



لجان الرُفَعَات

DISPENSING



MORPHINE ACADEMY

MORPHINE
ACADEMY

Dermatological Formulations: Ointments Creams and Pastes

← هذا هو كلهم بنوعهم semisolid dosage forms يعني لا هم سائل كامل ولا صلب كامل ، لكنهم قوام بينا وبينهم .

Dermatological Formulations

- Ointments, creams, pastes and gels are semisolid dosage forms intended for **topical application**. (الأشكال الدوائية السميكة)

They are also termed "semisolids" because they appear to be solid but still have fluid properties (نصف صلب ولبودا لدهوية)

- They may be applied to the skin, placed on the surface of the eye, or used nasally, vaginally, or rectally. (Ophthalmic ointments)

- Topical applications can be designed for either **local effects** or **systemic absorption**

له الدواء بديا ياد يصد في حلال الدم ← الدم

Transdermal patches (مكاف)

له الدواء بديا ياد يتغل مع الجلد نفسه (تعالج موضعي مكاف) skin is the target organ.

يوصل الدواء للجلد فقط لعلاج مكاف فيه (الذي يراه مكاف)

- A topical dermatological product is designed to deliver drug into the skin in **treating dermal disorders**, with the skin as the target organ.
- A transdermal product is designed to deliver drugs through the skin (percutaneous absorption) **to the general circulation for systemic effects**

يختص به الجلد ويوصل للدم ← عناء يتغل في الجسم كله

سلي solution

سلي suspension

- Pharmaceutical *creams* are semisolid preparations containing one or more medicinal agents dissolved or dispersed in either a w/o emulsion or an o/w emulsion.

ليجوا ال Creams الـ الـ ointments

- Many patients and physicians prefer creams to ointments because they are easier to spread and remove.

و سكره مقبوله اكثر
cosmetically elegant.

- Pharmaceutical manufacturers frequently manufacture topical preparations of a drug in both cream and ointment bases to satisfy the preference of the patient and physician.

الشركان عادة يصنعون الدواء مع سكره و مع سكره ointment مع cream

يعطوا اسواق السيب والحرفه (ب) اختلاف السبل

Purposes of dermatological formulations:

الحماية
Protection
ترطيب و
التعقيم

1. To protect the skin or mucous membranes from chemical or physical irritants in the environment thus permit the skin to rejuvenate and heal

لح تجديد الجلد فمهمة تجديد (Rejuvenate) وللتعافي (heal)

2. To provide emollient (skin softening) and occlusive effect

تجعل البشرة تعففة تمنع فقدان الماء من الجلد (Hydration) له مواد تنعقي الجلد النعم وامري زي الفازلين مثلا او الاليسين

وسيلة لنقل
الادوية

3. To provide a topical vehicle for medications for local (anti-infective, anti-pruritic, astringent, keratolytic) or transdermal/systemic effect (e.g. nitroglycerin)

ممكنة اخرى وسيلة لعلاج موضعي (local)

مضاد عدوي

من اجل علاج الجلد المتهمة قافية مضاد حساس

transdermal/systemic effect (e.g. nitroglycerin)

له كيفية وصول للدم

Structure of the skin

الجلد هو أكبر وأثقل عضو بالجسم (بن 17% من وزن الشخص)

- The skin is the largest and heaviest organ in the body and accounts for about 17% of a person's weight.

- Its major function is to protect the underlying organ systems from trauma, temperature, humidity, harmful penetrations, moisture, radiation, and microorganisms.

اصابة
ازالة او نقص
مواد مؤذية

It is composed of three layers of stratified tissue: epidermis, dermis, and subcutaneous tissue.

أغشية الجسم على
أربعة دوائر
دوران هامة

الجلد
طبقة خارجية

- The thickness of the skin is 3 - 5 millimeters. The thickness of the skin varies with the different parts of the body. The thickest parts of the skin are the palms and soles and the thinnest parts are the eyelids and genitals.

الجفون والأغشية
التالية

راحة اليد وباطن القدم

- Within the structure of the skin are several skin appendages: hair follicles, sebaceous glands, sweat glands, and nails.

ملحقات
الجلد

لصليان الشعر

غدد دهنية

غدد عرقية

أظافر

لدينا الدواء يتغلل موضعياً
 (eczema cream) ← أي
 (Topical)

هدول اهم حاجت قد ام اعصاب
 الاربعة

- Stratum corneum
- Stratum lucidum
- Stratum granulosum
- Stratum malphigii (spinosum)
- Stratum germinativum (basale)

- Dermal papillae
- Papillary
- Reticular
- Nerve endings
- Blood vessels

لدينا اعصاب جارية
 (systemic) → Transdermal patch

بال Dermis

الطبقة الخارجية وما فيها او عوية دوية
 مكونة من Strata (طبقات)

Epidermis

فيها دم / اعصاب / عروق / عيون دوية

Dermis

تحت الجلد

Subcutaneous tissue

Muscle

Local and systemic effects of Dermatological Formulations:

المستحضران الجلدية ممتدة تتغلغل على الجلد فلهذا داخله

- Dermatological formulations produce a local drug effect either **on or in** the skin.

- Besides the specific therapeutic action of incorporated active drugs, the formulations also serve as **protectants**, **lubricants**, **emollients**, or **drying agents**.

- Examples of treatments using dermatological formulations include **minor skin infections**, **itching**, **burns**, **diaper rash**, **insect stings and bites**, **athlete's foot**, **corns**, **calluses**, **warts**, **dandruff**, **acne**, **psoriasis**, and **eczema**.

Local and systemic effects of Dermatological Formulations:

و يعود بعضا للمستحضران *some* ليصل الدواء عبر خلال الجلد ← الدم

- Some dermatological formulations are intended to systemically deliver a drug.

الدواء يدخل لل *epidermis* ② يؤمن مع الجلد ①

- The formulation is placed on the skin, and the drug penetrates the epidermis into the dermis and subcutaneous tissues, where it is absorbed into the systemic circulation.

③ لوصول

يوصل للأوعية الدموية ← ينقل
systemic circulation

- Some dermatological formulations provide continual percutaneous absorption (i.e. transdermal patch).

توصيل الدواء بشكل مستمر

- Percutaneous (through the skin) absorption is the result of three competing processes:

لثلاثة عمليات الدواء عبر الجلد يعتمد على 3 عمليات متنافسة

- 1 - the potential of the drug to cross the stratum corneum
- 2 - the potential of the drug to leave the formulation
- 3 - the influence of the formulation on the stratum corneum.

