

Rosuvastatin Suspension 4 mg/mL

INGREDIENTS:

Rosuvastatin 40 mg tablet	10 tablets
Aspartame	190 mg
Cherry flavor	5.5 mg
Guar gum	500 mg
Orange flavor	133 mg
Sodium hydroxide	400 mg
Sodium saccharin	190 mg
Sorbitol instant	23.73 g
Trisodium citrate	330 mg
Reverse osmosis water	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Weigh out each additive powder and, under continual mixing and trituration, combine all additives.
3. Levigate powder with a small amount of vehicle to form a paste.
4. Add vehicle in increasing amounts while mixing thoroughly.
5. Transfer contents of the mortar to a graduated cylinder.
6. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
7. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
8. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
9. Shake well to mix.

Quality-Control Procedures — 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 at room temperature. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 30 days.

STABILITY STUDY DETAILS:

Study Container Type — Plastic, milky, high-density polyethylene bottle

Referenced Manufacturers — Rosuvastatin tablets (Crestor, AstraZeneca); orange flavor (Givaudan); cherry flavor (Firmenich); aspartame (Ajinomoto); sodium saccharin (Tianjin Food Co); trisodium citrate (Weifang Ensign Co, Ltd); sodium hydroxide (Merck & Co); guar gum (CP Kelco); sorbitol instant (Sugat Industries, Ltd).

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Rosuvastatin Suspension 4 mg/mL (continued)

Stability-Indicating Study — No

REFERENCE

1. Zaid AN, Shtayah R, Qadumi A, et al. Stability of extemporaneously prepared rosuvastatin oral suspension. *Am J Health Syst Pharm.* 2017;74:1579-1583.