

FORMULATION RECORD

Name: Metronidazole Topical Solution

Strength: 1%

Dosage Form: Solution

Route of Administration: Topical

Date of Last Review or Revision: Today

Person Completing Last Review or Revision: RPS

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 crystals	soluble in 2000 parts water	antifungal
Purified Water	qs 100 ml	clear, non-viscous liquid	NA	solvent

Calculations:

The amount of methylparaben and propylparaben are below the LWQ of a Class A balance. A trituration is required. Diluent should not change the pH of the solution (pH = 2.8) which is critical for metronidazole solubility. Diluent should not promote protozoal or fungal growth.

Equipment Required:

- Class A balance
- Small beaker
- Scintillation vial
- Appropriate container

Method of Preparation:

1. Accuracy weigh the powder ingredients.
2. Make the methylparaben and propylparaben trituration.
3. Add the metronidazole to about 50 ml of purified water in a beaker and begin stirring.
4. Add the hydrochloric acid solution.
5. Dissolve the paraben trituration in the propylene glycol (in a scintillation vial) and add to beaker solution.
6. Transfer to a precalibrated bottle.
7. Add sufficient purified water to volume rinsing both the scintillation vial and the beaker.

Description of Finished Product:

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

Quality Control Procedures:

Physical appearance
Weight
Analytical determination of metronidazole content

Packaging Container:

A plastic container appropriate to the dispensing of the formulation.

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.

Label Information:**Source of Recipe:**

Secundum Artem, volume 10 number 3, Paddock Laboratories

Literature Information: