

FORMULATION RECORD

Name: Cefazolin Ophthalmic Solution USP
Strength: 3.5 mg/ml
Dosage Form: Solution
Route of Administration: Ophthalmic

Date of Last Review or Revision: USP 26, 2003
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Cefazolin sodium	350.0 mg	white, crystalline powder	soluble in water; slightly soluble in methanol and ethanol	antibiotic
Thimerosal	2.0 mg	white to cream powder	1 g/ml water; 1 g/8 ml alcohol	anti-infective; preservative
0.9% Sodium Chloride Injection	qs 100 ml	clear, non-viscous liquid	NA	solvent

Calculations:

A stock solution of thimerosal in 0.9% Sodium Chloride Injection will be required for thimerosal. Maximum thimerosal concentration stated in Applied Pharmaceutics in Contemporary Compounding is 0.01%. Make stock solution 0.01% of thimerosal in 0.9% Sodium Chloride Injection. Use 20 ml of stock solution to deliver 2.0 mg of thimerosal.

Equipment Required:

- Class A prescription balance
- 50 ml beaker, 100 ml beaker
- 50 ml graduated cylinder
- 20 ml sterile syringe with luer-lok tip
- membrane filter, 0.22 micron pore size
- pH meter

Method of Preparation:

1. Accurately weigh cefazolin sodium and place in clean, calibrated 100 ml beaker
2. Add appropriate volume of thimerosal stock solution
3. QS with 0.9% sodium chloride injection in 100 ml beaker
4. Use about 50 ml for pH verification
5. Package remaining solution in laminar flow hood using aseptic techniques

Description of Finished Product:

After filtration, clear solution, free from particles

Quality Control Procedures:

chromatographic analysis for drug content
sterility challenge
pH measurement

Packaging Container:

Preserve in tight, sterile ophthalmic container.

Storage Requirements:

Store in a refrigerator.

Beyond-Use Date Assignment:

Official compounded formulation of USP 26/NF21. Beyond use date is 5 days.

Label Information:

For Use In The Eye
Do Not Use If A Precipitate Is Present

Source of Recipe:

Official Monographs of the USP 26, Cefazolin Ophthalmic Solution. The United States Pharmacopeia 26/National Formulary 21. The United States Pharmacopeial Convention, Inc., Rockville, MD, 2002, p. 358

Literature Information: