لجان الدفعات

DISPENSING

MORPHINE ACADEMY

Lozenges and Medication Sticks

Chapter 16

Introduction:

- Both are semisolid preparations, However:
  - The lozenge is intended for buccal (فم) or sublingual (تحت اللسان) administration
  - The medication stick is used for topical application


BONUS PACK
9 EXTRA PIECES
Nicorette
nicotine polacrilex lozenge, 2mg • stop smoking aid
Lozenge
Includes User's Guide
2 mg
FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.
If you smoke your first cigarette WITHIN 30 MINUTES of waking up, use Nicorette 4mg Lozenge
Mint
81 LOZENGES, 2mg Each


FOR THE REMOVAL OF COMMON WARTS
Drug Facts

Lozenges

1. "are semisolids preparations that are intended to dissolve or disintegrate slowly in the mouth
2. They contain one or two medicaments usually in a flavored, sweetened base
3. Used for localized effects in the mouth (most often)
4. Can be used for systemic effect if the drug is well absorbed from the buccal (بطانة الفم) lining or is swallowed
5. Troche and lozenge are used interchangeably (بالتبادل)

Look for drug in the market that is in the form of lozenges?

Lozenges

- Advantages:

1. Easy to administer to pediatric and geriatric patients
2. The formula are easy to change and can be patient and dosing specific
3. The drug stays in contact with the oral cavity for an extended time

يبقى تأثيره في الفم لفترة طويلة

Disadvantages:

1. "Gummy type" lozenge may not be perceived by children as a serious dosage form

بكل بساطة بحكي انه الشكل الي زي الحلوى ممكن يشكل خطر على الاطفال يمكن (ما يفكروها دواء اصلاً) ويأخذو منها بشكل خاطئ او جرعة زائدة

Lozenges

يمكن صنعها بطريقتين

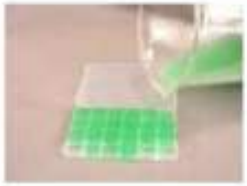
- Can be made by molding or by compression
- Commercial troches are made by compression using mucilages or natural gums to affect adhesion (harder than ordinary tablet so dissolve or disintegrate slowly)
- Compounded lozenges in a mold contain:

- Sugars to form a hard lozenge
- Polyethylene glycol (PEG) to form a soft lozenge
- Gelatin to form a chewable lozenges

Hard Lozenges

- Similar to hard candy
- Are made by heating sugars and other ingredients together to about 160 °C, then pouring the mixture into a mold
- 55-65% sucrose and 35-45% corn syrup (conc. of sugar is important so as not to become grainy) لازم ننتبه على تركيز السكر عشان ما يصير حبيبات
- They require a low moisture content (0.5-1.5%) → water is evaporated by boiling the sugar mixture during the process
- Instruction should be followed carefully
- Heat labile drugs cannot be used الادوية غير المستقرة حراريًا لا نستخدمها
- The mold's shape look like a sucker or lollipop شكل القالب زي المصاصة
- Hard lozenges will not disintegrate in the mouth تفكك وتذوب
- They will dissolve or erode over 5-10 minutes تذوب تتآكل

Soft Lozenges



- Easily compounded
- Dissolve in the mouth over 10-15 minutes
- Some soft lozenges are to be chewed مضغه
- Ingredients: PEG 1000 or 1450, chocolate, sugar-acacia base
- Acacia add texture يضيف الملمس and smoothness والنعومة
- Silica gel may be used as a suspending agent
- PEG contract as they cool (over fill the mold)
- Ingredients should be heat stable (up to 50°C)
- The warm mixture is poured into a plastic troche mold where the correct dose of drug can be assured يُسكب الخليط الدافئ في قالب بلاستيكي حيث يمكن ضمان الجرعة الصحيحة من الدواء.
- Soft textures

Chewable Lozenges:

- "Gummy type" lozenges
- Fruit-flavored with slightly acidic taste to cover the taste of glycerin
- Intended to be chewed and swallowed
- Popular for pediatrics
- Most are based on the glycerinated gelatin suppository formula: glycerin, gelatin, water

تحميلة

Calibration procedure

- Lozenge mold must be calibrated for each lozenge base (like any other mold e.g. suppository)
- Calibration procedure will be discussed in Chapter 17 (suppositories)
- Calibration procedure:

1. Determine the average weight of a lozenge using only the base materials

متوسط الوزن

من خلال المواد الاساسية

2. Calculate the density factor of substances that will be added to the lozenge base. Any substances added to the base will occupy a specific volume, so the amount of base required in the formulation will have to be adjusted. As an approximation if a density factor is not available, solid ingredients will displace most lozenge bases from 70-90%. Liquid ingredients will displace 100% of the base.

