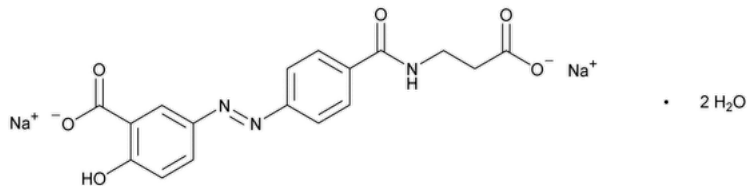


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Balsalazide Disodium

Change to read:



$C_{17}H_{13}N_3Na_2O_6 \cdot 2H_2O$ ▲437.32▲ (CN 1-Dec-2024)
Benzoic acid, 5-[[4-[(2-carboxyethyl)amino]carbonyl] phenyl]azo]-2-hydroxy-, disodium salt, dihydrate, (E)-;
(E)-5-[[p-[(2-Carboxyethyl)carbamoyl]phenyl]azo]salicylic acid, disodium salt, dihydrate CAS RN®: 150399-21-6; UNII: 1XL6BJI034.

DEFINITION
Balsalazide Disodium contains NLT 98.0% and NMT 102.0% of $C_{17}H_{13}N_3Na_2O_6 \cdot 2H_2O$, calculated on the as-is basis.

- IDENTIFICATION**
- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197K**
 - **B. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Ultraviolet-Visible Spectroscopy*: **197U**
 Sample solution: 10 µg/mL in water
 - **C. IDENTIFICATION TESTS—GENERAL, Sodium**(191).

- ASSAY**
- **PROCEDURE**
 Sample: 219 mg
 Analysis: Add 80 mL of glacial acetic acid to the *Sample*, sonicate to dissolve, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction (see [Titrimetry \(541\)](#)). Each mL of 0.1 N perchloric acid is equivalent to 21.87 mg of $C_{17}H_{13}N_3Na_2O_6 \cdot 2H_2O$.
 Acceptance criteria: 98.0%–102.0% on the as-is basis

IMPURITIES

ORGANIC IMPURITIES

[NOTE—On the basis of the synthetic route, perform either *Procedure 1* or *Procedure 2*. *Procedure 2* is recommended when impurities 1, 2, and 3 listed in [Impurity Table 2](#) may be present.]

- **PROCEDURE 1**
 Solution A: 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: Use *Solution A*.
 Solution B: Use acetonitrile.
 Standard solution: 0.5 µg/mL of [USP Balsalazide Disodium RS](#), 0.5 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*. If needed, a small amount of acetonitrile may be added to facilitate dissolution. [NOTE—[USP Balsalazide Related Compound A RS](#) is the disodium salt of (E)-5-[(p-carboxyphenyl)azo]-2-salicylic acid. Use the correction factor stated on the label of the USP Reference Standard to calculate the concentration, as appropriate.]
 Sample solution: 1 mg/mL of Balsalazide Disodium in *Diluent*
 Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	90	10
4	90	10
40	75	25

Time (min)	Solution A (%)	Solution B (%)
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****Sample:** *Standard solution***Suitability requirements****Resolution:** NLT 5 between balsalazide and balsalazide related compound B**Relative standard deviation:** NMT 5% for each peak**Tailing factor:** NMT 1.8 for the balsalazide peak**Analysis****Samples:** *Standard solution and Sample solution*

Calculate the percentage of each individual impurity in the portion of Balsalazide Disodium taken:

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

 r_U = peak response for each individual impurity from the *Sample solution* r_S = peak response for the corresponding impurity from the *Standard solution*. [NOTE—For unspecified impurities, r_S is the peak response for the balsalazide peak from the *Standard solution*.] C_S = concentration of the corresponding impurity in the *Standard solution* (mg/mL). [NOTE—For unspecified impurities, C_S is the concentration of balsalazide disodium in the *Standard solution*.] C_U = concentration of Balsalazide Disodium in the *Sample solution* (mg/mL)**Acceptance criteria****Individual impurities:** See [Impurity Table 1](#).**Reporting level for impurities:** 0.03%**Total impurities:** NMT 1.0%**Impurity Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid	0.37	0.05
Balsalazide related compound A ^a	0.70	0.05
Balsalazide	1.00	—
Balsalazide related compound B ^b	1.2	0.05



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