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Novobiocin Sodium

$C_{31}H_{35}N_2NaO_{11}$ 634.61

Benzamide, *N*-[7-[[3-*O*-(aminocarbonyl)-6-deoxy-5-*C*-methyl-4-*O*-methyl-β-L-*lyxo*-hexopyranosyl]oxy]-4-hydroxy-8-methyl-2-oxo-2*H*-1-benzopyran-3-yl]-4-hydroxy-3-(3-methyl-2-butenyl), monosodium salt.

Novobiocin, monosodium salt CAS RN®: 1476-53-5; UNII: Q9S9NQ5YIY.

» Novobiocin Sodium has a potency equivalent to not less than 850 µg of novobiocin ($C_{31}H_{36}N_2O_{11}$) per mg, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Novobiocin RS

Identification—

A: Prepare a test solution by dissolving a quantity of it in methanol to obtain a concentration of about 1 mg of novobiocin per mL. Similarly prepare a Standard solution, using USP Novobiocin RS. Separately apply 1-µL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture, and allow the spots to dry. Place the plate in a chromatographic chamber equilibrated with a solvent system consisting of a mixture of chloroform, methanol, and ammonium hydroxide (75:25:1), and develop the chromatogram. When the solvent front has moved about three-fourths of the length of the plate, remove the plate from the chamber, and allow to dry. Locate the spots on the plate by examination under short-wavelength UV light: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

B: The residue obtained by igniting it responds to the tests for *Sodium* ⟨191⟩.

Specific rotation ⟨781S⟩: between −50° and −58°.
Test solution: 50 mg per mL, in a mixture of methanol and hydrochloric acid (100:1).

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 6.5 and 8.5, in a solution containing 25 mg per mL.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 6.0% of its weight.

Residue on ignition ⟨281⟩: between 10.5% and 12.0%, the charred residue being moistened with 2 mL of sulfuric acid and an ignition temperature of 550 ± 50° being used.

Assay—Dissolve a suitable quantity of Novobiocin Sodium, accurately weighed, in an accurately measured volume of *Buffer B.3* sufficient to obtain a stock solution of convenient concentration. Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of this stock solution diluted quantitatively and stepwise with *Buffer B.6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
NOVOBIOCIN SODIUM	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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