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Phenylbutazone Tablets

» Phenylbutazone Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of phenylbutazone ($C_{19}H_{20}N_2O_2$) and nominally not more than 200 mg of phenylbutazone per Tablet.

Packaging and storage—Preserve in tight containers.

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

USP Reference standards ⟨11⟩—
USP Phenylbutazone RS

Identification—Transfer to a 250-mL conical flask a portion of powdered Tablets, equivalent to about 500 mg of phenylbutazone, 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*.

Dissolution ⟨711⟩—
Medium: pH 7.5 simulated intestinal fluid TS (without the enzyme); 900 mL.
Apparatus 1: 100 rpm.
Time: 30 minutes.
Procedure—Determine the amount of $C_{19}H_{20}N_2O_2$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 264 nm on filtered portions of the solution under test, suitably diluted, if necessary, with *Medium,* using a suitable spectrophotometer, 1-cm cells, and *Medium* as the blank, in comparison with a solution of known concentration of USP Phenylbutazone RS in the same *Medium.*
Tolerances—Not less than 70% *(Q)* is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.
Procedure for content uniformity—Transfer 1 Tablet to a 100-mL volumetric flask, add 60 mL of methanol, and shake by mechanical means for about 20 minutes or until the tablet is completely disintegrated. Dilute with methanol to volume, and mix. Filter a portion of mixture, discarding the first 10 mL of the filtrate. Dilute an accurately measured portion of the filtrate with sodium hydroxide solution (1 in 2500) to obtain a solution containing about 10 µg per mL. Prepare a solution of USP Phenylbutazone RS in methanol having a known concentration of about 1 mg per mL. Quantitatively dilute a portion of this solution with sodium hydroxide solution (1 in 2500) to obtain a Standard solution having a final known concentration of about 10 µg per mL. Concomitantly determine the absorbances of the solution from the Tablet and the Standard solution at the wavelength of maximum absorbance at about 264 nm with a suitable spectrophotometer, using sodium hydroxide solution (1 in 2500) as the blank. Calculate the quantity, in mg, of $C_{19}H_{20}N_2O_2$ in the Tablet by the formula:

$$(TC/D)(A_U/A_S)$$

in which T is the labeled quantity, in mg, of phenylbutazone in the Tablet; C is the concentration, in µg per mL, of USP Phenylbutazone RS in the Standard solution; D is the concentration, in µg per mL, of phenylbutazone in the solution from the Tablet based on the labeled quantity per Tablet and the extent of dilution; and A_U and A_S are the absorbances of the solution from the Tablet and the Standard solution, respectively.

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 not fewer than 20 Tablets. Accurately weigh a portion of the powder, equivalent to about 500 mg of phenylbutazone, and transfer to a 250-mL volumetric flask. Pipet 50 mL of water into 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. Centrifuge a portion of this solution. Pipet 7 mL of the solution into a 50-mL volumetric flask, add 10.0 mL of *Internal standard solution,* dilute with acetonitrile to volume, and mix. Pass a portion through a 0.5-µm filter, discarding the first few mL of the filtrate. [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 phenylbutazone ($C_{19}H_{20}N_2O_2$) in the portion of Tablets 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 response of phenylbutazone to that of the internal standard for 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 TABLETS	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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