

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Dec-2024
Document Type: USP Monographs
DocId: GUID-33BF1AF7-E24D-4C00-904C-16029ED4DA46_3_en-US
DOI: https://doi.org/10.31003/USPNF_M6990_03_01
DOI Ref: 2c4ss

© 2025 USPC
Do not distribute

Balsalazide Disodium Capsules

DEFINITION

Balsalazide Disodium Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of balsalazide disodium ($C_{17}H_{13}N_3Na_2O_6 \cdot 2H_2O$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)

Using a 0.2-cm cell, record the UV spectrum of the *Sample solution*, obtained in the Assay, in the range of 200–400 nm: it exhibits maxima at about 261 nm and 357 nm.

ASSAY

• PROCEDURE

Buffer: Add 5 mL of triethylamine to 1000 mL of water, and adjust with phosphoric acid to a pH of 6.00 ± 0.1 .

Mobile phase: Acetonitrile and *Buffer* (1:4)

Diluent: Water

Standard solution: 60 µg/mL of [USP Balsalazide Disodium RS](#) in *Diluent*. [NOTE—Use sonication as necessary.]

Sample stock solution: Transfer an equivalent to 150 mg of balsalazide disodium, from the Capsules contents, to a 100-mL volumetric flask, add 70 mL of *Diluent*, sonicate for 5 min, and dilute with *Diluent* to volume.

Sample solution: 60 µg/mL of balsalazide disodium, from the *Sample stock solution*, in *Diluent*. Pass a portion of this solution through a suitable filter, discarding the first 3 mL.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 360 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 10,000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Sample: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of $C_{17}H_{13}N_3Na_2O_6 \cdot 2H_2O$ in the portion of Capsules 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 Balsalazide Disodium RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

ORGANIC IMPURITIES

• PROCEDURE

Buffer: Dissolve 2.7 g of monobasic potassium phosphate in 1000 mL of water, and adjust with 10% potassium hydroxide solution to a pH of 6.00 ± 0.1 .

Diluent: Water

Solution A: *Buffer*

Solution B: Acetonitrile

Sample solution: Transfer an amount of finely crushed powder equivalent to 100 mg of balsalazide disodium to a 100-mL volumetric flask, add 70 mL of *Diluent*, sonicate for 5 min, and dilute with *Diluent* to volume. Pass a portion of this solution through a PVDF filter of 0.45-µm pore size.

Standard solution: 1.0 µg/mL of [USP Balsalazide Disodium RS](#) in *Diluent*

System suitability solution: 1.0 µg/mL of [USP Balsalazide Disodium RS](#), 1.5 µg/mL of [USP Balsalazide Related Compound A RS](#), 0.5 µg/mL of [USP Balsalazide Related Compound B RS](#), and 0.5 µg/mL of [USP Salicylic Acid RS](#) in *Diluent*

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	90	10
4	90	10
40	75	25
47	75	25
55	50	50
60	50	50
60.1	90	10
70	90	10

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 238 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection size: 30 µL

System suitability

Samples: *Standard solution and System suitability solution*

Suitability requirements

Resolution: NLT 5 between balsalazide and balsalazide related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Tailing factor: NMT 1.5, *Standard solution*

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of each impurity in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response for each individual impurity from the *Sample solution*

r_S = peak response for the balsalazide peak from the *Standard solution*

C_S = concentration of [USP Balsalazide Disodium RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of balsalazide disodium in the *Sample solution*, based on the label claim (mg/mL)

F = relative response factor (see [Impurity Table 1](#))

Acceptance criteria

Individual impurities: See [Impurity Table 1](#).

Reporting level for impurities: 0.05%