① قدرة الدواء على عبور ال SC

② قدرة الدواء لترك المستحضر نفسه

③ تأثير طبيعة المستحضر على ال SC

المخاطر:

عوامل مؤثرة

Aspect	Local formulations	Systemic formulations (Transdermal)
Target	Skin itself (surface or within skin layers)	Whole body via systemic circulation
Barrier to cross	Usually stratum corneum (جزئياً أو سطحياً فقط)	Must fully cross stratum corneum → dermis → blood vessels
Examples of use	Eczema, psoriasis, acne, minor infections, burns, diaper rash, dandruff, warts	Nitroglycerin, nicotine, fentanyl, hormone patches
Main functions	Therapeutic + protectant, emollient, lubricant, drying agent	Deliver drug at controlled/continuous rate to bloodstream
Formulations	Ointments, creams, gels, pastes	Transdermal patches, medicated gels/ointments for systemic use
Key factors affecting action	Condition of skin, hydration, type of base	Drug lipophilicity, MW, release from formulation, hydration of SC

اصحاب الدواء يجب الحيلولة

العوامل التي تزيد الامتصاص عبر الجلد:

Percutaneous absorption

كلما زادت المساحة التي يتخذه عليها الدواء ← زاد الامتصاص

• More drug is absorbed when the formulation is applied to a larger **surface area**

مساحة التغطية

المستحضر الذي dressing occlusive الذي يتحبس الماء بترطيب الجلد ← يزيد الامتصاص

• Formulations or dressing that increase **hydration** of the skin generally enhance percutaneous absorption

ترطيب الجلد

• The greater the amount of **rubbing** the formulation, the greater is the absorption

الفرك

الرفرف Rubbing يزيد دوران الدم بالمنطقة + يسهل الدواء يدخل ← الامتصاص ↑

• The longer the formulation remains in **contact** with the skin, the greater is the absorption

مدة البقاء

كل ما بقي المستحضر مع الجلد اطول ← امتصاص اكثر

① surface area

② Hydration

③ Rubbing.

④ contact time.

Percutaneous absorption:

كمية الامتصاص
البيعية

- The amount of drug that can be absorbed is about 2mg/day
- Thus: (Enhancers) هذا هو الحد الأقصى لامتصاص الدواء عن طريق الجلد

1. percutaneous enhancers are used: (تستخدمها لتعزيز امتصاص الدواء)

1- زيادة ذوبانية الدواء بالـ SC

2- تسهيل انتشار الدواء بالدم (Diffusion)

أدوية

1. Improve the solubility of active drug in the stratum corneum

2. Facilitate the drug's diffusion into the systemic circulation

- DMSO, Urea, Triethanolamide, Dimethyl formamide

2. Mechanical methods: (طرق ميكانيكية)

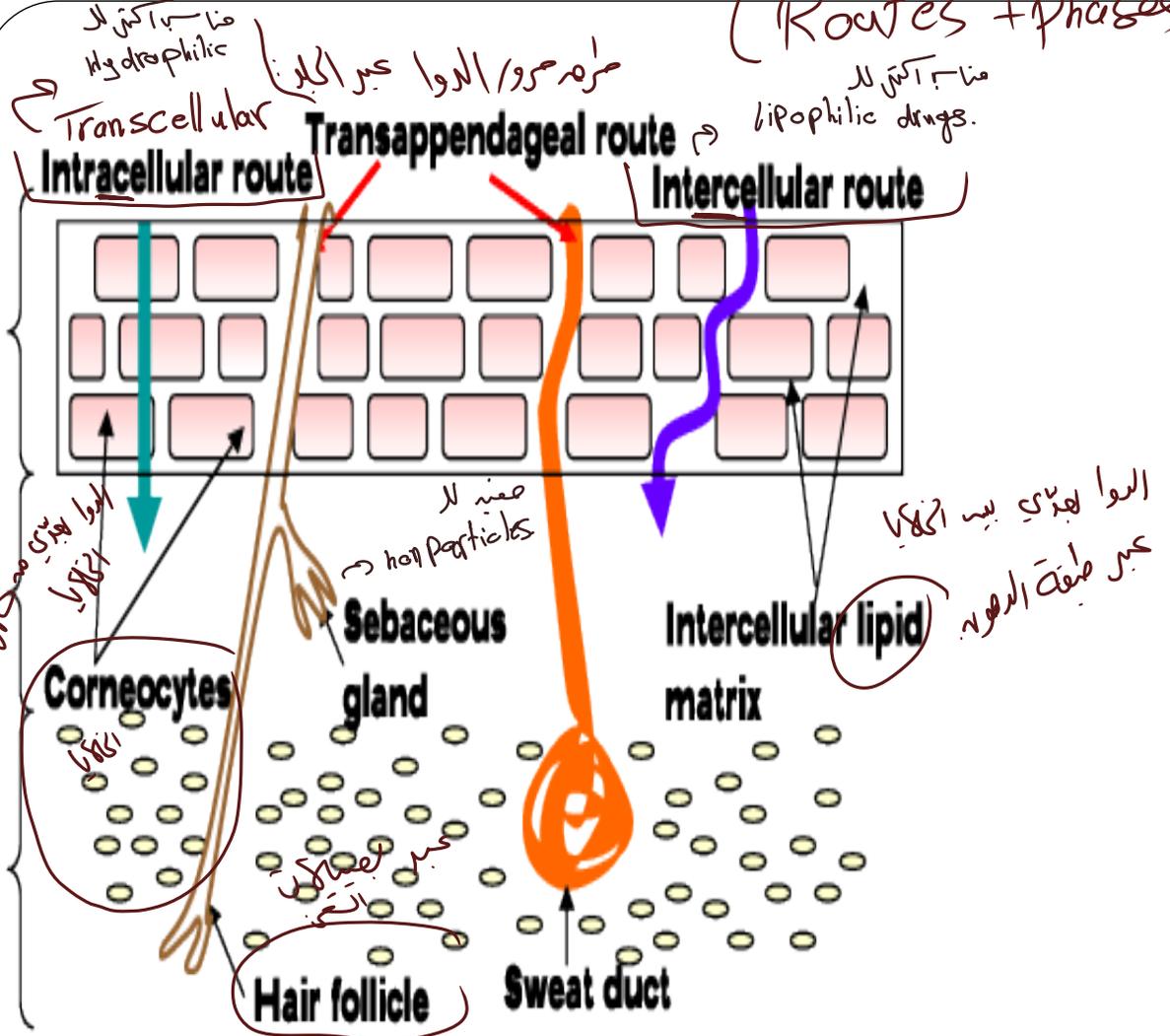
- Phonophoresis uses ultrasonic vibrations to increase the absorption of drugs such as lidocaine, tetracycline into and through the skin

