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Phenylbutazone Boluses

» Phenylbutazone Boluses contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of phenylbutazone ($C_{19}H_{20}N_2O_2$) and nominally not less than 1 g of phenylbutazone per bolus.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label Boluses to indicate that they are for veterinary use only.

USP Reference standards ⟨11⟩—
USP Phenylbutazone RS

Identification—

A: Transfer a portion of powdered Boluses, 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*.

Disintegration ⟨701⟩: 45 minutes with disks, determined as directed for *Uncoated Tablets*, simulated gastric fluid being used as the immersion fluid.

Uniformity of dosage units ⟨905⟩—meet the requirements for *Weight Variation*.

Assay—

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

Assay preparation—Weigh and finely powder a Phenylbutazone Bolus. Transfer an accurately weighed portion of the powder, equivalent to about 500 mg of phenylbutazone, to a 250-mL volumetric flask. Transfer 10.0 mL of water to the flask, and shake by mechanical means for 15 minutes. Add about 120 mL of acetonitrile, and sonicate until insoluble material is dispersed into fine particles. Shake by mechanical means for 20 minutes, 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. Pass a portion of this solution through a filter having a porosity of 0.5 µm or finer, discarding the first few mL of the filtrate. Use the clear filtrate as the *Assay preparation.* [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 the portion of the Bolus taken by the formula:

$$1786C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Phenylbutazone RS in the *Standard 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 BOLUSES	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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