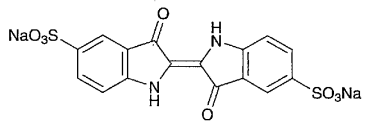
Each mL of 0.1 mol/L perchloric acid VS
= 28.380 mg of $C_{15}H_{21}NO_2.HCl$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Indigocarmine

インジゴカルミン



$C_{16}H_8N_2Na_2O_8S_2$: 466.35
Disodium 3,3′-dioxo-[$\Delta^{2,2'}$-biindoline]-5,5′-disulfonate
[*860-22-0*]

Indigocarmine, when dried, contains not less than 95.0% of $C_{16}H_8N_2Na_2O_8S_2$.

Description Indigocarmine occurs as blue to dark blue powder or granules. It is odorless.

It is sparingly soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

It is hygroscopic.

When compressed, it has a coppery luster.

Identification **(1)** A solution of Indigocarmine (1 in 100) is dark blue in color. Perform the following tests with this solution as the sample solution: the dark blue color of each solution disappears.

(i) Add 1 mL of nitric acid to 2 mL of the sample solution;

(ii) Add 1 mL of bromine TS to 2 mL of the sample solution;

(iii) Add 1 mL of chlorine TS to 2 mL of the sample solution;

(iv) Add 2 mL of sodium hydroxide TS and 0.2 g of zinc powder to 2 mL of the sample solution, and warm.

(2) Dissolve 0.1 g of Indigocarmine in 100 mL of a solution of ammonium acetate (1 in 650). To 1 mL of the solution add a solution of ammonium acetate (1 in 650) to make 100 mL. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(3) Ignite 1 g of Indigocarmine to carbonize. After cooling, add 20 mL of water to the residue, shake, and filter the mixture: the filtrate responds to the Qualitative Tests for sodium salt and for sulfate.

pH Dissolve 0.10 g of Indigocarmine in 20 mL of water: the pH of the solution is between 5.0 and 6.0.

Purity **(1)** Water-insoluble substances—To 1.00 g of Indigocarmine add 200 mL of water, shake, and filter through a tared glass filter (G4). Wash the residue with water until the blue color of the filtrate becomes practically colorless, and dry the residue at 105°C for 4 hours: the mass of the residue does not exceed 5.0 mg.

(2) Arsenic—Place 0.8 g of Indigocarmine in a Kjeldahl flask, add 5 mL of sulfuric acid and 5 mL of nitric acid, and ignite gently. Repeat the addition of 2 to 3 mL of nitric acid occasionally, and continue to heat until a colorless to light yellow solution is obtained. After cooling, add 15 mL of a saturated ammonium oxalate solution, heat the solution until dense white fumes are evolved, and concentrate to 2 to 3 mL. After cooling, dilute with water to 10 mL, and perform the test using Apparatus B with 5 mL of this solution as the test solution (not more than 5 ppm).

Loss on drying Not more than 10.0% (1 g, 105°C, 2 hours).

Residue on ignition Not less than 28.0% and not more than 38.0% (after drying, 1 g).

Assay Weigh accurately about 0.5 g of Indigocarmine, previously dried, add 15 g of sodium hydrogen tartrate monohydrate, and dissolve in 200 mL of water, boil with bubbling of a stream of carbon dioxide, and titrate, while being hot, with 0.1 mol/L titanium (III) chloride VS until the color of the solution changes from blue through yellow to orange.

Each mL of 0.1 mol/L titanium (III) chloride VS
= 23.318 mg of $C_{16}H_8N_2Na_2O_8S_2$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Indigocarmine Injection

インジゴカルミン注射液

Indigocarmine Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of indigocarmine ($C_{16}H_8N_2Na_2O_8S_2$: 466.35).

Method of preparation Prepare as directed under Injection, with Indigocarmine.

