

Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: SILDENAFIL CITRATE 2.5 mg/mL SUSPENSION

Date Prepared: _____

FINAL PRODUCT CHECKED BY: _____

EXPIRY DATE: _____

INGREDIENTS	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Sildenafil Citrate 50 mg tablet				1 tablet			
Ora-Blend®	Paddock			qs to 20 mL			

EQUIPMENT

- Mortar and pestle
- Graduated cylinder

SAMPLE LABEL

SILDENAFIL CITRATE 2.5 mg/mL Suspension
Shake well. Refrigerate/Room Temperature
Date Prepared: _____ Date Expired: _____

MANUFACTURING DIRECTIONS

1. Crush tablets to make a fine powder in a mortar.
2. Levigate powder with a small amount of the vehicle to make a fine paste.
3. Continue to add vehicle by geometric dilution until product liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with vehicle and add to product in graduated cylinder.
5. QS to final volume with vehicle.
6. Dispense in amber plastic bottles.

STABILITY

60 days in fridge or at room temperature

REFERENCE(S)

Nahata, MC et al. Extemporaneous sildenafil citrate oral suspensions for the treatment of pulmonary hypertension in children. AM J Health – Syst Pharm. 2006; 63: 254-7

FINAL APPEARANCE

Opaque, bluish suspension

Master Sheet Revision Dates: 20 Oct 04; 14 Oct 05; 16 Feb 06; 18 Oct. 06; Aug 2018

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