Hard Lozenge

Drug	1 gm
Powdered sugar	42 gm
Corn Syrup	16 gm
Water	24 ml
Mint extract	1.2 ml
Color qs	

Soft Lozenge

Drug	1 gm
Polyethylene glycol 1000	10 gm
Aspartame	20 packets
Mint extract	1 ml
Color qs	

Chewable Lozenge

Drug	0.5 gm
Glycerin	70 ml
Gelatin	18 gm
Water	12 ml
Methylparaben	0.4 gm
Flavoring oil	3 to 4 drops
Color qs	

Medication Sticks

نقل بسهولة مريح

- Sticks are an easily transportable and convenient dosage form for administering topical medications.
- They can be compounded in different sizes and shapes for application to different areas of the body.
- They can be applied directly to the affected site of the body for local activity.
- Or they can be applied to different epidermal sites if systemic activity is desired. Epidermal penetration enhancers can be added to the formulation to promote this later use.
- تأخذ القوام من
- Sticks get their consistency from a combination of waxes, polymers, resins
- Local anesthetics, sunscreens, antivirals, and antibiotics

Soft Sticks

- Medication sticks contain waxes, polymers, oils, and gels (or combination of theses) that will soften at body temperature
- Allow the formulation to be spread evenly over the affected area and they leave no visible residue ننشرها على المنطقة المعينة وبعدين ما رح تترك أثر مرئي
- Clear (شفاف) or opaque (أو معتم) depending (حسب القاعدة) on the base
- Soft clear sticks contain sodium stearate, glycerin, and/or propylene glycol in their base.
- Soft opaque stick bases may contain petrolatum, cocoa butter, and polyethylene glycol (PEG).

Soft Sticks

- Soft stick consistency is determined by the blend of high and low melting point ingredients used as the base.
- Sometimes additional high melting point ingredients are added to "stiffen" (i.e., make more solid) some bases.

Ingredient	Melting Point (°C)
Carnauba wax	81 - 86
Cetyl alcohol	45 - 50
Cetyl esters wax	43 - 47
Cholesterol	147 - 150
Cocoa butter	30 - 35
Glyceryl monostearate	55
Stearic acid	69 - 70
Stearyl alcohol	55 - 60
White wax (Beeswax, white and yellow)	62 - 65
PEG 1500	44 - 48
PEG 3350	54 - 58
PEG 6000	58 - 63

When combining materials that have a range of melting points, it is best to melt the material with the highest melting point first, and then melt the material with the second highest melting point second, and so forth. As each new ingredient is added to the melt, the temperature can be reduced. This will prevent over heating the lower melting point ingredients.

عند خلط مواد مختلفة في درجة الانصهار:
ابدأ بإذابة المادة الأعلى في درجة الانصهار أولاً.
بعد ما تذوب، أضف المادة ذات درجة الانصهار الأقل وهكذا بالتسلسل.
مع كل إضافة خفّض الحرارة تدريجيًا.
الفائدة: هذا يمنع ارتفاع حرارة المواد ذات درجة الانصهار المنخفضة وبالتالي يحميها من التحلل أو التلف.

Hard Sticks

- Hard sticks are made of crystalline powders that are either fused together by heat or held together with a binder.
- The stick must be moistened to be "activated." When it is wetted, a concentrated solution of the drug forms on the wetted part of the stick and the solution is transferred when the stick is touched to the affected area.
- The crystalline powder in the stick may leave a white residue on the skin.
- The prime example of a hard stick is a styptic pencil.

يجب ترطيبها

يترك بقايا بيضاء على الجلد

مضاد للنزيف

- A **styptic** (also spelled **stiptic**) is a specific type of antihemorrhagic agent that works by contracting tissue to seal injured blood vessels. Styptic pencils contain astringents. (wikipedia)

عمل الانسجة الانقباضية لاغلاق الاوعية الدموية المصابة

Soft Opaque Stick

White Beeswax	30 gm
Cetyl alcohol	8 gm
Cocoa butter (or FattibaseT)	6 gm
Carnauba wax	1 gm
Castor Oil Tasteless	2 ml
AquabaseT	20 gm
Petrolatum	13.5 gm
Perfume	0.9 ml
Preservative	0.1 gm
Butyl Stearate	5 mg
Active Drug qs	

Soft Clear Stick

Sodium stearate	13%
Methyl salicylate	35%
Menthol	15%
Propylene glycol	25%
Water	12%

Hard Stick

Ammonium chloride	7 gm
Aluminum sulfate	27 gm
Ferric sulfate	40 gm
Copper sulfate	26 gm

Filling Applicators

- Applicators are administration devices that hold the medication stick formulation
- Two sizes are typically available: 45 g and 5 g (lip balm)
- After all the ingredients have been incorporated into a melt, they are poured into the applicator

Observing the formulations for evidence of instability

- The USP Chapter <1191> has no specific recommendations for lozenges and sticks for signs of instability
- In general, the primary indication of instability is either discoloration or a change in consistency or odor
- Hard lozenges and PEG polymer (hygroscopic and soften at elevated temperature)
- Store in tight containers and keep it from drying out (especially chewable lozenges)