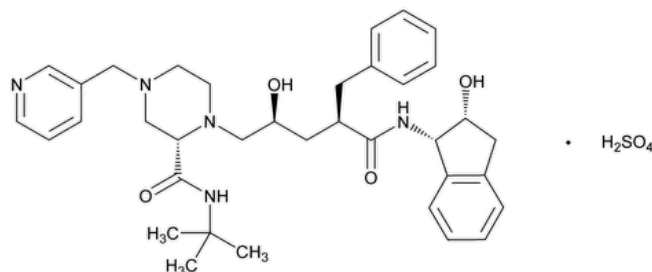


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Indinavir Sulfate



$C_{36}H_{47}N_5O_4 \cdot H_2SO_4$ 711.87

D-erythro-Pentonamide, 2,3,5-trideoxy-N-(2,3-dihydro-2-hydroxy-1H-inden-1-yl)-5-[2-[[[(1,1-dimethylethyl)amino] carbonyl]-4-(3-pyridinylmethyl)-1-piperazinyl]-2-(phenylmethyl)-, [1(1S,2R),5(S)]-, sulfate (1:1) (salt);
 (αR,γS,2S)-α-Benzyl-2-(tert-butylcarbamoyl)-γ-hydroxy-N-[(1S,2R)-2-hydroxy-1-indanyl]-4-(3-pyridylmethyl)-1-piperazinevaleramide sulfate (1:1) (salt) CAS RN®: 157810-81-6; UNII: 771H53976Q.

DEFINITION

Indinavir Sulfate contains NLT 98.5% and NMT 101.5% of $C_{36}H_{47}N_5O_4 \cdot H_2SO_4$, calculated on the anhydrous, solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** **▲ SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197M** ▲ (CN 1-MAY-2020) : Maxima at about 3.0–3.1, 5.9, 6.2, and 13.6 μm
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** **IDENTIFICATION TESTS—GENERAL, Sulfate(191):** Meets the requirements

Sample solution: A solution of 10 mg/mL in water

ASSAY

PROCEDURE

Solution A: Dibutyl ammonium phosphate and water (1:50). Adjust with sodium hydroxide TS to a pH of 6.5 ± 0.5 .

Mobile phase: Acetonitrile and *Solution A* (9:11)

Standard solution: 0.5 mg/mL of [USP Indinavir RS](#) in *Mobile phase*

Sample solution: 0.6 mg/mL of Indinavir Sulfate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 25-cm; 5-μm packing L7

Column temperature: 40°

Flow rate: 1 mL/min

Injection size: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 4000 theoretical plates

Tailing factor: Less than 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{36}H_{47}N_5O_4 \cdot H_2SO_4$ in the portion taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Indinavir RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Indinavir Sulfate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of indinavir sulfate, 711.87

M_{r2} = molecular weight of indinavir, 613.79

Acceptance criteria: 98.5%–101.5% on the anhydrous, solvent-free basis

OTHER COMPONENTS

• PROCEDURE 1: CONTENT OF SULFATE

Solution A: Methanol and formaldehyde (1000:0.3)

Diluent: *Solution A* and water (1:1)

Sample solution: 6.25 mg/mL of Indinavir Sulfate in *Diluent*

Analysis: Titrate with 0.1 M lead perchlorate VS, using a lead-specific electrode in conjunction with a suitable reference electrode. Each mL of 0.1 M lead perchlorate VS is equivalent to 9.604 mg of sulfate.

Acceptance criteria: 13.2%–14.4%, calculated on the anhydrous and solvent-free basis

• PROCEDURE 2: CONTENT OF ALCOHOL

Standard solution: 0.001 mL/mL of dehydrated alcohol, in water. [NOTE—Dehydrated alcohol is at 20°.]

Sample solution: 4 mg/mL of Indinavir Sulfate in water

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column with a 1.0-μm film of phase G16

Temperature

Column: 35°

Injector: 140°

Detector: 220°

[NOTE—At the end of each 5-min isothermal run, increase the oven temperature to 200° before adjusting the column temperature to 35° for the next injection.]

Flow rate: 10 mL/min

Carrier gas: Helium

Injection size: 0.1 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of alcohol in the portion of Indinavir Sulfate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times D \times 100$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of dehydrated alcohol in the *Standard solution* (mL/mL)