

Status: Currently Official on 15-Feb-2025  
Official Date: Official as of 01-May-2018  
Document Type: USP Monographs  
DocID: GUID-F122A026-5680-4C96-9494-B5C2F4639CE5\_3\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M40150\\_03\\_01](https://doi.org/10.31003/USPNF_M40150_03_01)  
DOI Ref: yvy0p

© 2025 USPC  
Do not distribute

## 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  $\mu$ g 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  $\mu$ g 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	<a href="#">Documentary Standards Support</a>	SM42020 Small Molecules 4

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID: GUID-F122A026-5680-4C96-9494-B5C2F4639CE5\_3\_en-US**

**Previous DocID: GUID-F122A026-5680-4C96-9494-B5C2F4639CE5\_1\_en-US**

**DOI: [https://doi.org/10.31003/USPNF\\_M40150\\_03\\_01](https://doi.org/10.31003/USPNF_M40150_03_01)**

**DOI ref: yvy0p**