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Phenylbutazone Injection

» Phenylbutazone Injection is a sterile solution of Phenylbutazone in Sterile Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{20}N_2O_2$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Protect from light, and store in a refrigerator.

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

USP Reference standards ⟨11⟩—

USP Phenylbutazone RS

Clarity of solution—The Injection is essentially free from particles of foreign matter that can be observed on visual inspection.

Identification—

A: Transfer a volume of Injection, equivalent to about 500 mg of phenylbutazone, to a 250-mL conical flask, add 100 mL of solvent hexane, and heat the mixture under reflux for 15 minutes. Filter the hot mixture, and allow the filtrate to cool. Separate the crystals thus formed by filtration, and dry in vacuum at 80° for 30 minutes: the phenylbutazone so obtained responds to *Identification* test *A* under *Phenylbutazone*.

B: The retention time of the phenylbutazone peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

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

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.1 USP Endotoxin Units per mg of phenylbutazone.

pH ⟨791⟩: between 9.5 and 10.0.

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

Change to read:

Assay—

Acetate buffer, Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Phenylbutazone*.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 200 mg of phenylbutazone, to a 100-mL volumetric flask. Dilute with acetonitrile to volume, and mix. Transfer 7.0 mL of this solution to a 50-mL volumetric flask, add 10.0 mL of *Internal standard solution*, dilute with acetonitrile to volume, and mix. [Note—Use this solution within 8 hours of its preparation.]

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Phenylbutazone*. Calculate the quantity, in mg, of $C_{19}H_{20}N_2O_2$ in each mL of the Injection taken by the formula:

$$▲714.3▲_{\text{(ERR 1-Jun-2019)}}\,(C/V)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Phenylbutazone RS in the *Standard preparation*, V is the volume, in mL, of Injection taken to prepare the *Assay preparation*, and R_U and R_S are the ratios of the peak responses of phenylbutazone to that of the internal standard obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PHENYLBUTAZONE 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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