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Indigotindisulfonate Sodium Injection

» Indigotindisulfonate Sodium Injection is a sterile solution of Indigotindisulfonate Sodium in Water for Injection. It contains not less than 90.0 percent and not more than 105.0 percent of the labeled amount of $C_{16}H_8N_2Na_2O_8S_2$.

Packaging and storage—Preserve in single-dose, light-resistant containers, preferably of Type I glass.

USP Reference Standards (11).—
[USP Indigotindisulfonate Sodium RS](#)

Identification—It responds to *Identification* tests B, C, and D under [Indigotindisulfonate Sodium](#).

Bacterial Endotoxins Test (85).—It contains not more than 5.0 USP Endotoxin Units per mg of indigotindisulfonate sodium.

pH (791): between 3.0 and 6.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Quantitatively dilute a portion of Injection, equivalent to about 40 mg of indigotindisulfonate sodium, with dilute hydrochloric acid (1 in 100) to obtain a solution having a known concentration of about 10 µg of indigotindisulfonate sodium per mL. Proceed as directed in the Assay under [Indigotindisulfonate Sodium](#), beginning with “Concomitantly determine the absorbances.” Calculate the quantity, in mg, of $C_{16}H_8N_2Na_2O_8S_2$ in each mL of the Injection taken by the formula:

$$4(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of [USP Indigotindisulfonate Sodium RS](#) in the Standard solution; V is the volume, in mL, of Injection taken; and A_U and A_S are the absorbances of the solution from the Injection and the Standard solution, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
INDIGOTINDISULFONATE SODIUM INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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