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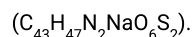
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Indocyanine Green for Injection

DEFINITION

Change to read:

Indocyanine Green for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of ▲indocyanine green▲ (USP 1-Aug-2022)



IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Sodium](#) and [Sulfate](#)

Analysis: Incinerate a portion of Indocyanine Green for Injection and use the residue.

Acceptance criteria: Meets the requirements

Change to read:

- **B.**

Sample solution: 0.05 mg/mL of indocyanine green from Indocyanine Green for Injection in [water](#)

Analysis: Add 10 drops of ▲[sodium hydroxide TS](#)▲ (USP 1-Aug-2022) to the *Sample solution* and heat to about 60°. Add 10 drops of [hydrogen peroxide TS](#) and mix.

Acceptance criteria: A red color develops within 4 min, which on standing, fades to a pale orange.

ASSAY

Change to read:

- **PROCEDURE**

Standard solution: 2 µg/mL of [USP Indocyanine Green RS](#) in [methanol](#)

Sample solution: Nominally 2 µg/mL of indocyanine green from Indocyanine Green for Injection in [methanol](#)

Instrumental conditions

▲(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)▲ (USP 1-Aug-2022)

Mode: UV-Vis

Analytical wavelength: 785 nm

Cell: 1 cm

Blank: [Methanol](#)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of indocyanine green ($C_{43}H_{47}N_2NaO_6S_2$) in the portion of Indocyanine Green for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Indocyanine Green RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of indocyanine green in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

Delete the following:

▲OTHER COMPONENTS• **SODIUM IODIDE**

Sample: Nominally 200 mg of indocyanine green from Indocyanine Green for Injection

Titrimetric system

Mode: Direct titration

Titrant: 0.01 N silver nitrate VS

Electrode system: Silver-glass

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 100 mL of [water](#). Add 1 mL of [nitric acid](#) and mix. Titrate with *Titrant* to a potentiometric endpoint.

Calculate the percentage of sodium iodide (Nal) in the portion of Indocyanine Green for Injection taken:

$$\text{Result} = [(V \times N \times F)/W] \times 100$$

V = volume of *Titrant* consumed by the *Sample* (mL)

N = *Titrant* concentration, in normality (mEq/mL)

F = equivalency factor of sodium iodide, 149.9 mg/mEq

W = nominal weight of indocyanine green in the *Sample* taken (mg)

Acceptance criteria: NMT 5.0% on the dried basis ▲ (USP 1-Aug-2022)

PERFORMANCE TESTS**Change to read:**• **▲UNIFORMITY OF DOSAGE UNITS** ▲ (USP 1-Aug-2022)

Standard solution and Instrumental conditions: Proceed as directed in the Assay.

Sample stock solution: Individually transfer the contents of each of 5 containers of Indocyanine Green for Injection to separate 100-mL volumetric flasks with the aid of [methanol](#) and dilute with [methanol](#) to volume.

Sample solution: Nominally 2.5 µg/mL of indocyanine green from the *Sample stock solution* in [methanol](#)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the label claim of indocyanine green ($C_{43}H_{47}N_2NaO_6S_2$) in each container of Indocyanine Green for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Indocyanine Green RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of indocyanine green in the *Sample solution* (µg/mL)

Acceptance criteria: ▲The requirements are met if the content is 85%–115% of label claim in NLT 4 of the containers and is 75%–125% of label claim in all 5 containers. ▲ (USP 1-Aug-2022)

Delete the following:**▲IMPURITIES**• [ARSENIC \(211\), Procedures, Method II](#): NMT 8 ppm• [LEAD \(251\)](#):

Sample solution: A 5-mL portion of the solution prepared for the test for [Arsenic \(211\), Procedures, Method II](#)

Analysis: Proceed as directed for the limit test of [Lead \(251\)](#). Use 3 mL of *Ammonium Citrate Solution*, 1 mL of *Potassium Cyanide Solution*, and 0.5 mL of *Hydroxylamine Hydrochloride Solution*.

Acceptance criteria: NMT 10 ppm ▲ (USP 1-Aug-2022)

SPECIFIC TESTS

- **CONSTITUTED SOLUTION:** At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Completeness and Clarity of Solutions](#).
 - **STERILITY TESTS (71):** Meets the requirements
- Change to read:**
- **BACTERIAL ENDOTOXINS TEST (85):** ▲Meets the requirements▲ (USP 1-Aug-2022)
 - **pH (791)**
Sample solution: 5 mg/mL of Indocyanine Green for Injection in [water](#)
Acceptance criteria: 5.5–7.5
 - **OTHER REQUIREMENTS:** It meets the requirements in [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging, Packaging for Constitution](#).
- **USP REFERENCE STANDARDS (11)**
[USP Indocyanine Green RS](#)

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

Topic/Question	Contact	Expert Committee
INDOCYANINE GREEN FOR INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 47(2)

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