

Formulation Record

Name: Lidocaine Dental Gel
Strength: 2.0%
Dosage Form: Gel
Route of Administration: Buccal

Date of Last Review or Revision: 10/20/02
Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Lidocaine USP	2.0%	white crystalline solid	insoluble in water; soluble in alcohol	local 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

Additional Information:

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

Example Calculations:

For 20 gm of gel:

2% lidocaine = 0.4 gm

2% carbopol 940 = 0.4 gm

90% alcohol = 18.0 gm; (density = 0.810) = 22.2 ml

6% distilled water = 1.2 gm; (density = 1.000) = 1.2 ml

Equipment Required:

- Class A prescription balance
- 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 the lidocaine in a beaker. Add the alcohol and water to the beaker and dissolve the lidocaine.
3. Add carbopol in portions to the mixture with continual stirring. As the powder surfaces, push in down into the mixture. Use the end of a glass stirring rod to break-up and "grind" the powder into smaller particles.
4. When a few, very small particles remain, cover with Parafilm and leave to complete hydration overnight.
5. Package in dental syringes

Description of Finished Product:

Clear to semi-clear viscous gel

Quality Control Procedures:

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

Packaging Container:

1 ml dental syringe with dental tip

Storage Requirements:

Store 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.

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. However, there is no reference that provides stability studies for this formulation. Therefore, a 14 day beyond-use date should be assigned.

Label Information:

For Oral Use Only

Source of Recipe:

Supporting web page: pharmlabs.unc.edu, then select Suspensions and Gels

Literature Information:

Merck Index, 12th Edition, 1996