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FORMULA NUMBER: 752

FORMULA NAME: Nicotine Polacrilex 2-mg Lollipops

DOSAGE FORM: Lozenge

FORMULA (Rx):

Ingredients	For: One Lollipop		Lot#	RPh Initials
Nicotine Polacrilex	1.1	g	_____	_____
Alcohol	[95%] 17	mL	_____	_____
Stevioside (Stevia)	1.25	g	_____	_____
Flavor	qs		_____	_____
Sorbitol Lollipop Base	qs		_____	_____

SYNONYMS:
Nicorette

USE/TYPE:
Human Use
Non-Sterile Preparation

CATEGORY:
Cholinergic Agent
Smoking Cessation Adjunct

NOTES:
Sorbitol candies (commercial vehicles) may be substituted for the lollipop vehicle. Nicotine polacrilex 1.1-gram is equivalent to 200-mg nicotine. For preparation of lollipop base: The size of the lollipop mold must be determined before the final weight of the base that will be used is selected. The sucrose lollipop base can be prepared with powdered sugar (42- g), light corn syrup (16-mL), and purified water (24-mL). Combine those three ingredients in a beaker and stir until they are well mixed. Cover the mixture and heat it on a hot plate at a high setting until the mixture boils. Continue boiling for 2-minutes. Uncover the mixture, remove it from the heat, and allow it to set for a few minutes. Then add the nicotine salicylate solution and mix thoroughly. Add the stevia and flavor, mix well and pour the mixture into molds. Commercial sources are also available. The density of the dosage form will be different when varying amounts of active pharmaceutical ingredients are used. Prior to beginning, it is necessary that any mold used be calibrated with the formula to determine the quantity of base required. It is desirable to calculate for approximately 10% overage of the ingredients to adjust for the excess material required.

SPECIALIZED EQUIPMENT:
Biohazard or Chemo Materials Equipment

METHOD OF PREPARATION:

1. Calculate the required quantity of each ingredient for the total amount to be prepared.

2. Accurately weigh and/or measure each ingredient.

3. Disperse the nicotine polacrilex in the alcohol.

4. Melt the sorbitol candies at a temperature that is not higher than 70°C.

5. Add the nicotine dispersion and mix well.

6. Add the stevia and mix well; then add the flavor.

7. Cool the mixture slightly and pour it into lollipop molds while the mixture is still fluid.

8. Allow the mixture to cool, and remove it from the molds. The lollipops can be dusted with powdered sugar if they are sticky.

9. Package and label. For unique packaging, drill a hole in the cap of a plastic vial for tablets or capsules and insert a lollipop into the cap from the underside before securing the cap.

LABELING:
For Oral Use as a Lollipop. Store Away from Children Keep Out of Reach of Children

PRESERVATION, PACKAGING AND STORAGE:
Tight, Light Resistant Container Keep Out of Direct Sunlight
Store at Room Temperature Away from Excessive Heat Do Not Use After _____

STABILITY:
A beyond-use date of 6 months can be used for this preparation.

ENDOTOXIN ASSESSMENT:

USE:
This preparation has been used as a smoking-cessation aid. Novel dosage forms (chewing gum, transdermal patches, lollipops), which are often used as part of a smoking-cessation program, can contribute to the participant's success. Nicotine polacrilex is a complex of nicotine with a methacrylic acid polymer. Nicotine can be absorbed from the gastrointestinal or respiratory tract and through intact skin; however, absorption of the nicotine base is more rapid than that of the polacrilex form. Note: Prior to compounding, check the nicotine equivalent of the polacrilex actually available.

STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL:
Quality control assessment may include weight, specific gravity, active drug assay, color and texture of the surface. Other observations: appearance, feel, melting test, macro physical observation and physical stability.

REGULATORY CONTROL:

REFERENCES:

1. Allen Loyd V Jr. Standard Operating Procedure for Performing Physical Quality Assessment of Suppositories, Troches, Lollipops and Sticks. International Journal of Pharmaceutical Compounding. 3(1); 1999:56.
2. Mason Dave, Fields Shannon. Lollipops: The Evolution of a Dosage Form. International Journal of Pharmaceutical Compounding. 6(3); 2002:178.
3. Ashworth Lisa D. Quality Control: Standard Operating Procedures--An Essential Tool for Developing Quality Preparations. International Journal of Pharmaceutical Compounding. 11(3); 2007:226.
4. United States Pharmacopeial Convention, Inc. United States Pharmacopeia 24-National Formulary 19. United States Pharmacopeia, Rockville MD; 2000:2698-2702.
5. McEvoy GK. AHFS-Drug Information 2001. American Society of Health-System Pharmacists, Bethesda MD; 2001:1335-1352.
6. O'Neil MJ Sr, Ed. The Merck Index. 12th Ed. Merck & Co., Inc, Whitehouse Station NJ; 1996:1119-1120.
7. Reynolds JEF, Ed. Martindale: The Extra Pharmacopoeia. 30th Ed. The Pharmaceutical Press, London; 1993:1049.
8. Allen Loyd V Jr. Nicotine 2-mg Lollipops. International Journal of Pharmaceutical Compounding. 6(3); 2002:205.
9. United States Pharmacopeial Convention. United States Pharmacopeia 31-National Formulary 26. Chapter <795> United States Pharmacopeia, Rockville MD; 2008.
10. The United States Pharmacopeial Convention. USP-Pharmacists' Pharmacopeia. 2nd Ed., Rockville MD; 2008:775-779.
11. Fuller MA, Sajatovic M. Drug Information Handbook for Psychiatry. 7th Ed. Lexi-Comp Inc, Hudson OH; 2009:1133-1136.
12. Sweetman SC, Ed. Martindale: The Complete Drug Reference. 36th Ed. Pharmaceutical Press, London UK; 2009:2352-2354.
13. US FDA Office of Regulatory Affairs for Drug Evaluation and Research (CDER). U.S. 21 CFR Policy Guide (CPG) for FDA Staff and Industry: Sec.[§] 460.200 Pharmacy Compounding., www.fda.gov/ora/compliance; 2013.
14. United States Pharmacopeia 41-National Formulary 36 [May 2018]., Rockville MD; 2018.
15. Goldwire M, Lehano C, Ostenson A. Nicotine replacement therapy in the hospitalized patient. US Pharmacist. 39(10); 2014:HS20-HS24.
16. Trissel LA, Ashworth LD, Ashworth J. Trissel's Stability of Compounded Formulations. 6th Ed. American Pharmacists Assn, Washington DC; 2018.

More information about this formula and its components available at the formula section of https://CompoundingToday.com

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