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Bisacodyl Suppositories

» Bisacodyl Suppositories contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{19}NO_4$.

Packaging and storage—Preserve in well-closed containers at a temperature not exceeding 30°.

USP Reference standards ⟨11⟩—

USP Bisacodyl RS

Identification—

A: Transfer a quantity of Suppositories, equivalent to about 150 mg of bisacodyl, to a 500-mL conical flask, add 75 mL of solvent hexane, and heat on a steam bath until they are melted. Filter the solution, with the aid of vacuum, through a medium-porosity, sintered-glass funnel, and wash the residue with about 100 mL of warm solvent hexane until it is free from fat. Continue the vacuum until the residue appears dry. Dissolve the residue by rinsing the filter with about 50 mL of warm acetone, collecting the filtrate in a 150-mL beaker, and evaporate the filtrate on a steam bath to a volume of about 5 mL. To the residual liquid add about 75 mL of water, heat on a steam bath for 15 minutes, and cool. Scratch the sides of the beaker to induce crystallization, filter the crystals, and dry at 100° for about 15 minutes: the bisacodyl so obtained melts between 129° and 135°, and responds to *Identification* test *A* under *Bisacodyl.*

B: The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for bisacodyl, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation.*

Assay—

Mobile phase—Prepare a filtered and degassed mixture of 0.074 M sodium acetate in water [adjusted with 2.5% (v/v) acetic acid to a pH of 7.4] and acetonitrile (55:45). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Bisacodyl RS in acetonitrile to obtain a *Standard preparation* having a known concentration of about 0.5 mg per mL.

Assay preparation—Transfer a number of Suppositories, equivalent to about 100 mg of bisacodyl, to a 500-mL separator, add 150 mL of *n*-hexane, and shake until all the suppositories are dissolved. Add 50 mL of acetonitrile, shake for 1 minute, and allow the layers to separate. Drain the lower layer into a 200-mL volumetric flask, and extract the *n*-hexane layer remaining in the separator with two 50-mL portions of acetonitrile, combining the lower layers in the volumetric flask. Dilute the combined extracts in the volumetric flask with acetonitrile to volume, mix, and filter.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 265-nm detector, a 3.9-mm × 30-cm column that contains packing L1, and a guard column that contains packing L2. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{22}H_{19}NO_4$ in the Suppositories taken by the formula:

$$200C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Bisacodyl RS in the *Standard preparation;* and r_U and r_S are the peak responses 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
BISACODYL SUPPOSITORIES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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