

Lozenges and Medication Sticks

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أشعل + سواف

Introduction:

- Both are **semisolid preparations**, However:
 - The lozenge is intended for buccal or sublingual administration
 - The medication stick is used for topical application





- medication sticks -

Lozenges

- “are **semisolids preparations** that are intended to dissolve or disintegrate slowly in the mouth
- They contain one or two medicaments usually in a flavored, sweetened base
- Used for localized effects in the mouth (most often)
- Can be used for **systemic effect** if the drug is well absorbed from the buccal lining or is swallowed
- ^{نفساً الأني} Troche and lozenge are used interchangeably

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

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ال troche هي نفسها ال
الجواب كان f اتوقع

Lozenges

- Advantages:

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

Disadvantages:

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

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Question 15 / 50

Which of the following statements is correct

1. ☐ Lozenges are semisolid preparations for topical dermatological use ~~x~~ For - buccal
- sublingual
2. ☐ Medicated sticks are semisolid preparations that dissolve inside the mouth ~~x~~ administration
3. ☐ Lozenges could be used for systemic effect ✓
4. ☐ Hard lozenges are preferred for children and can't be considered as a serious dosage form ~~x~~
5. ☐ None of the choices

Can be used for systemic effect if the drug is well absorbed from the buccal lining or is swallowed

Disadvantages:

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

Lozenges

- 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
- used as drug vehicle ←

3 types - hard lozenges
- soft lozenges
- chewable lozenges

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Question 8 / 50

Which of the following combinations is incorrect regarding preparation of lozenges

1. ☐ Sugars ---- Gummy lozenges ×
2. ☐ Sugars ---- Hard lozenges ✓
3. ☐ PEG-----Soft lozenge ✓
4. ☐ Gelatin----- Chewable lozenges ✓
5. ☐ More than one choice

Next

5. Commercial troches are often made by compression. What is added to these formulations to ensure they are harder than ordinary tablets?

A. Large amounts of water

B. Low-density lubricants

C. Mucilages or natural gums

D. Effervescent salts



4. Which combination of base material and lozenge type is CORRECT?

A. Polyethylene glycol (PEG) — Chewable Lozenges

B. Sugars — Hard Lozenges

C. Chocolate — Hard Lozenges

D. Gelatin — Hard Lozenges

B

suger

Hard Lozenges



- Similar to hard candy
- Are made by heating sugars and other ingredients together to about 160 oC, then pouring the mixture into a mold

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- 55-65% sucrose and 35-45% corn syrup (conc. of sugar is important so as not to become grainy)
- They require a low moisture content (0.5-1.5%) ☐
water is evaporated by boiling the sugar mixture during the process $160\text{ }^{\circ}\text{C}$
- Instruction should be followed carefully
- ^{sensitive} Heat labile drugs cannot be used
- The mold's shape look like a sucker or lollipop

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All of the following properties of hard lozenges except

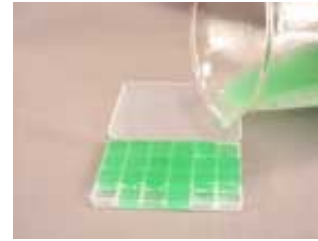
1-contain 55%-65% sucrose ✓

2-will dissolve over 5-10 minutes ✗ soft lozenges

3-require a low moisture content 0.5-1.5

~~وكان في خيار غلط مش ذاكرتو الي هو الجواب~~

Soft Lozenges



- Easily compounded
- Dissolve in the mouth over 10-15 minutes
- Some soft lozenges are to be chewed
- Ingredients: PEG 1000 or 1450, chocolate, sugar-acacia base

جابت سؤال اي نوع من انواع ال lozenges بيحتوي على ال peg الجواب soft lozenge

جابت ليه بضيف ال Acacia على ال Soft Lozenges الجواب كان texture and smoothness

natural polysaccharide + natural emulsifying agent

- Acacia add texture and smoothness
- Silica gel may be used as a suspending agent
- PEG contract as they cool (over fill the mold) *shrink* *overflow the mold to ensure the full dose.*
- Ingredients should be heat stable (up to 50oC)
- The warm mixture is poured into a plastic troche mold where the correct dose of drug can be assured

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 (Kids) ✓
- Most are based on the glycerinated gelatin suppository formula: glycerin, gelatin, water

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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:

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

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,

Hard Lozenge (suger)

Drug	1 gm
<u>Powdered sugar</u> ^{بسرعة تصف}	42 gm
<u>Corn Syrup</u> ^{hald}	16 gm
Water	24 ml
Mint extract ^{flavor agent}	1.2 ml
Color qs	

Base

Soft

Drug	Lozenge	1 gm
<u>Polyethylene glycol 1000</u>		10 gm
<u>Aspartame</u> $\Rightarrow$ Sweetner		20 packets
Mint extract ^{flavor agent}		1 ml
Color qs		

Chewable Lozenge

Drug	0.5 gm
<u>Glycerin</u>	70 ml
<u>Gelatin</u>	18 gm
<u>Water</u>	12 ml
Methylparaben ^{preservative}	0.4 gm
<u>Flavoring oil</u>	3 to 4 drops
Color qs	

• Artificial sweeteners (saccharin, aspartame and cyclamates) can be used. Saccharin and cyclamates are suspected to be carcinogenic and so aspartame is the most accepted one.



أنواع
تحضير
مزوق
مكونات

Medication Sticks



- 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.
- Sticks get their consistency from a combination of waxes, polymers, resins

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مواد صلبة

- waxes
- resins
- polymers

14. To promote systemic activity from a topical medication stick, what type of ingredient should be added?

A. Opacifiers like Zinc oxide

B. Carnauba wax for hardness

C. Astringents like Aluminum sulfate

D. Epidermal penetration enhancers



13. How do medication sticks primarily obtain their consistency?
- A. Through the use of high-fructose corn syrup.
 - B. From a combination of waxes, polymers, and resins.
 - C. By high-pressure compression of powders alone.
 - D. By freezing liquid oils into a solid state.



Soft Sticks

soft opaque sticks
soft clear sticks

- Medication sticks contain waxes, polymers, oils, and gels (or combination of these) that will soften at body temperature
- Allow the formulation to be spread evenly over the affected area and they leave no visible residue ✨
- Clear or opaque depending 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.

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.

- stops bleeding
- 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)

substance that tightens body tissues and reduces bleeding



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Question 9 / 50

Which of the following statements is correct regarding medicated sticks

1. ☐ Cocoa butter is used to prepare ^{opaque} ~~clear~~ soft sticks ✗
2. ☐ ^{hard} ~~Soft~~ sticks are made of crystalline powders fused together by heat or a binder
3. ☐ ^{hard} ~~Soft~~ stick may leave a white residue on the skin.
4. ☒ A styptic pencil is a hard sticks used to stop bleeding from the small injuries ✓
5. ☐ ^{hard} ~~Soft~~ stick must be moistened before application

Next

إضافة ملاحظة

- petrolatum
- cocoa butter
- polyethylene glycol

Soft Opaque Stick

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

Soft Clear Stick

- sodium stearate
- glycerin
- propylene glycol

soft
clear
stick

Sodium stearate	13%
<u>Methyl salicylate</u>	35%
<u>Menthol</u>	15%
Propylene glycol	25%
Water	12%

Hard Stick

solid

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



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) absorbs water easily from the air
- Store in tight containers and keep it from drying out (especially chewable lozenges)

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Question 48 / 50

Hard and soft lozenges must be kept in air-tight containers in dry place

1. ☒ True
2. ☐ False

Next

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