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Probenecid Tablets

» Probenecid Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $C_{13}H_{19}NO_4S$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Probenecid RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: Assay preparation.

B: Finely powder a quantity of Tablets, equivalent to about 500 mg of probenecid, triturate the powder with alcohol, and filter. Evaporate the filtrate to about 20 mL, cool, acidify with hydrochloric acid until acid to litmus, remove the crystals by filtration, and recrystallize from diluted alcohol: the probenecid so obtained melts between 196° and 200°, as determined by the method for *Class Ia* under *Melting Range or Temperature ⟨741⟩*, and responds to *Identification* test *A* under *Probenecid.*

Dissolution ⟨711⟩—

Medium: simulated intestinal fluid TS, prepared without pancreatin, pH 7.5 ± 0.1; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{13}H_{19}NO_4S$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 244 nm on filtered portions of the solution under test, suitably diluted with 0.1 N sodium hydroxide, if necessary, in comparison with a Standard solution having a known concentration of USP Probenecid RS.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{13}H_{19}NO_4S$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—Weigh and finely powder not less than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 100 mg of probenecid, and transfer to a 250-mL volumetric flask. Add chloroform to volume, and mix. Filter a portion of the chloroform solution, discarding the first 20 to 25 mL of the filtrate, and pipet 5 mL of the filtrate into a 125-mL separator containing 10 mL of chloroform. Extract the chloroform layer with four 15-mL portions of sodium carbonate solution (1 in 100). Render the combined extracts distinctly acid with 5 N hydrochloric acid, and extract with four 20-mL portions of chloroform, filtering each extract through a small pledget of cotton into a 100-mL volumetric flask. Wash the cotton filter with 10 mL of chloroform, add chloroform to volume, and mix. Dissolve an accurately weighed quantity of USP Probenecid RS in chloroform, and dilute quantitatively and stepwise with chloroform to obtain a Standard solution having a known concentration of about 20 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 257 nm, with a suitable spectrophotometer, using chloroform as the blank. Calculate the quantity, in mg, of $C_{13}H_{19}NO_4S$ in the portion of Tablets taken by the formula:

$$5C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Probenecid RS in the Standard solution; and A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
PROBENECID TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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