Formulation Record

Name: Benzocaine
Strength: 2.0%
Dosage Form: Gel
Route of Administration: Topical

Date of Last Review or Revision: 10/12/00
Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Benzocaine USP	2.0%	white crystalline powder	1 g/2500 ml water or 5 ml alcohol	anesthetic
Carbopol 940 NF	2.0%	White, very fluffy powder	soluble in water; soluble in alcohol after neutralization	gelling agent
Alcohol USP	90.0%	clear liquid	miscible with water	diluent
Distilled Water	6.0%	clear liquid	NA	diluent

Example Calculations:

Least Weighable Quantity (LWQ) on Class A Prescription Balance is 120 mg.

For 240 gm of gel:

2% benzocaine = 4.8 gm
2% carbopol 940 = 4.8 gm
90% alcohol = 216 gm; (density = 0.810) = 266.7 ml
6% distilled water = 14.4 gm; (density = 1.000) = 14.4 ml water

Equipment Required:

- Class A prescription balance meeting USP specifications
- Graduated cylinders
- Stirring rod (**DO NOT USE A STIRRING HOT PLATE**)

Method of Preparation:

1. Using the prescription balance, weigh the powders. Mark each weigh boat with the drug name.
2. Put alcohol in beaker, and add benzocaine with stirring.
3. Add carbopol in portions to the alcohol-benzocaine mixture with continual stirring.
4. Add the water and mix thoroughly.
5. Pour mixture into ointment tube, and crimp end

Description of Finished Product:

Clear, viscous gel

Carbomer is the generic name for Carbopol family of resins. Carbomer resins are allylpentaerythritol-cross-linked, acrylic acid-based polymers. Carbopol 940 is highly effective in forming thick, clear gels.

Quality Control Procedures:

Product should be well mixed. Complete gelling (hydration of carbomer) may require 24 hours.

Packaging Container:

2 oz. metal ointment tube with telescope box.

Storage Requirements:

Benzocaine is stable in air (Merck Index).

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.

Approximately 18% Alcohol USP will preserve a formulation. This formulation will be preserved due to the very high alcohol concentration. The 14 day beyond-use date can thus be extended. The reference gives a beyond-use date of 1 year, but the warning of periodically observing the formulation for signs of physical instability.

Label Information:

For External Use Only

Source of Recipe:

Apothecary Products, Inc., TSN 033

Supporting web page: http://www.unc.edu/courses/phar051l/, then select Suspensions and Gels
Supporting web page: http://www.unc.edu/courses/phar051l/, then select Ointments: media clips titled," How to Fold an Ointment Tube."

Literature Information:

Merck Index, 12th Edition, 1996
International Journal of Pharmaceutical Compounding, Vol. 3 (6): 479-486, 1999

Compounding Record

Name: _____
Strength: _____
Dosage Form: _____
Route of Administration: _____

Quantity Prepared: _____
Date of Preparation: _____

Person Preparing Formulation: _____

Person Checking Formulation: _____

Formula:

Ingredient	Manufacturer and Lot Number	Purity Grade	Description	Quantity Required	Actual Quantity Used

Calculations:

[Calculations performed at the time of compounding]

Equipment Required and its Operation:

[Equipment performance notes or alternate equipment used]

Method of Preparation:

[Description of any deviation from the Formula Record method of preparation]

Description of Finished Product:

Quality Control Procedures:

[Details of quality assurance test results and data]

Packaging Container:

Storage Requirements:

Beyond-Use Date Assignment:

[What beyond-use date was assigned, and reasons for difference from Formula Record if applicable]

Label Information: