is the concentration, in mg per mL, of USP Ivermectin RS in the *Standard preparation;* C_U is the concentration, in mg per mL, of ivermectin in the *Assay preparation;* r_U is the total peak response of H_2B_{1a} plus H_2B_{1b} peaks obtained from the *Assay preparation;* and r_S is the total peak response of H_2B_{1a} plus H_2B_{1b} peaks obtained from the *Standard preparation*. Calculate the ratio of the contents, in percent, of $H_2B_{1a}/(H_2B_{1a} + H_2B_{1b})$ in the portion of Injection taken by the formula:

$$100(r_1/r_U)$$

in which r_1 is the peak response of H_2B_{1a} obtained from the *Assay preparation;* and r_U is as defined above.

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

Topic/Question	Contact	Expert Committee
IVERMECTIN INJECTION	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

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