Lisinopril 1-mg/mL, Sodium Citrate, and Citric Acid Oral Liquid

Rx

For 100 mL		
Lisinopril		100 mg
Purified water		5 mL
Bicitra		15 mL
Ora-Sweet SF	qs	100 mL

METHOD OF PREPARATION

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Weigh and/or measure each ingredient accurately.
3. Pulverize the lisinopril tablets to a fine powder.
4. Add the purified water to the powder and mix well.
5. Add the Bicitra and mix well.
6. Add the Ora-Sweet SF to volume and mix well.
7. Package and label.

PACKAGING

Package in tight, light-resistant containers.[1]

LABELING

Keep out of reach of children. Use only as directed.

STABILITY

A beyond-use date of 6 weeks is appropriate for this preparation.[1,2]

USE

Lisinopril with sodium citrate and citric acid oral solution has been used for the treatment of hypertension, heart failure, and acute myocardial infarction.[2]

QUALITY CONTROL

Quality-control assessment can include weight/volume, pH, specific gravity, active drug assay, color, clarity, rheological properties/pourability, physical observation, and physical stability (discoloration, foreign materials, gas formation, mold growth).[3]

DISCUSSION

Lisinopril is an angiotensin-converting enzyme (ACE) inhibitor used alone or in combination with other classes of antihypertensive agents in the management of mild to severe hypertension. It is also listed as useful in congestive heart failure, acute myocardial infarction, and diabetic nephropathy.[4]

Lisinopril ($C_{21}H_{31}N_3O_5.2H_2O$, MW 441.52, Prinivil, Zestril) occurs as a white, crystalline powder that is soluble in water and practically insoluble in alcohol. It melts at about 160°C. The 5-, 10-, 20-, and 40-mg Prinivil tablets also contain calcium phosphate, mannitol, magnesium stearate, and starch. The 10-, 20-, and 40-mg tablets also contain iron oxide. The 2.5-, 5-, 10-, 20-, 30-, and 40-mg Zestril tablets also contain calcium phosphate, mannitol, magnesium stearate, and starch. The tablets differ in the coloring agent used; the 2.5-mg tablets contain no coloring agent; the 5-, 10-, 20-, and 30-mg tablets contain red ferric oxide; and the 40-mg tablets contain yellow ferric oxide.[5]

Purified water is water that is obtained by distillation, ion exchange, reverse osmosis, or some other suitable process. Water is used to describe potable water from a public water supply that is suitable for drinking and is the beginning point of the official waters. It is a clear, colorless, odorless, and tasteless liquid. Water has a specific gravity of 0.9971 at room temperature, a melting point of 0°C, and a boiling point of 100°C. It is miscible with most polar solvents and is chemically stable in all physical states (ice, liquid, steam).[6]

Bicitra is a stable and pleasant-tasting grape-flavored citrate oral systemic alkalizer. It contains sodium citrate and citric acid in a sugar-free vehicle. It contains, in each 5 mL, sodium citrate dihydrate 500 mg (0.34 M) and citric acid monohydrate 334 mg (0.32 M). It also contains butylparaben, flavoring, maltitol, and sodium saccharin.[7]

Ora-Sweet SF syrup is a flavoring vehicle for oral extemporaneous preparations. It is a sugar-free, alcohol-free syrup flavored with a citrus-berry flavor blend. It is buffered to a pH of approximately 4.2 and may be used alone or in combination with other vehicles. It will tolerate dilution to 50% with dissolved actives in water or suspending agents and still retain an acceptable taste. It has an osmolality of 2,150 mOsm/kg. It contains water, sodium saccharin, xanthan gum, glycerin, and sorbitol; citric acid and sodium citrate as buffers; methylparaben, propylparaben, and potassium sorbate as preservatives; and flavoring agents.[8]

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