

Formulation Record

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

Date of Last Review or Revision: 8/12/04
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Lidocaine USP	2.0%	white crystalline solid	insoluble in water; soluble in alcohol	local anesthetic
Carbopol 941 NF	2.0%	white, very fluffy powder	soluble in water; soluble in alcohol after neutralization	gelling agent
Alcohol USP	90.0%	clear, nonviscous liquid	miscible with water	diluent
Distilled Water	6.0%	clear, nonviscous 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.

Example Calculations:

For 20 gm of gel:

2% lidocaine = 0.4 gm

2% carbopol 941 = 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 plate and bar
- 50 ml beaker
- Parafilm ®

Method of Preparation:

1. Using the prescription balance, weigh the powders. Mark each weigh boat with the drug name.
2. Add the alcohol and water to the beaker and dissolve the lidocaine with moderate stirring.
3. With vigorous stirring, add carbopol in portions to the mixture.
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, moderately viscous gel

Quality Control Procedures:

Product should be clear, colorless, with no visible particles.

Packaging Container:

1 ml dental syringe with dental tip

Storage Requirements:

Store at cold 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 could 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 Buccal Use Only
Store in Refrigerator

Source of Recipe:

Supporting web page: <http://pharmlabs.unc.edu>, then select Suspensions and Gels

Literature Information:

Merck Index, 12th Edition, 1996 for solubility information

Handbook of Pharmaceutical Excipients, 4th edition, 2003, pp. 89-92 (carbomers)