

NOTE: This worksheet for making LET Gel is provided for your pharmacist to review. Your institution is fully responsible for any decision regarding its manufacture and/or use.

LIDOCAINE/EPINEPHRINE/TETRACAINE GEL
Manufacturing Worksheet

PRODUCT: L.E.T. Topical Gel (Lidocaine 4%, Epinephrine 0.05%, Tetracaine 0.5% Gel)

Quantity: _____ LOT NUMBER DATE: _____ EXP DATE: _____ DATE MADE: _____

CONSTITUENTS	QUANTITY	MFGR	LOT#	EXP.DATE	INITIALS
Lidocaine Hydrochloride	8 gram	Spectrum			
Tetracaine Powder	1.72 Grams	Spectrum			
Na Bisulfite	260 mg	Spectrum			
Adrenalin Chloride Solution for Inhalation					
(Epinephrine 10mg/ml)	17.5ML(175mg)	Monarch			
Lidocaine Jelly 2%	10 X 30 gram	Copley			
Sterile Water for Irrigation	qs 40 ml				

FINAL VOLUME of above = 350 ml (for calculations)
 *8/2003 Used Adrenalin Inhalation to replace racemic epi

PROCEDURE:

1. CLEAN 1 X 400ML GLASS BEAKER AND 1 X 100ML GLASS BEAKER THOROUGHLY WITH HOT-WATER. RINSE WITH STERILE WATER FOR IRRIGATION AND DRY.
2. WEIGH THE Lidocaine HCL (must use the HCL salt-dissolves in H₂O) TETRACAINE AND NA BISULFITE POWDERS INTO THE 100ML BEAKER. Dissolve in Sterile water for irrigation -qs to 40 ML
3. IN A LAFH, ADD THE LIDOCAINE POWDER. & EPINEPHRINE INHALATION SOLUTION TO THE POWDERS IN THE GLASS BEAKER, Dissolve in Sterile Water SWIRL GENTLY TO DISSOLVE THE POWDERS,
4. EMPTY THE CONTENTS OF THE (10X30 GM TUBES)-(DOUBLE BATCH) INTO THE 400ML GLASS BEAKER. MAKE SURE THE VOLUME IS ABOUT 300ML (of Lidocaine Gel) (DOUBLE BATCH), USING GRADUATIONS ON THE BEAKER.
5. DRAW LIDOCAINE/EPINEPHRINE/TETRACAINE/NA BISULFITE SOLUTION INTO A 60ML SYRINGE (DOUBLE BATCH) USING A NEEDLE. REPLACE NEEDLE WITH 0.2 MICRON MILLEX-GS FILTER, FILTER SYRINGE CONTENTS INTO THE JELLY IN THE LARGE BEAKER SLOWLY TO AVOID AIR BUBBLES.
6. STIR THOROUGHLY USING A GLASS ROD THAT WAS CLEANED WITH AN ALCOHOL SWAB.
7. TAKE CARE NOT TO INCORPORATE A LOT OF AIR INTO JELLY MIXTURE, STIR SLOWLY IN A FIGURE 8 PATTERN,
8. ALLOW MIXTURE TO SIT IN THE HOOD UNTIL THE AIR BUBBLES HAVE RISEN TO TOP IF NECESSARY. **QS to FINAL VOLUME of 350 ML with Sterile Water.**
9. DRAW GEL INTO THE ORAL SYRINGE (AMBER) TO A VOLUME OF 1.7 ML TO ACCOUNT FOR ANY AIR BUBBLES, IT IS NOT IMPORTANT TO GET EXACTLY 1.7ML, MANUFACTURING NOTE-
 ^Draw L.E.T. Gel into a 60 ML Leur Lock Syringe, USING a LEUR to ORAL adaptor, place product Into 3 ML ORAL Syringes to 1.7 ML-
 This gives a clean TIP on which to place CAPS, eliminating need to wipe with alcohol swab,
10. LABEL TO REFRIGERATE
11. PLACE IV SYRINGE IN A PLASTIC ZIP LOCK BAG AND STORE IN REFRIGERATOR UNTIL DISPENSED TO. E.R,

EXPIRATION: 5 MONTHS
CLOSURE: BLUE SYRINGE CAP
CONTAINER: 3 ML AMBER ORAL SYRINGE
NUMBER OF UNITS: APPROX 210 X (1.7ML) SYRINGES

Example Label: L.E.T.Topical Gel 1.5 ML
 Lidocaine 4% Refrigerate
 Epinephrine 0.05%
 Tetracaine 0.5%
 Lot:MMYY123 Exp:mm/dd/yy