استخدام موجات فوق صوتية ← بتفتيح المسام + تسهيل الامتصاص

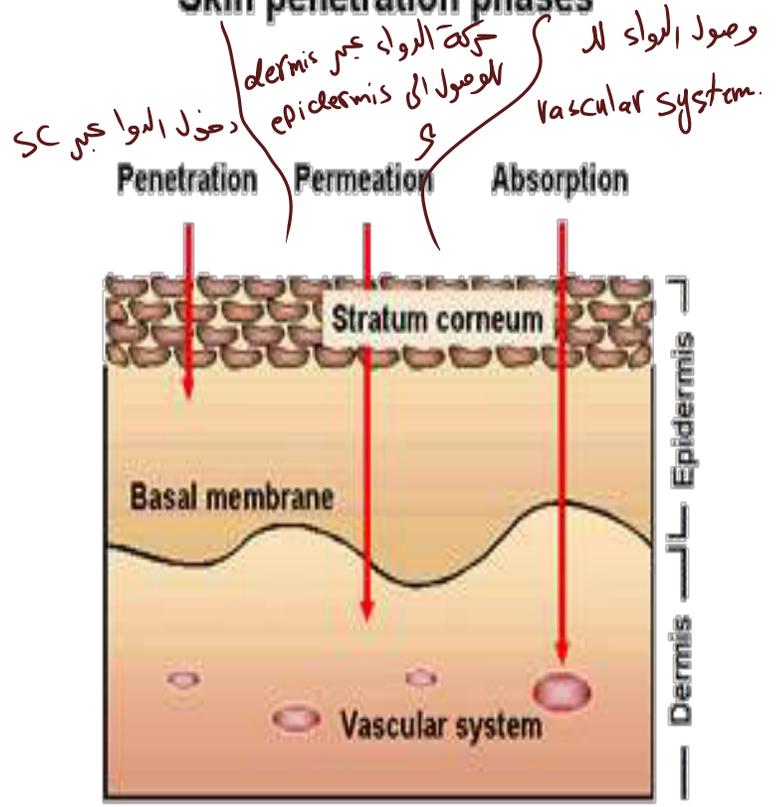
- Iontophoresis uses electrical field to aid in the transportation of local anesthetic and analgesic, peptides and proteins

استخدام مجال كهربائي يساهم في الأدوية (خصوصاً المشحونة زي Peptides) لأنها تعجز الكبد

(Routes + Phases of Penetration)



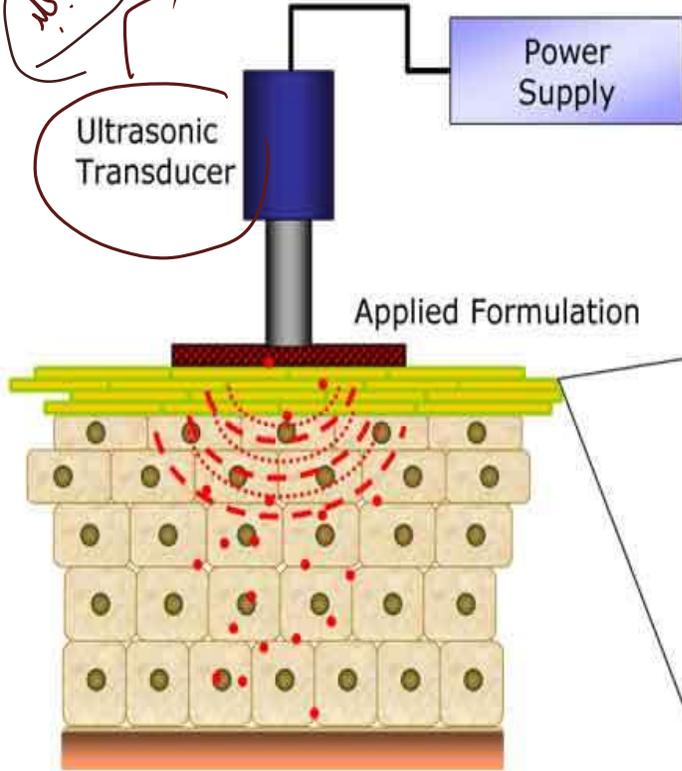
Skin penetration phases



A) Epidermis (S. corneum), B) Dermis, C) subcutaneous layer

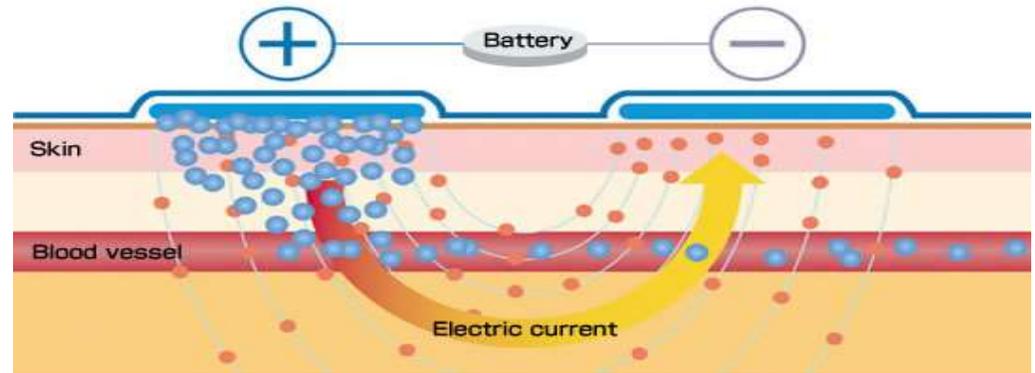
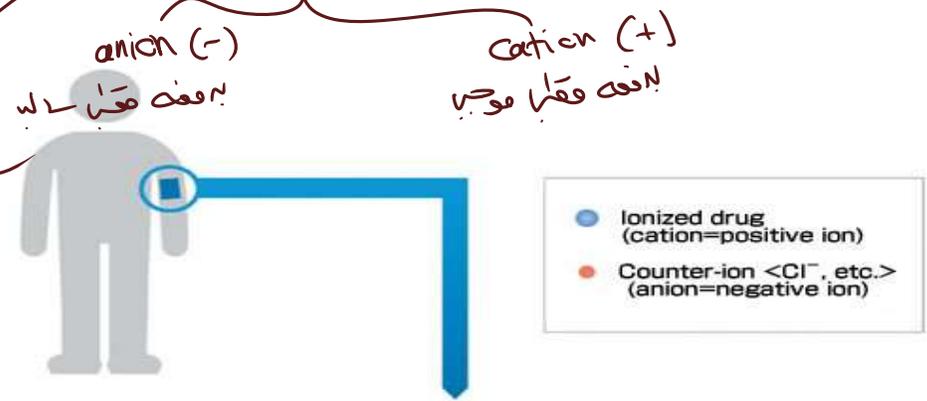
(Mechanical enhancement methods)

