FORMULATION RECORD

Name: Ciprofloxacin and Hydrocortisone Otic Solution
Strength: 0.3% ciprofloxacin, 0.5% hydrocortisone
Dosage Form: Solution
Route of Administration: Otic

Date of Last Review or Revision: 08/01/12
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Ciprofloxacin hydrochloride	0.36 g	light yellow crystalline powder	soluble in water 1g/25ml	antibacterial
Hydrocortisone	0.5 %	white to creamy-white, odorless powder	insoluble in water (0.028%) and glycerin; propylene glycol 12.7 mg/ml	glucocorticoid, anti-inflammatory
Glycerin	60 ml	viscous, clear, colorless, odorless, hygroscopic liquid	sp. gr. = 1.25 g/ml; miscible with water and alcohol	antimicrobial preservative (>20%), emollient and humectant (<30%)
Propylene glycol	qs 120 ml	viscous, clear, colorless, odorless, tasteless, hygroscopic liquid	miscible with water, glycerin, alcohol; sp. gr. = 1.038 g/ml	humectant (15%), inhibitor of mold growth (15-30%); solubilization agent (10-25%)

Calculations:

Equipment Required:

- 125 ml droptainer with regulator and cap
- SI-203 digital balance
- mortar and pestle
- 100 ml graduated cylinder

Method of Preparation:

1. Calibrate the droptainer with water to 120 ml. Empty the water and stand the bottle on its opening to drain.
2. Accurately weigh the powders.
3. Triturate the powders in a mortar with a pestle, and add about 5 ml of propylene glycol. Triturate the powders until a paste is formed.
4. Add about 40 ml of propylene glycol (in increments) to the mortar, triturating between each addition. Do over a period of 20 minutes.
5. Pour the contents of the mortar into the droptainer, and rinse the mortar and pestle with increments of glycerin.
6. Bring the droptainer to final volume with propylene glycol.

Description of Finished Product:

Clear, slight yellowish color, odorless, viscous solution. No visible particles.

Quality Control Procedures:

Physical appearance
Weight of final product
Analytical determination of active drug content

Packaging Container:

A 125 ml air-tight plastic droptainer with regulator and cap.

Storage Requirements:

Can be stored at room temperature.

Beyond-Use Date Assignment:

Per <795> nonsterile compounding default value: Not later than the time remaining until the earliest expiration date of any API, or 6 months, whichever is earlier.

Label Information:

protect from light

Source of Recipe:

Literature Information:

Das Gupta V. The effect of some formulation adjuncts on the stability of hydrocortisone. *Drug Dev Ind Pharm 11:2083-2097, 1985*. Stability of hydrocortisone: stable at room temperature in aqueous buffered soltuion containing 50% propylene glycol without preservative.

Applied Pharmaceutics in Contemporary Compounding, 2nd edition (© 2008, p. 83).
Notes: glycerin preservation: volume x 2; propylene glycol preservation: as Alcohol USP.