Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-97839DCC-F12B-4F84-9750-A826F98F5FEA_2_en-US
DOI: https://doi.org/10.31003/USPNF_M9695_02_01
DOI Ref: u92lw

Bisacodyl Delayed-Release Tablets

DEFINITION
Bisacodyl Delayed-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bisacodyl ($C_{22}H_{19}NO_4$).

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197S**▲ (CN 1-May-2020)

Cell: 1.0 mm

Sample solution: Macerate a portion of powdered Tablets, equivalent to 300 mg of bisacodyl, with 100 mL of acetone. Heat on a steam bath to boiling, filter, and evaporate to about 20 mL. Add 200 mL of water, and warm the mixture on the steam bath, passing a stream of nitrogen over the surface to evaporate the acetone. After 30 min, cool the mixture, and filter through a sintered-glass funnel. Discard the filtrate, and dissolve the crystals in 50 mL of acetone. Evaporate the solution to about 15 mL, add about 75 mL of water, heat on a steam bath for 15 min, and then cool. Scratch the sides of the beaker to induce crystallization, filter the crystals, and dry at 100° for about 15 min. Using the crystals, prepare a solution (1 in 200) in chloroform.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 0.074 M sodium acetate in water, adjusted with 2.5% (v/v) acetic acid to a pH of 7.4

Mobile phase: Acetonitrile and *Buffer* (45:55)

Standard solution: 0.5 mg/mL of USP Bisacodyl RS in acetonitrile

Sample solution: Transfer a portion of finely powdered Tablets equivalent to 100 mg of bisacodyl, to a 200-mL volumetric flask, add 25 mL of water, and shake by mechanical means for 15 min followed by sonication for 15 min. Add 100 mL of acetonitrile, and shake by mechanical means for 15 min followed by sonication for 15 min. Dilute with acetonitrile to volume, mix, and filter.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 265 nm

Columns

Guard: Packing L2

Analytical: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bisacodyl ($C_{22}H_{19}NO_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Bisacodyl RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of bisacodyl in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩:** Proceed as directed for *Delayed-Release (Enteric-Coated) Tablets*. The Tablets do not disintegrate after 1 h of agitation in simulated gastric fluid TS, but then disintegrate within 45 min in simulated intestinal fluid TS.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers at a temperature not exceeding 30°.

• **USP Reference Standards ⟨11⟩**

USP Bisacodyl RS

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

Topic/Question	Contact	Expert Committee
BISACODYL DELAYED-RELEASE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(3)

Current DocID: GUID-97839DCC-F12B-4F84-9750-A826F98F5FEA_2_en-US

DOI: https://doi.org/10.31003/USPNF_M9695_02_01

DOI ref: u92lw