ما هي الموجات التي تنتج micropores
تزيد fluidity lipid matrix



التيمة : الموجة
كمياتها لا Dermis
وهي الدم

يتم تغيير تركيزه بالأيون المنصف عبر الجهد ، الدواء اذ كان ionized



Phonophoresis

الموجات فوق الصوتية

Iontophoresis

التيار الكهربائي

Routes of Percutaneous Absorption

Route	كيف يمر الدواء؟	مناسب لمين؟
Intracellular (Transcellular)	يمر من خلال الخلايا (corneocytes)	أدوية محبة للماء (Hydrophilic)
Intercellular	يمر بين الخلايا عبر طبقة الدهون (lipid matrix)	أدوية محبة للدهون (Lipophilic)
Transappendageal	عبر بصيلات الشعر والغدد (sebaceous, sweat)	طريق ثانوي – مفيد للـ nanoparticles وبعض الأدوية

Phases of Skin Penetration

1. Penetration → دخول الدواء للـ **Stratum corneum**.
2. Permeation → مروره عبر الـ **Epidermis** → **Dermis**.
3. Absorption → وصوله للأوعية الدموية (Systemic circulation).

Enhancement Methods

Method	آلية العمل	أمثلة للأدوية
Chemical enhancers (DMSO, Urea...)	↑ ذوبان الدواء بالـ SC + ↑ Diffusion	مختلف حسب الصيغة
Phonophoresis (Ultrasound)	موجات صوتية تعمل Micropores + ↑ نفاذية	Lidocaine, Tetracycline
Iontophoresis (Electric field)	تيار كهربائي يدفع الأيونات عبر الجلد	Local anesthetics, peptides, proteins

الدهن

Ointments

- Traditionally the term *ointment* has been used for (i) the general class name for all external-use semisolids and (ii) the subclass, oleaginous semisolids.
- USP 31 Chapter <1151> defines ointments very generally as “semisolid preparations intended for external application to the skin or mucous membranes”.
 (فانكس دهني) oleaginous base او قديج داخل
 ointment (دهني) الرواد قديان او قديج داخل
- However, pharmaceutical manufacturers use the word ointment more specifically to indicate that a drug is incorporated into an oleaginous ointment base; for example, the name Hydrocortisone Ointment means that hydrocortisone is incorporated into an oil-type semisolid base.
 قديان
 oleaginous
- Thus, the term semisolid would be used for naming the general class, and the term ointment would be redefined more narrowly as “a viscous oleaginous or polymeric semisolid dosage form”, which is consistent with current usage by the pharmaceutical industry

الدهن (الدهني)

الدهني semi solid → قديان / creams / gels / pastes

ointment → (oleginous / polymeric viscous semisolid) عباره عن مزيج من عيار صلب

Types of Ointments

- Ointments are semisolid preparations intended for external application to the skin or mucous membranes.
- Ointments may be medicated or Unmedicated ointments
- Unmedicated ointments are used for the physical effects they provide as protectants, emollients, or lubricants.
- Ointment bases, as described, may be used for their physical effects or as vehicles for medicated ointments.

سبب استخدامها؟

① اما كحامل للمركبات (حماة او مرطبات)

② ادوية كحامل (medicated ointments vehicle)

 ointment هو semisolid
 semisolid هو ointment

Medicated ointments:
 active ingredient (المركب النشط)
 vehicle (الحامل)

Unmedicated ointments:
 vehicle (حامل) وادوية (مركبات) كحامل
 (المركبات النشطة)

Oleaginous Ointment Bases

له مرهم دهني بيت

Absorption Ointment Bases

Water/Oil Emulsion Ointment Bases

This is correctly classified as cream

اصيانتا غير قابله للعزل

Oil/Water Emulsion Ointment Bases

This is correctly classified as cream

قابله للعزل

Water-miscible Ointment Bases

More correctly called gels

Composition

oleaginous compounds

oleaginous base + w/o surfactant

oleaginous base + water (< 45% w/w) + w/o surfactant (HLB ≤8)

oleaginous base + water (> 45% w/w) + o/w surfactant (HLB ≥9)

Polyethylene Glycols (PEGs)

Water Content

ما بجدت الهيا anhydrous

anhydrous

✓ hydrous

hydrous

anhydrous, hydrous

Affinity for Water

hydrophobic

hydrophilic

hydrophilic

hydrophilic

hydrophilic

Spreadability

difficult

difficult

moderate to easy

easy

moderate to easy

Washability

nonwashable

nonwashable

non- or poorly washable

washable

washable

Stability

oils poor; hydrocarbons better

oils poor; hydrocarbons better

unstable, especially alkali soaps and natural colloids

unstable, especially alkali soaps and natural colloids; nonionics better

stable

Drug Incorporation Potential

solids or oils (oil solubles only)

solids, oils, and aqueous solutions (small amounts)

solids, oils, and aqueous solutions (small amounts)

solid and aqueous solutions (small amounts)

solid and aqueous solutions

Drug Release Potential*

poor

poor, but > oleaginous

fair to good

fair to good

good

Occlusiveness

yes

yes

sometimes

no

no

Uses

protectants, emollients (+/-), vehicles for hydrolyzable drugs

protectants, emollients (+/-), vehicles for aqueous solutions, solids, and non-hydrolyzable drugs

emollients, cleansing creams, vehicles for solid, liquid, or non-hydrolyzable drugs

emollients, vehicles for solid, liquid, or non-hydrolyzable drugs

drug vehicles

ما بفعلي من صيب

Examples

White Petrolatum, White Ointment

Hydrophilic Petrolatum, Anhydrous Lanolin, Aquabase™, Aquaphor®, Polysorb®

Cold Cream type, Hydrous Lanolin, Rose Water Ointment, Hydrocream™, Eucerin®, Nivea®

Hydrophilic Ointment, Dermabase™, Velvachol®, Unibase®

PEG Ointment, Polybase™

ببتمنع عقده الهيا صبر باله

Oleaginous ointment Bases

- *Petrolatum, USP, is a purified mixture of semisolid hydrocarbons obtained from petroleum.*

اللون

vary in color from yellowish to light amber.

