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Perphenazine Tablets

DEFINITION

Perphenazine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of perphenazine ($C_{21}H_{26}ClN_3OS$).

[Note—Throughout the following procedures, protect samples, the Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.]

IDENTIFICATION

• **A.**

Standard solution: 1 mg/mL of USP Perphenazine RS in methanol

Sample solution: Shake a portion of finely powdered Tablets, nominally equivalent to 5 mg of perphenazine, with 10 mL of chloroform. Filter, evaporate the filtrate on a steam bath nearly to dryness, and dissolve the residue in 5 mL of methanol.

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: Acetone and ammonium hydroxide (200:1)

Iodoplatinic acid: Dissolve 100 mg of chloroplatinic acid in 1 mL of 1 N hydrochloric acid. Add 25 mL of potassium iodide solution (4 in 100), dilute with water to 100 mL, and add 0.50 mL of formic acid.

Spray reagent: *Iodoplatinic acid*

Analysis

Samples: *Standard solution* and *Sample solution*

Develop using the *Developing solvent system* until the solvent front has moved 15 cm. Air-dry the plate, and spray lightly with *Spray reagent*.

Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from the *Standard solution.*

ASSAY

• **Procedure**

Solution A: Transfer 10 mL of hydrochloric acid to a 1000-mL flask containing 500 mL of alcohol and 300 mL of water. Dilute with water to volume.

Solution B: Dissolve 100 mg of palladium chloride in a mixture of 1 mL of hydrochloric acid and 50 mL of water in a 100-mL volumetric flask, heating on a steam bath to effect solution. Cool, dilute with water to volume, and mix. Store in an amber bottle and use within 30 days. On the day of use, transfer 50 mL to a 500-mL volumetric flask, add 4 mL of hydrochloric acid and 4.1 g of anhydrous sodium acetate, dilute with water to volume, and mix.

Standard solution: 160 µg/mL of USP Perphenazine RS in *Solution A*

Sample solution: Nominally 160 µg/mL of perphenazine prepared as follows. Transfer a portion of powder, equivalent to 4 mg of perphenazine from NLT 20 finely powdered Tablets, to a glass-stoppered conical flask. Pipet into the flask 25 mL of *Solution A*, shake by mechanical means for 30 min, and centrifuge a portion of the mixture. Use the clear supernatant fluid.

Instrumental conditions

Mode: Vis

Analytical wavelength: Maximum absorbance at about 480 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Solution B*

Mix 10.0 mL each of the *Sample solution* and the *Standard solution* with 15.0 mL of *Solution B*. Filter, if necessary, and determine the absorbances of these solutions against a reagent blank.

Calculate the percentage of the labeled amount of perphenazine ($C_{21}H_{26}ClN_3OS$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Perphenazine RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of perphenazine in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of USP Perphenazine RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* to a concentration similar to that of the *Standard solution.*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 257 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of perphenazine ($C_{21}H_{26}ClN_3OS$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of perphenazine ($C_{21}H_{26}ClN_3OS$) is dissolved.

• **Uniformity of Dosage Forms** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Perphenazine RS

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

Topic/Question	Contact	Expert Committee
PERPHENAZINE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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