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# Indapamide Tablets

» Indapamide Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{16}H_{16}ClN_3O_3S$.

**Packaging and storage**—Preserve in well-closed containers.

**USP Reference standards** ⟨11⟩—

USP Indapamide RS

**Identification**—

**A:** Crush a quantity of Tablets, equivalent to about 15 mg of indapamide, remove and discard any coating material, and finely powder the remaining tablet cores. Agitate the powdered tablets with two 30-mL portions of 0.2 N sodium hydroxide in a centrifuge tube for 10 minutes. Centrifuge each mixture, and combine the supernatants in a 250-mL separator. Acidify the liquid with about 12 mL of dilute hydrochloric acid (1 in 10). Extract the acidic solution with two 4.0-mL portions of ether, filter the extracts through anhydrous sodium sulfate contained in a filter paper, and evaporate the ether, with the aid of a current of dry air, on a water bath. Dry the crystals at 105° for 1 hour: the crystals so obtained respond to *Identification* test *A* under *Indapamide.*

**B:** The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* obtained as directed in the *Assay.*

**Dissolution** ⟨711⟩—

*Medium:* 0.05 M pH 6.8 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

*Apparatus 1:* 100 rpm.

*Time:* 45 minutes.

Determine the amount of $C_{16}H_{16}ClN_3O_3S$ dissolved by employing the following method.

*Mobile phase*—Proceed as directed in the *Assay*.

*Standard solution*—Dissolve an accurately weighed quantity of USP Indapamide RS in methanol, and dilute quantitatively, and stepwise if necessary, with a mixture of *Medium* and methanol (99:1) to obtain a solution having a known concentration equivalent to the solution under test.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 242-nm detector and a 4.6-mm × 15-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 50 µL) of a filtered portion of the solution under test and the *Standard solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Determine the amount of $C_{16}H_{16}ClN_3O_3S$ dissolved.

*Tolerances*—Not less than 75% *(Q)* of the labeled amount of $C_{16}H_{16}ClN_3O_3S$ is dissolved in 45 minutes.

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

**Assay**—

*Mobile phase*—Dissolve 1.08 g of sodium 1-octanesulfonate in 700 mL of water, add 10 mL of glacial acetic acid, and mix. Add 300 mL of acetonitrile, mix, filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

*Internal standard solution*—Prepare a solution of 2'-chloroacetophenone in acetonitrile having a concentration of about 0.25 mg per mL.

*Standard preparation*—Dissolve an accurately weighed quantity of USP Indapamide RS in acetonitrile to obtain a solution having a known concentration of about 0.1 mg per mL. Transfer 5.0 mL of this solution and 3.0 mL of *Internal standard solution* to a 50-mL volumetric flask, dilute with a mixture of water and acetonitrile (50:10) to volume, and mix.

*Assay preparation*—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of powder, equivalent to about 2.5 mg of indapamide, to a 50-mL volumetric flask, add about 25 mL of acetonitrile, and sonicate for about 20 minutes. Cool, dilute with acetonitrile to volume, and mix. Transfer this solution to a 50-mL centrifuge tube, and centrifuge at 2000 rpm for about 10 minutes. Transfer 10.0 mL of the supernatant to a 50-mL volumetric flask, add 3.0 mL of *Internal standard solution*, dilute with a mixture of water and acetonitrile (70:4) to volume, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 242-nm detector and a 4.5-mm × 10-cm column that contains a 3-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte peak and the internal standard peak is not less than 3.0, and the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The retention time, relative to indapamide, is about 1.18 for the internal standard. Calculate the quantity, in mg, of $C_{16}H_{16}ClN_3O_3S$ in the portion of Tablets taken by the formula:

$$250C(R_U/R_S)$$

in which $C$ is the concentration, in mg per mL, of USP Indapamide RS in the *Standard preparation;* and $R_U$ and $R_S$ are the ratios of the peak responses of indapamide to 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 |
|---|---|---|
| INDAPAMIDE TABLETS | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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