

FORMULATION RECORD

Name: Metronidazole Topical Solution
Strength: 1%
Dosage Form: Solution
Route of Administration: Topical

Date of Last Review or Revision: 09/26/05
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Metronidazole	1.0 g	cream colored powder	1 g/100 ml water; 0.5 g/100 ml ethanol; soluble in dilute acid	antiprotozoal
HCl 10%	1.5 ml	clear, non-viscous liquid	miscible with water	solubilizing agent
Propylene glycol	10.0 ml	clear, hygroscopic liquid	miscible with water	inhibitor of mold growth; solubilization agent
Methylparaben	100 mg	white crystalline needles	1 g/400 ml water; 1 g/ 70 ml warm glycerol	preservative
Propylparaben	50 mg	white crystal	soluble in 2000 parts water	antifungal, preservative
Purified Water	qs 100 ml	clear, non-viscous liquid	NA	solvent

Calculations:

The amounts of methylparaben and propylparaben are below the LWQ of a Class A prescription balance. A stock solution or trituration will be required. Make a stock solution that has 100 mg methylparaben and 50 mg propylparaben in 10 ml of propylene glycol or make a trituration that has 100 mg methylparaben and 50 mg of propylparaben per 150 mg of powder.

Equipment Required:

- Class A prescription balance
- 100 ml beaker
- scintillation vial
- 50, 100 ml graduated cylinder

Method of Preparation:

1. Make the methylparaben and propylparaben trituration.
2. Add the methylparaben and propylparaben trituration to a scintillation vial and add 10 ml propylene glycol rinsing the weigh boat. Continue to shake the vial contents until powders are dissolved.
3. Add the metronidazole to about 50 ml of purified water in a 100 ml beaker and begin stirring with a stir bar.
4. Add the hydrochloric acid solution to the beaker.
5. Add the methylparaben and propylparaben – propylene glycol mixture to the beaker. Rinse the scintillation vial with a few portions of purified water.
6. Transfer the beaker contents to a precalibrated prescription bottle.
7. Add sufficient purified water to volume rinsing the beaker.

Description of Finished Product:

Clear, colorless to slightly yellow, non-viscous solution. No visible particles.

Quality Control Procedures:

Physical appearance
Weight of final product
Solution pH (2.5 – 3.5)
Analytical determination of metronidazole content

Packaging Container:

A plastic prescription container

Storage Requirements:

Can be stored at room temperature.

Beyond-Use Date Assignment:

USP Guidelines:

Aqueous solutions:

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Assign 14 days. Storage in cold temperature is not required due to presence of preservatives.

Label Information:

For External Use Only

Source of Recipe:

Secundum Artem, volume 10 number 3, Paddock Laboratories

Literature Information:

The Merck Index, 12th edition, copyright 1996