الاستخدام

نقطة الانصهار

It melts at 38°C to 60°C and may be used alone or in combination with other agents as an ointment base.

الكلمات الأخرى

Petrolatum is also known as yellow petrolatum and petroleum jelly.

A commercial product is Vaseline.

صنعت تجارية

Oleaginous ointment Bases

- White Petrolatum, USP, is a purified mixture of semisolid hydrocarbons from petroleum that has been wholly or nearly decolorized. كع يتم إزالة لونه بالكامل أو تقريبا.
- It is used for the same purpose as petrolatum, but because of its lighter color, it is considered more esthetically pleasing by some pharmacists and patients. لونه الفاتح يجعله أكثر جاذبية من الناحية الجمالية.
- White petrolatum is also known as white petroleum jelly.
- A commercial product is White Vaseline

قاعدة زبدية

Oleaginous ointment Bases

- **Yellow Ointment, USP:** This ointment has the following formula for the preparation of 1000 g:
 - Yellow wax 50 g
 - Petrolatum 950 g
 - Yellow wax is the purified wax obtained from the honeycomb of the bee *Apis mellifera*.

القوة الاصفر : شمع نحل وحبوب كلبه من قرصه الى النحل *Apis mellifera*

Oleaginous ointment Bases

- *White Ointment, USP. This ointment differs from yellow ointment by substitution of white wax (bleached and purified yellow wax) and white petrolatum in the formula.*

الفرق بين المرمم الأصفر والأبيض: يتم استبدال الشمع الأصفر بشمع أبيض (صبيغ وصفتي) والبتول والشمع الأصفر بالأبيض

Oleaginous ointment Bases

- Hydrocarbon bases, known also as "oleaginous ointment bases"

القوة على
اصطفا الماء

- Only small amounts of an aqueous component can be incorporated into these bases

بكميات صغيرة جداً بقدر دمجها مع المكونات المائية
بها القواعد

الوقاية

- Hydrocarbon bases serve to keep medicaments in prolonged contact with the skin and act as occlusive dressings.

① الاصطفاً بالمواد مع الجلد

② التآني الاصطفاً: تمنع فقدان الرطوبة

الخلاصة:
 • قواعد المرهم الزيتية تستخدم لتضمين المرهم الطبية.
 • تتميز بغيرتها على الاصطفاً بالمواد على الجلد لفترات طويلة مع التآني الاصطفاً (occlusive).
 • التبريد والامراض والالتهاب والالتهاب احمر احمرار لا سبب جاليج بيدي لونهم الغالب.
 • طاب القواعد لا تمتص الماء بسهولة، كما يعطى ملائمة لادوية التي تتطلب تماساً طويلاً مع الجلد.

قاعدة صمغ استحبابية تستخدم لدفع المكونات
المائية في المرهم

Absorption Ointment Bases

- Hydrophilic Petrolatum, USP has the following formula for the preparation of 1000 g:
 - Cholesterol 30 g
 - Stearyl alcohol 30 g
 - White wax 80 g
 - White petrolatum 860 g

Absorption ointment Bases

اعزائها بالسكنجبين

• **Lanolin, USP (Anhydrous lanolin)** obtained from the wool of sheep (*Ovis aries*), is a purified wax-like substance that has been cleaned, deodorized, and decolorized.

لحوق الصمغ

ازالة الرائحة
ازالة اللون
لا يتجاوز 0.25%

• It contains not more than 0.25% water. → (Anhydrous Lanoline)

ال Lanolin المعدّل

• **Modified Lanolin, USP**, is lanolin processed to reduce the contents of free lanolin alcohols and any detergent and pesticide residues.

يتمّ معالجته لتقليل محتوى الكحول الحرة بار Lanolin وبقايا المنظفات والمبيدات الحشرية

properties:

Absorption ointment Bases

القدرة على دمج
المحاليل المائية

هذه القواعد تصبح بدرجة المحاليل المائية عند مزجها مع w/o emulsion

بعضها انزواج
الدهون وادخل القاعدة
الدهنية

- Permit the incorporation of aqueous solutions with the formation of a water-in-oil emulsion (e.g., Hydrophilic Petrolatum and Anhydrous Lanolin, both USP),
- Cholesterol and Stearyl alcohol are added as emulsifiers

علاوة على ذلك، يضاف الكوليسترول والستيرويل كإضافات

الغرض ليس قوائم المرهم الامتصاصية والدهنية:
 الدهنية: لا تستطيع دمج كميات كبيرة من الماء.
 الامتصاصية: مصممة لدمج المحاليل المائية مما يجعلها أكثر مرونة في تحضير المرهم التراكيبات كما قلنا سابقاً.
 مائية.

Water/Oil Emulsion Bases

- Are more correctly called “creams”.
- Consists of water-in-oil emulsions that permit the incorporation of additional quantities of aqueous solutions (Cold cream type, Hydrous Lanolin, USP).
- <http://www.cosmeticsandskin.com/aba/cold-cream.php>: refer to this article for the history of cold cream
- Why is it called cold cream?
- What is the role of borax in this formula?

تسمى كريمات
الماء في الزيت
التي هي الكريمات الباردة

• Why is it called cold cream?

بسبب الاحتكاك بالبرودة الذي ينتج عن الجمال

عند تعبئة هذا المنتج ينتج عنه تآكل الماء الموجود بالمصطب (w/o) عند الخلط

• What is the role of borax in this formula?

Borax : هو ملح معدني يستخدم كمصطب في تركيب الكريم البارد

Emulsifier : الرول

تثبيت اللدائم

تأثير مطري ضئيل

7:32 PM Fri 22 Aug

69%

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cosmetics and skin

Cold Creams

Described as an emulsion “based on beeswax as emulsifier and thickener” (deNavarre, 1941, p. 237) these creams have a long history of cosmetic use. The first cold cream has been attributed to the Roman physician Galen (C.E. 150) who reputedly made a primitive emulsion by mixing water with molten beeswax and olive oil. It was laborious to make – requiring a great deal of mixing – and tended to separate on standing. However, the formulation persisted – generally using rose-water and/or oil of roses as a perfume – and was included in the first edition of the ‘Pharmacopœa Londinensis’ in 1618.

In later formulations, sweet almond oil replaced the olive oil.

4 oz. of the purest almond oil.

1¼ oz. of white wax.



