and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat the plate at 110°C for 10 minutes: the spots other than the principal spot from the sample solution are not larger than and not more intense than the spot from the standard solution.

Optical rotation $[\alpha]_D^{20}$: +6.5 - +8.5° (after drying, 0.5 g, anhydrous pyridine, 25 mL, 100 mm).

Loss on drying Not more than 8.0% (0.5 g, in vacuum, phosphorus (V) oxide, 60°C, 4 hours).

Residue on ignition Not more than 0.5% (0.1 g).

Assay Dissolve about 0.012 g each of Deslanoside and Deslanoside Reference Standard, previously dried and accurately weighed, in 20 mL each of methanol, add water to make exactly 100 mL, and use these solutions as the sample solution and the standard solution, respectively. Pipet 5 mL each of these solutions, transfer to light-resistant, 25-mL volumetric flasks, shake well with 5 mL each of 2,4,6-trinitrophenol TS and 0.5 mL each of a solution of sodium hydroxide (1 in 10), add diluted methanol (1 in 4) to make 25 mL, and allow to stand at a temperature between 18°C and 22°C for 25 minutes. Determine the absorbances, A_T and A_S, of the subsequent solutions of the sample solution and the standard solution, respectively, at 485 nm as directed under the Ultraviolet-visible Spectrophotometry, using a solution prepared with 5 mL of diluted methanol (1 in 5) in the same manner as the blank.

Amount (mg) of $C_{47}H_{74}O_{19}$
= amount (mg) of Deslanoside Reference Standard
$\times \frac{A_T}{A_S}$

Containers and storage Containers—Tight containers.

Deslanoside Injection

デスラノシド注射液

Deslanoside Injection is an aqueous solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of deslanoside ($C_{47}H_{74}O_{19}$: 943.08).

Method of preparation Dissolve Deslanoside in 10 vol% ethanol and prepare as directed under Injections. It may contain Glycerin. It may be prepared with a suitable amount of Ethanol and Water for Injection.

Description Deslanoside Injection is a clear and colorless liquid.
pH: 5.0 - 7.0

Identification (1) Place a volume of Deslanoside Injection, equivalent to 2 mg of Deslanoside according to the labeled amount, in a separator, add sodium chloride in the ratio of 0.2 g to each mL of this solution, and extract with three 10-mL portions of chloroform. Combine the chloroform extracts, mix uniformly, pipet 15 mL of this solution, and evaporate the chloroform under reduced pressure. Proceed with the residue as directed in the Identification under Deslanoside.

(2) Place a volume of Deslanoside Injection, equivalent to 1 mg of Deslanoside according to the labeled amount, in a separator, add sodium chloride in the ratio of 0.2 g to each mL of this solution, and extract with three 5-mL portions of chloroform. Combine the chloroform extracts, evaporate the chloroform under reduced pressure, dissolve the residue in 5 mL of methanol, and use this solution as the sample solution. Separately, dissolve 1 mg of Deslanoside Reference Standard in 5 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μL each of these solutions on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of dichloromethane, methanol and water (84:15:1) to a distance of about 13 cm, and air-dry the plate. Spray evenly dilute sulfuric acid upon the plate, and heat the plate at 110°C for 10 minutes: the spots from the sample solution and the standard solution show a black color and have the same Rf value.

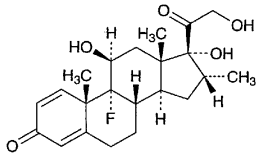
Assay Measure exactly a volume of Deslanoside Injection, equivalent to about 3 mg of deslanoside ($C_{47}H_{74}O_{19}$). Add 5 mL of methanol and water to make 25 mL. Use this solution as the sample solution, and proceed as directed in the Assay under Deslanoside.

Amount (mg) of deslanoside ($C_{47}H_{74}O_{19}$)
= amount (mg) of Deslanoside Reference Standard
$\times \frac{A_T}{A_S} \times \frac{1}{4}$

Containers and storage Containers—Hermetic containers. Storage—Light-resistant.

Dexamethasone

デキサメタゾン



$C_{22}H_{29}FO_5$: 392.46
9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione [*50-02-2*]

Dexamethasone, when dried, contains not less than 97.0% and not more than 102.0% of $C_{22}H_{29}FO_5$.

Description Dexamethasone occurs as white to pale yellow crystals or crystalline powder. It is odorless.

