

Indinavir Liquid 10 mg/mL

INGREDIENTS:

Indinavir 400 mg capsule	6 capsules
Azorubin powder	18 mg
Citric acid powder	0.72 g
Lemon oil	5 drops
Purified distilled water	24 mL
Simple syrup NF	36 mL
Sodium hydroxide 0.1 M	QS to pH 3
Viscous sweet base*	QSAD: 200 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, graduated cylinder, ultrasonic water bath, hot plate, magnetic stirrer, filter paper

PREPARATION DETAILS:

1. Add 20 mL purified distilled water into an appropriately sized amber glass bottle.
2. Open capsules and empty contents into the bottle.
3. Place the bottle in an ultrasonic water bath filled with water at approximately 37°C. Stir the solution every 10 minutes.
4. After 60 minutes, pass the solution through a rough filter paper and collect the filtrate in another amber glass bottle.
5. Wash the first bottle and the filter with the remaining 4 mL of purified distilled water.
6. Allow the solution of indinavir 100 mg/mL concentrate to cool to room temperature.
7. Add 144 mL of vehicle into an appropriately sized amber glass bottle.
8. Add simple syrup NF and mix the solution.
9. Add citric acid and azorubin and allow them to dissolve. Mix the solution until it is homogeneous.
10. Add 20 mL of the indinavir 100 mg/mL concentrate to the mixture.
11. Measure the pH and adjust it to 3 by adding sodium hydroxide 0.1 M solution.
12. Add the lemon oil and mix.
13. Shake well to mix.

Special Instructions — *Heat 160 mL of purified distilled water to boiling. While stirring the water, add 2.4 g of methylcellulose 400 mPa-s. Continue stirring while the solution cools. Dissolve 48 mg of saccharine sodium in the cooled (to <37°C) solution. Use the mixture as vehicle.

Indinavir Liquid 10 mg/mL (continued)

Quality-Control Procedures — Conduct pH testing to adjust for a pH of 3. Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

Labeling Requirements — Extemporaneously compounded preparation. For oral use only. Store in refrigerator. Shake well before use.

Storage Conditions/Stability — Refrigerate. Stable for 14 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber glass bottle

Referenced Manufacturers — Indinavir capsules (Crixivan, Merck & Co); purified distilled water (not specified); methylcellulose, saccharine sodium, simple syrup, citric acid, azorubine, lemon oil (Genfarma Laboratorio SL); sodium hydroxide (Merck & Co).

Stability-Indicating Study — Yes

REFERENCE

1. Hugen PWH, Burger DM, ter Hofstede HJM, et al. Development of an indinavir oral liquid for children. *Am J Health Syst Pharm.* 2000;57:1332-1339.