Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-EF0F7AF8-7553-4AD6-A6CF-4676C2AE8039_2_en-US
DOI: https://doi.org/10.31003/USPNF_M9680_02_01
DOI Ref: nme5s

Bisacodyl Rectal Suspension

» Bisacodyl Rectal Suspension is a suspension of Bisacodyl in a suitable aqueous medium. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{22}H_{19}NO_4$.

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

USP Reference standards ⟨11⟩—

USP Bisacodyl RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

pH ⟨791⟩**:** between 5.0 and 6.8.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and 0.01 M monobasic potassium phosphate (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Dissolve a suitable quantity of ethylparaben in methanol, and dilute with an equal volume of water to obtain a solution containing about 5.0 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Bisacodyl RS in methanol, add an accurately measured volume of *Internal standard solution*, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having known concentrations of about 67 µg per mL and 250 µg per mL for bisacodyl and ethylparaben, respectively.

Assay preparation—Transfer an accurately measured volume of Rectal Suspension, equivalent to 6.7 mg of bisacodyl, to a 100-mL volumetric flask. Add 5.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column containing packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 2.0 for bisacodyl and 1.0 for ethylparaben; the resolution, *R,* between bisacodyl and the internal standard is not less than 7.0; the column efficiency, determined for the analyte peak, is not less than 2000 theoretical plates; the tailing factor is not more than 1.2; 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 portion of Rectal Suspension taken by the formula:

$$100C(R_U/R_S)$$

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 response ratios of the bisacodyl peak to the internal standard peak 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 RECTAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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Current DocID: GUID-EF0F7AF8-7553-4AD6-A6CF-4676C2AE8039_2_en-US
Previous DocID: GUID-EF0F7AF8-7553-4AD6-A6CF-4676C2AE8039_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9680_02_01
DOI ref: nme5s