A jar of Vaseline Cold Cream. First produced by the

↑ Top

هذا وصفها

Oil/Water Emulsion Bases

- oil-in-water emulsions (e.g., Hydrophilic Ointment, USP), and are more correctly called “creams”.
- They also are described as “water-washable” because they may be readily washed from the skin or clothing with water an attribute that makes them more acceptable for cosmetic purposes.
- Some medicaments may be more effective in these bases than in hydrocarbon bases. Other advantages of the water removable bases are that they may be diluted with water and that they favor the absorption of serous discharges in dermatological conditions. *لأنه على اعتقاد الأثر لأن الماء*

أ. قابلية على الماء

إمكانية التحسين بالماء

اعتقاد الأثر لأن الماء

الغزيريسيا w/o و o/w (التوافق):

w/o \Leftarrow تحتوي على كمية أكبر من الزيت، مما يجعلها مرطبة ومناسبة للجلد الجاف أو

كصناديد أو دهانات occlusive (مثل الكريم البارد).

o/w \Leftarrow تحتوي على كمية أكبر من الماء مما يجعلها خفيفة، سهلة الفل، مناسبة للأغراض

التجميلية أو للعلاج الحامض الجليدي التي تتبخر افرازات

Water-Removable Bases (o/w emulsion bases)

- following formula for the preparation of about 1000 g:

Ingredient Amount (grams)

- Methylparaben 0.25
- Propylparaben 0.15
- Sodium lauryl sulfate 10.00 →
- Propylene glycol 120.00
- Stearyl alcohol 250.00
- White petrolatum 250.00
- Purified water 370.00

بازي سائل

الجزء المائي من المستحلب

Water Miscible Ointment Bases

خالية من الدهن

- Water-miscible Bases—This group of so-called “greaseless ointment bases” comprises water-soluble constituents.

بالكامل

- # Polyethylene Glycol Ointment (NF) is the only pharmacopeial preparation in this group.

المعروف في الصيدلانية باسم البولي إيثيلين جليكول

- Bases of this type offer many of the advantages of the water-removable bases and in addition, contain no water-insoluble substances such as petrolatum, anhydrous lanolin, or waxes.

They are more correctly called Gels.

يُعتبرها Gels بدلاً من المراهم التقليدية بسبب قوامها وقدرتها على الذوبان بالماء.

Water-Miscible Ointment Bases

- *Polyethylene Glycol Ointment, NF*
- *PEG is a polymer of ethylene oxide and water represented by the formula $H(OCH_2CH_2)_nOH$, in which n represents the average number of oxyethylene groups.*
- The numeric designations associated with PEGs refer to the average molecular weight of the polymer.
- PEGs having average molecular weight below 600 are clear, colorless liquids
- those with molecular weight above 1,000 are waxlike white materials; and those with molecular weight in between are semisolids
- The greater the molecular weight, the greater the viscosity

semisolids \leftarrow 600 و 1000

كل ما زاد الوزن الجزيئي \leftarrow زادت اللزوجة (العوالم).

عوامل اختيار في عدة مناسبة للمرض :

SELECTION OF THE APPROPRIATE BASE

Desired release rate of the drug substance from the ointment base

Desirability of topical or percutaneous drug absorption

Desirability of occlusion of moisture from the skin

Stability of the drug in the ointment base

Desire for a base easily removed by washing with water

Characteristics of the surface to which it is applied: an ointment is generally applied to dry, scaly skin; a cream is applied to weeping or oozing surfaces

الاصح المبللة لانها تساعد على امتصاص الاغذية

معدل انطلاق الدواء من القاعدة
اعنى امتصاص الدواء موضعياً او عبر الجلد
اعنى احتشاء الصبغة الرطوبة على الجلد
استقرار الدواء بالقاعدة
سهولة ازالة القاعدة بالماء
فضائل الطح المراد وضع السرم عليه

SELECTION OF THE APPROPRIATE BASE

- Oleaginous (hydrophobic) bases release drugs slowly and unpredictably because water cannot penetrate the base sufficiently to dissolve the drug. *لا يستطيع اختراقه*

- Water miscible and hydrophilic bases tend to release drugs more rapidly and more predictably because water can penetrate into the base.

- Once the drug has been released from the base the penetration through skin is influenced by the area to which the ointment is applied, the condition of the skin, the location, and method of application.

بعد إطلاق الدواء من القاعدة يتأثر اختراقه عبر الجلد بالعوامل التالية:

③ طريقة التصنيع

*① حالة الجلد
② موقع التصنيع*

الفرصة:

PREPARATION OF OINTMENTS

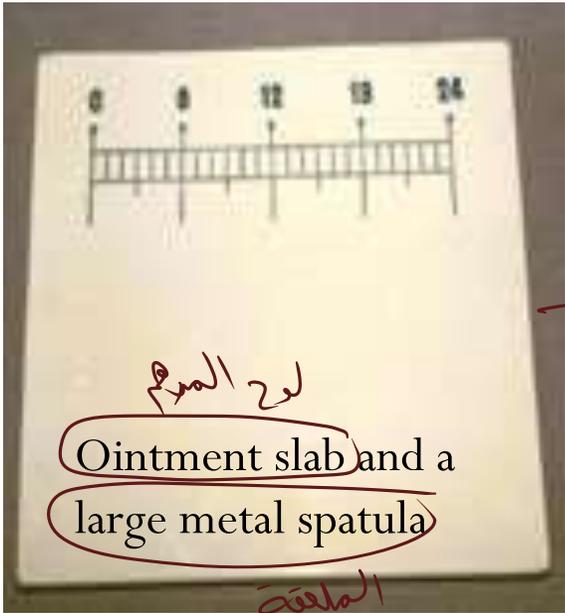
- Ointments are prepared by two general methods,
- (a) ^{دعج}incorporation and (b) ^{الانصهار}fusion



Incorporation

- The components are mixed until a uniform preparation is attained.
- On a small scale, as in extemporaneous compounding, the pharmacist may mix the components using a mortar and pestle, or a spatula may be used to ^{مزك} rub the ingredients together on an ointment slab (a large glass or porcelain plate or pill tile).
- Others will use an ointment mill





Ointment slab and a large metal spatula

المسكات

mortar and pestle



ointment mill



Incorporating a drug into an ointment base:

- Insoluble powders that are added into ointment base should be in the finest possible state of subdivision: →

لازم تكون في ادفه حاله تقسيم
ممتدة لتمام توزعها المتجانس

- Powder form used instead of crystalline form

ص

- Triturate the powder in a mortar & pestle

- Levigating agents (miscible with the ointment base)

- Some powders are incorporated into ointment base by dissolving the solid in a low vapor pressure solvent or oil that can be taken up by the ointment base

Incorporating a drug into an ointment base:

- levigating, or mixing the solid material in a vehicle in which it is insoluble to make a smooth dispersion.
- The levigating agent (e.g., mineral oil for bases in which oils are the external phase, or glycerin for bases in which water is the external phase).
- The levigating agent should be about equal in volume to the solid material.
- A mortar and pestle are used for levigation. This allows both reduction of particle size and dispersion of the substance in the vehicle.
- After levigation, the dispersion is incorporated into the ointment base by spatulation or with the mortar and pestle until the product is uniform.

