

Children's Hospital Of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: OSELTAMIVIR 12 MG/ML Suspension [for RETAIL pharmacy use if Ora-Sweet SF not available]

Date Prepared: \_\_\_\_\_

FINAL PRODUCT CHECKED BY: \_\_\_\_\_

EXPIRY DATE: \_\_\_\_\_

INGREDIENT	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Tamiflu® [oseltamivir] 75 mg capsules	ROCHE			16 capsules			
PCCA PLUS® or ORA-PLUS®	PCCA or Paddock Laboratories			100 ml			

**EQUIPMENT**

- Mortar and Pestle
- Graduated Cylinders
- Amber Plastic Bottle

**STABILITY**

- Original study states 90 days at room temp or refrigerated, HOWEVER, due to the fluctuations in stability seen in this study, **CHEO recommends stability of 5 days (duration of therapy) refrigerated.**

**MANUFACTURING DIRECTIONS**

\*\*\*Oseltamivir is a difficult drug to work with as it tends to “clump.” It is important to finely grind the powder, and add only small amounts of vehicle at a time.

1. Empty the powder from the Tamiflu® capsules into a mortar. Finely triturate with the pestle.
2. Add a small quantity of vehicle to the powder. Incorporate into a paste
3. Continue to add small amounts of vehicle and incorporate well with each addition.
4. Rinse mortar with the vehicle (to ensure all of the drug end up in the final bottle), and pour into graduated cylinder to QS to final volume
5. Transfer to amber plastic bottle.

**REFERENCE(S)**

- Stability of Oseltamivir in Various Extemporaneous Liquid Preparations. IJPC Vol 11 No.2, March/April 2007.
- PCCA plus® interchangeable with Ora-Plus®, PCCA, personal communication, Oct 26, 2009

**\*\* Please note strength of suspension is 12 mg/mL\*\***

Revision Dates: 28OCT09 \_\_\_\_\_ Final Approval By: AB/CM Signatures: \_\_\_\_\_/\_\_\_\_\_