

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.

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

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 μ L 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 R_f value.

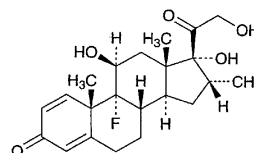
Assay Measure exactly a volume of Deslanoside Injection, equivalent to about 3 mg of deslanoside ($C_{47}H_{74}O_{19}$). Add 5 mL of methanol and water to make 25 mL. Use this solution as the sample solution, and proceed as directed in the Assay under Deslanoside.

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

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-11 β ,17,21-trihydroxy-16 α -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