Tramadol HCl 1% - Lidocaine HCl 4% Cream (Pentravan®)

Total Formula Quantity

100 grams

Ingredients	Quantity	
Tramadol Hydrochloride USP	1 grams	
Lidocaine Hydrochloride USP Monohydrate	4.28 grams	
Diethylene Glycol Monoethyl Ether NF	5 grams	5.05 milliliters
Pentravan®	89.72 grams	

Ingredient Disclaimer

Lidocaine Hydrochloride 1mg is equivalent to 1.07mg Lidocaine Hydrochloride Monohydrate

The density of Diethylene Glycol Monoethyl Ether is 0.991 g/mL

Method/Instructions

1. Calculate amount of ingredients needed.
2. Accurately weigh and measure each ingredient.
3. Combine Tramadol Hydrochloride, Lidocaine Hydrochloride, and Diethylene Glycol Monoethyl Ether in an appropriate size FagronLab EMP jar then mix for 1-2 minutes at a low mix speed.
4. Add Pentravan to Step #3 and mix again for 2-3 minutes at a medium mix speed.
5. Process through Three Roll/Ointment Mill as needed.
6. Mix compound again for 1 minute at a low mix speed, or by hand, and package in an appropriate dispensing device.

Formulation Notes

- A stabilizing/emulsifying/thickening agent may be added to help stabilize the formulation. An addition of 1-5% stabilizing/emulsifying/thickening agent is recommended, subtracting amount added from the base quantity. Mix stabilizing/emulsifying/thickening agent thoroughly in aqueous phase, compatible solvent phase or add in final step along with base.
- For optimal results this formulation should be compounded using a mechanical mixing device to ensure thorough mixing. Next, process through a three roll/ointment mill to reduce ingredient particle size, eliminate grittiness, and enhance the elegance of the final compounded product. Finally, remix in a mechanical mixing device to ensure thorough dispersion.

Equipment

FagronLab EMP
Balance
FagronLab PM 140
FagronLab TRM Ointment Mill
Hood
Hot/Stir Plate
Tube Sealer

Supplies/Dispensers

Topi-Click
Topi-Pump
ExactDose Adapter
Syringe
Tube
Varionozzle
Vaginal Cream Applicator

PPE Notes

Refer to USP <795> current guidelines for specific minimum garbing requirements. Gloves must be worn for all compounding activities. Additional garb may be necessary depending on the type of compounding performed and per the facility's SOP.

Storage

Controlled Room Temperature 20 to 25 °C
Store in a tightly closed container
Protect from light

BUD

Dating per USP <795>

- Non-preserved aqueous = 14 days
- Preserved aqueous = 35 days
- Nonaqueous oral liquids = 90 days
- Other nonaqueous dosage forms = 180 days

AUX

This medication was specially compounded in our pharmacy for you at the direction of your prescriber.

References

- United States Pharmacopeia - National Formulary. Chapter <795> United States Pharmacopeia, Rockville, MD.

QC check section

Describe the appearance of the finished compound (color, odor, etc):

Compounded Active Pharmaceutical Ingredients match the original prescription document: Yes / No

Describe the closure container used for finished compound (Topiclick, etc.):

Quality control measures taken and results (pH measurements ,etc):

Visual inspection of compound within expectations: Yes / No

Container closure checked for and free of any leakage and/or cracks: Yes / No

Compounded preparation released for dispensing by (name):

Disclaimer

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