It is sparingly soluble in methanol, in ethanol (95), in acetone and in 1,4-dioxane, and practically insoluble in water and in diethyl ether.

Melting point: about 245°C (with decomposition).

Identification (1) Dissolve 2 mg of Dexamethasone in 40 mL of ethanol (95), add 5 mL of 2,6-di-*tert*-butylcresol TS and 5 mL of sodium hydroxide TS, and heat under a reflux condenser on a water bath for 20 minutes: a green color develops.

(2) Dissolve 0.01 g of Dexamethasone in 1 mL of

methanol by warming, add 1 mL of Fehling's TS, and heat: a red precipitate is produced.

(3) Proceed with 0.01 g of Dexamethasone as directed under the Oxygen Flask Combustion Method, using a mixture of 0.5 mL of 0.01 mol/L sodium hydroxide TS and 20 mL of water as the absorbing liquid: the solution obtained responds to the Qualitative Tests for fluoride.

(4) Dissolve 1.0 mg of Dexamethasone in 10 mL of ethanol (95). Mix 2.0 mL of the solution with 10 mL of phenylhydrazine hydrochloride TS, heat in a water bath at 60°C for 20 minutes, and cool the solution. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, using as the blank the solution prepared with 2.0 mL of ethanol (95) in the same manner as the former solution, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Dexamethasone Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(5) Determine the infrared absorption spectrum of Dexamethasone, 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 previously dried Dexamethasone Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers. If any difference appears between the spectra, dissolve Dexamethasone and Dexamethasone Reference Standard in acetone, respectively, then evaporate the acetone to dryness, and repeat the test on the residues.

Optical rotation $[\alpha]_D^{20}$: +72 - +80° (after drying, 0.1 g, 1,4-dioxane, 10 mL, 100 mm).

Purity **(1)** Heavy metals—Proceed with 1.0 g of Dexamethasone according to Method 2, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 30 ppm).

(2) Other steroids—Dissolve 0.10 g of Dexamethasone in 10 mL of acetone, and use this solution as the sample solution. Pipet 2 mL of the sample solution, add acetone to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 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 dichloromethane and methanol (45:4) to a distance of about 15 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% (0.2 g, 105°C, 3 hours).

Residue on ignition Not more than 0.1% (0.2 g, platinum crucible).

Assay Dissolve about 0.01 g each of Dexamethasone and Dexamethasone Reference Standard, previously dried and accurately weighed, in 70 mL each of diluted methanol (1 in 2), add exactly 5 mL each of the internal standard solution, then add diluted methanol (1 in 2) to make 100 mL, and use these solutions as the sample solution and the standard solution. Perform the test with 10 μL each of these solutions as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of dexamethasone to that of the internal standard, respectively.

$$\text{Amount (mg) of } C_{22}H_{29}FO_5 = \text{amount (mg) of Dexamethasone Reference Standard} \times \frac{Q_T}{Q_S}$$

Internal standard solution—A solution of propyl parahydroxybenzoate in diluted methanol (1 in 2) (1 in 1000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (10 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: A mixture of water and acetonitrile (2:1).

Flow rate: Adjust the flow rate so that the retention time of dexamethasone is about 6 minutes.

Selection of column: Dissolve 2 mg of methyl parahydroxybenzoate and 4 mg of ethyl parahydroxybenzoate in 100 mL of diluted methanol (1 in 2). Proceed with 10 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of methyl parahydroxybenzoate and ethyl parahydroxybenzoate in this order with the resolution between these peaks being not less than 5.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Dextran 40

デキストラン 40

Dextran 40 is a product obtained by partial decomposition of polysaccharide, which is produced by fermentation of sucrose with *Leuconostoc mesenteroides* van Tieghem (*Lactobacillaceae*), and the average molecular mass is about 40,000.

When dried, it contains not less than 98.0% and not more than 102.0% of dextran 40.

Description Dextran 40 occurs as a white, amorphous powder. It is odorless and tasteless.

It is practically insoluble in ethanol (95) and in diethyl ether.

It dissolves gradually in water.

It is hygroscopic.

Identification To 1 mL of a solution of Dextran 40 (1 in 3000) add 2 mL of anthrone TS: a blue-green color develops and turns gradually dark blue-green. Then to this solution add 1 mL of diluted sulfuric acid (1 in 2) or 1 mL of acetic acid (100): the solution does not change in color.

pH Dissolve 1.0 g of Dextran 40 in 10 mL of water: the pH of this solution is between 5.0 and 7.0.