عج = هم المادة الصلبة

تحت الجربان

تخليل مع الجربان

بعد الlevigation، يتم دمج التشتت الناتج في قاعدة المرهم باستخدام الملاط mortar and pestle حتى يصبح المنتج متجانسًا.

Fusion

- By the fusion method, all or some of the components of an ointment are combined by being melted together and cooled with constant stirring until congealed.
- Components not melted are added to the congealing mixture as it is being cooled and stirred.
- On a small scale, fusion may be conducted in a porcelain dish or glass beaker.
- On a large scale, it is carried out in large steamjacketed kettles.

تتضمن هاتين الطريقتين إذابة جميع أو بعض مكونات المرهم بالحرارة، وبعدها يترك الخليط حتى يبرد مع التحريك المستمر حتى يتصلب.

يتم إجراء هذه العملية حتى يتصلب الخليط بالكامل.

لحجم التكميم بالحرارة.

Fusion

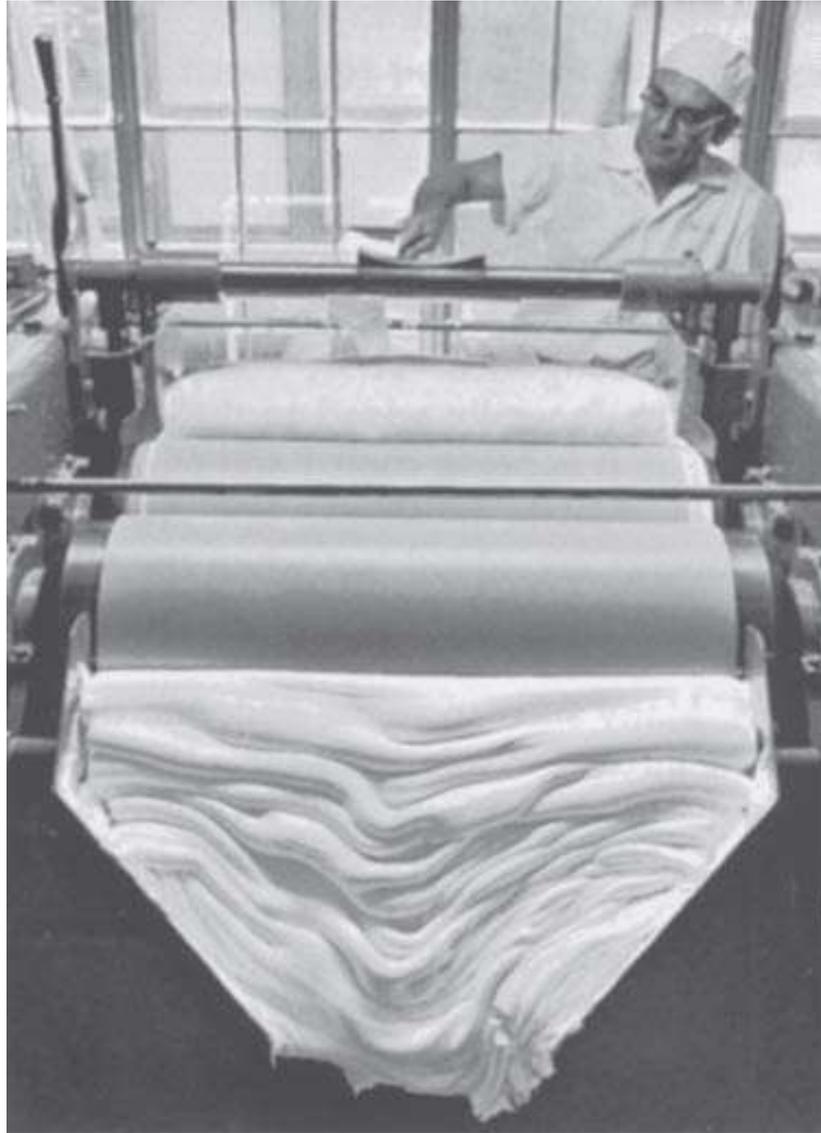
يُصْر الملبد عبر الآلة.

- Once congealed, the ointment may be passed through an ointment mill (in large-scale manufacture) or rubbed with a spatula or in a mortar to ensure a uniform texture.

- The materials with the highest melting points are heated to the lowest required temperature to produce a melt. The additional materials are added with constant stirring during cooling of the melt until the mixture is congealed. In this way, not all of the components are subjected to the highest temperature.

تُضاف المواد ذات نقاط انصهار الأرفع المنخفضة أثناء تبريد الملبد لتجنب
تعرُّبها جميع المكونات لأعلى درجة حرارة، مما يؤدي إلى استقرار الدواء أو التدهور
المبكر.

ointment mill



PASTES

- Pastes are semisolid preparations intended for application to the skin. They generally contain a larger proportion of solid material (such as 25%) than ointments and therefore are stiffer.
أكثر صلابة
- Stiffer than ointments
بب صلابة
- The stiffness reduce the percutaneous absorption potential of any drug incorporated in the paste
تقلل من قدرته الرواء للمدغ منها على الامتصاص عبر الجلد
- They are used for their :
 - protective action *اقتصاص اعراض ان سانه*
 - and ability to absorb serous discharge from skin lesions
 - and ability to remain in place longer than ointments
البقاء مدة طويلة
- E.g. Zinc Oxide paste USP, Carboxymethylcellulose Sodium Paste USP, Triamcinolone Acetonide Dental Paste USP.

COMPENDIAL REQUIREMENTS FOR OINTMENTS

المتطلبات الدوائية للمراهم

- Ointments and other semisolid dosage forms must meet USP tests for microbial content, minimum fill, packaging, storage, and labeling.
- ophthalmic ointments must also meet tests for sterility and metal particles content.

التجانس (مما التعميم)

لصغار سلامة العين

MICROBIAL CONTENT

- With the exception of ophthalmic preparations, topical applications are not required to be sterile.
- They must, however, meet acceptable standards for microbial content, and preparations prone to microbial growth must contain antimicrobial preservatives.
- Dermatologic products should be examined for *P. aeruginosa* and *S. aureus*, and those intended for rectal, urethral, or vaginal use should be tested for yeasts and molds.

