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Stanozolol Tablets

» Stanozolol Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of stanozolol ($C_{21}H_{32}N_2O$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Stanozolol RS

Identification—Boil an amount of powdered Tablets, equivalent to about 2 mg of stanozolol, with 5 mL of benzene, filter, and evaporate on a steam bath to dryness. Add 3 mL of *p*-dimethylaminobenzaldehyde TS to the residue: a yellow color develops, which exhibits a green fluorescence under long-wavelength UV light.

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 500 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Determine the amount of $C_{21}H_{32}N_2O$ dissolved by employing the following method.

Bromocresol purple solution—Mix 1.0 g of bromocresol purple with 1000 mL of dilute glacial acetic acid (1 in 50), and filter if necessary to obtain a clear solution.

Standard preparations—[Note—Prepare *Standard preparations* on the day of use.] Transfer about 50 mg of USP Stanozolol RS, accurately weighed, to a 50-mL volumetric flask, add 15.0 mL of methanol, and mix to dissolve. Add 5.0 mL of 1.0 N hydrochloric acid, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 200-mL volumetric flask, dilute with *Dissolution Medium* to volume, and mix. Separately pipet 2-mL, 4-mL, and 6-mL portions of the solution into three 60-mL separators, add accurately measured volumes of *Dissolution Medium* to adjust the volumes in each to 25.0 mL, and pipet 25 mL of *Dissolution Medium* into a fourth 60-mL separator.

Procedure—Pipet 25 mL of a filtered portion of the solution under test into a 60-mL separator. To this separator and to each of the four separators containing *Standard preparations* add 1.0 mL of *Bromocresol purple solution* and 10.0 mL of chloroform. Insert the stopper in each, shake gently for 1 minute, allow the phases to separate, and swirl if necessary to break up emulsions. Transfer the lower chloroform layers to separate 50-mL centrifuge tubes, insert the glass stoppers, and centrifuge for 5 minutes to clarify the solutions. Concomitantly determine the absorbances of the solutions obtained from the solution under test and from the *Standard preparation* in 1-cm cells, at the wavelength of maximum absorbance at about 420 nm, with a suitable spectrophotometer, using chloroform as the blank. Construct a standard plot of absorbances versus the concentrations of the solutions from the *Standard preparations.* From the plot so obtained, determine the amount of $C_{21}H_{32}N_2O$ dissolved in the solution from the solution under test.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{21}H_{32}N_2O$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩—[Note—Maintain the acid concentration at a uniform level in the solutions being compared spectrophotometrically; the same acidic alcohol solution is to be used throughout this procedure. Also, take precautions throughout this procedure to minimize evaporation.] Transfer 1 Tablet to a 25-mL volumetric flask, add 0.5 mL of water, and shake to disintegrate. Add about 20 mL of alcohol, heat on a steam bath, with occasional swirling, for 10 to 15 minutes, then cool, dilute with alcohol to volume, and mix. Filter through medium-porosity filter paper, taking precautions to minimize evaporation, discard the first 5 mL of the filtrate, and proceed as directed for *Assay preparations* in the *Assay*, beginning with “Transfer 5.0 mL of the filtrate.”

Assay—[Note—Maintain the acid concentration at a uniform level in the solutions being compared spectrophotometrically; the same acidic alcohol solution is to be used throughout this procedure.]

Standard preparations—Dissolve a suitable quantity of USP Stanozolol RS, accurately weighed, in alcohol, and dilute quantitatively and stepwise with alcohol, if necessary, to obtain a stock solution having a known concentration of about 80 µg per mL. Transfer 5.0 mL of this stock solution to a 10-mL volumetric flask, dilute with alcohol to volume, and mix to prepare the *Neutral standard preparation.* Transfer another 5.0-mL portion of the stock solution to a second 10-mL volumetric flask, dilute with acidic alcohol (1.5 mL of hydrochloric acid in 100 mL of alcohol) to volume, and mix to prepare the *Acidic standard preparation.* The concentration of USP Stanozolol RS in the *Standard preparations* is about 40 µg per mL.

Assay preparations—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 4 mg of stanozolol, to a 50-mL volumetric flask, add about 25 mL of alcohol, and heat on a steam bath, with frequent swirling, for 15 minutes. Cool, dilute with alcohol to volume, mix, filter through medium-porosity filter paper, taking precautions to minimize evaporation, and discard the first 10 mL of the filtrate. Transfer 5.0 mL of the filtrate to a 10-mL volumetric flask, dilute with alcohol to volume, and mix to prepare the *Neutral assay preparation.* Transfer another 5.0-mL portion of the filtrate to a second 10-mL volumetric flask, dilute with acidic alcohol (1.5 mL of hydrochloric acid in 100 mL of alcohol) to volume, and mix to prepare the *Acidic assay preparation.*

Procedure—Concomitantly determine the absorbances of the acidic alcohol solution, the *Acidic standard preparation*, and the *Acidic assay preparation* in 1-cm cells at the wavelength of maximum absorbance at about 235 nm, with a suitable spectrophotometer, using alcohol, the *Neutral standard preparation*, and the *Neutral assay preparation*, respectively, as the blanks. Calculate the quantity, in mg, of $C_{21}H_{32}N_2O$ in the portion of Tablets taken by the formula:

$$0.1C(A_U - A_O)/(A_S - A_O)$$

in which C is the concentration, in µg per mL, of USP Stanozolol RS in the *Standard preparations;* and A_U, A_S, and A_O are the absorbances of the *Acidic assay preparation*, the *Acidic standard preparation*, and the acidic alcohol solution, respectively.

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

Topic/Question	Contact	Expert Committee
STANOZOLOL TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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