Description Indigocarmine Injection is a dark blue liquid.

pH: 3.0 – 5.0

Identification **(1)** To a volume of Indigocarmine Injection, equivalent to 0.02 g of Indigocarmine according to the labeled amount, add 1 mL of nitric acid: the dark blue color of the liquid disappears, and a yellow-brown color develops.

(2) To a volume of Indigocarmine Injection, equivalent to 0.02 g of Indigocarmine according to the labeled amount, add 1 mL of bromine TS: the dark blue color disappears, and a yellow-brown color develops.

(3) To a volume of Indigocarmine Injection, equivalent to 0.02 g of Indigocarmine according to the labeled amount, add 1 mL of chlorine TS: the dark blue color disappears, and a yellow-brown color develops.

(4) To a volume of Indigocarmine Injection, equivalent to 0.01 g of Indigocarmine according to the labeled amount, add ammonium acetate solution (1 in 650) to make 1000 mL, and determine the absorbance of the solution as directed under the Ultraviolet-visible Spectrophotometry: it ex-

hibits a maximum between 610 nm and 614 nm.

Assay Measure exactly a volume of Indigocarmine Injection, equivalent to about 0.2 g of indigocarmine ($C_{16}H_8N_2Na_2O_8S_2$), add 6 g of sodium hydrogen tartrate monohydrate, and dissolve in water to make 200 mL. Then boil under a carbon dioxide stream, and proceed as directed in the Assay under Indigocarmine.

Each mL of 0.1 mol/L titanium (III) chloride VS
= 23.318 mg of $C_{16}H_8N_2Na_2O_8S_2$

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Indium (^{111}In) Chloride Injection

塩化インジウム (^{111}In) 注射液

Indium (^{111}In) Chloride Injection is an aqueous solution for injection containing indium-111 (^{111}In) in the form of indium chloride.

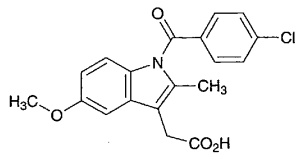
It conforms to the requirements of Indium (^{111}In) Chloride Injection in the Minimum Requirements for Radiopharmaceuticals.

The Insoluble Particulate Matter Test for Injections is not applied to this injection.

Description Indium (^{111}In) Chloride Injection is a clear, colorless liquid.

Indometacin

インドメタシン



$C_{19}H_{16}ClNO_4$: 357.79

[1-(4-Chlorobenzoyl)-5-methoxy-2-methyl-1*H*-indol-3-yl]acetic acid [*53-86-1*]

Indometacin, when dried, contains not less than 98.0% of $C_{19}H_{16}ClNO_4$.

Description Indometacin occurs as a white to light yellowish white, very fine crystalline powder.

It is sparingly soluble in methanol, in ethanol (95) and in diethyl ether, and practically insoluble in water.

It dissolves in sodium hydroxide TS.

It is colored by light.

Melting point: 155 - 162°C

Identification (1) Dissolve 2 mg of Indometacin in 100 mL of methanol. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Indometacin Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Indometacin, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of dried Indometacin Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers. If any difference appears between the spectra, recrystallize the sample and the Reference Standard with diethyl ether, filter and dry the crystals, and perform the test with the crystals.

(3) Perform the test with Indometacin as directed under the Flame Coloration Test (2): a green color appears.

Purity (1) Acid—To 1.0 g of Indometacin add 50 mL of water, shake for 5 minutes, and filter. To the filtrate add 0.20 mL of 0.1 mol/L sodium hydroxide VS and 1 drop of phenolphthalein TS: a red color develops.

(2) Heavy metals—Proceed with 1.0 g of Indometacin according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Indometacin according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.10 g of Indometacin in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add methanol to make exactly 50 mL. Pipet 5 mL of this solution, add methanol to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 25 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of dehydrated diethyl ether and acetic acid (100) (100:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 4 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.7 g of Indometacin, previously dried, dissolve in 60 mL of methanol, add 30 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS
= 35.779 mg of $C_{19}H_{16}ClNO_4$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.