للكشف عن الميكروبات والعفن.

MINIMUM FILL

- The USP's *minimum fill test* is determination of the net weight or volume of the contents of filled containers to ensure proper contents compared with the labeled amount.

أخذ العزرة الصافي أو الحجم للصوبات العبوات المملوءة للتأكد من
أنها تتطابق مع الكمية المرادجة على الملصق.

PACKAGING SEMISOLID PREPARATIONS

- Topical dermatologic products are packaged in either jars, tubes, or syringes whereas ophthalmic, nasal, vaginal, and rectal semisolid products are almost always packaged in tubes or syringes.
- The so-called ointment jars are made of clear or opaque glass or plastic
- Ointment tubes are made of aluminum or plastic

زجاج عاتم او شفاف

PACKAGING, STORAGE, AND LABELING

بمحافظة من التلوث.

- Semisolid preparations must be stored in well-closed containers to protect against contamination and in a cool place to protect against product separation in heat.
- light-sensitive preparations are packaged in opaque or light-resistant containers.
- In addition to the usual labeling requirements for pharmaceutical products, the USP directs the labeling for certain ointments and creams include the type of base used (e.g., water soluble or water insoluble).

في أمواج نبي القائمة المستقرة مع نوعية الصام والكريمات.

PACKAGING, STORAGE, AND LABELING

لغى

- Tubes of aluminum generally are coated with an epoxy resin, vinyl, or lacquer to eliminate any interactions between the contents and the tube.

لـ لمنع التفاعل بين المحتوى والانبوب.

- Plastic tubes are made of high- or low-density polyethylene (HDPE or LDPE) or a blend of each, polypropylene (PP), polyethylene terephthalate (PET)

- LDPE is soft and resilient, and it provides a good moisture barrier. HDPE provides a superior moisture barrier but is less resilient. PP has a high level of heat resistance, and PET offers transparency and a high degree of product chemical compatibility.

• خصائص المواد:

- LDPE: ناعم وقوي، ويوفر حاجزًا جيدًا ضد الرطوبة.
- HDPE: يوفر حاجزًا أفضل ضد الرطوبة، لكنه أقل مرونة.
- PP: يتميز بمقاومة عالية للحرارة.
- PET: يوفر شفافية وتوافقًا كيميائيًا عاليًا مع المنتجات.

PACKAGING, STORAGE, AND LABELING

- Packaging should keep the formulation clean during repeated use and as free from air exposure and microbial contamination as feasible
- Tubes, jars, applicators, syringes, patches, pump dispensers
- Jars does not meet the above requirements, thus a tongue depressor can be used to remove the required quantity of formulation and keep the formulation free from hand contamination
- Pastes are generally packed in ointments jars

التعبئة لازم تحافظ على نقاوة المنتج أثناء الاستخدام المتكرر وتقلل من التعرض للهواء والتلوث من الأماكن

كما في

ما يتلبي متطلبات الحماية الكاملة من التلوث

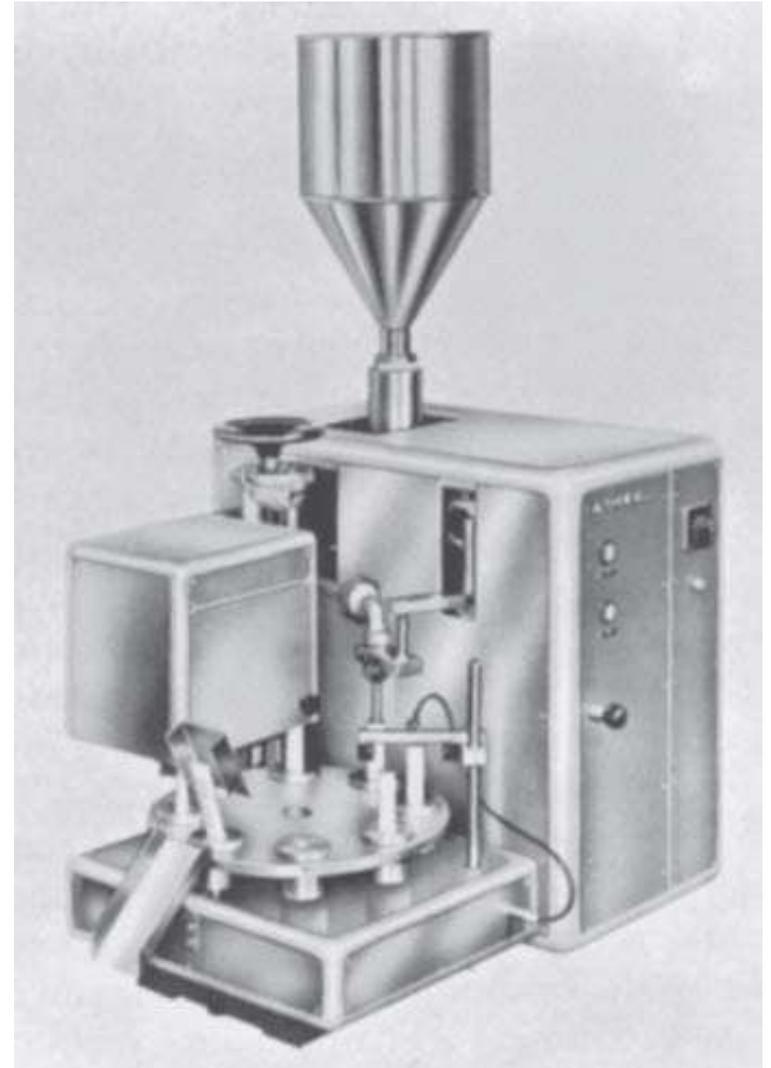
لذا يُنصح باستخدام Tongue depressor لأخذ كمية معلومة ومحبب تلوث اليدين

تعبئة بار "جول" ملدة
بسبب قوتها الملدة

Filling Ointment Tubes

- Tubes are filled from the open back end of the tube, opposite from the cap end. (لَمَّا مَدَّ مِنَ الْغُرْفِ الْخَلْفِيِّ الْمَعْتَوِيَّةِ بِعِيقِهَا مِنْ مَرْفَعِ الْعَقَاءِ)
- Ointments prepared by fusion may be poured while still soft but viscous directly into the tubes with caution to prevent stratification of the components. (لَمَّا سَكَبَ الْمُرَامَ الْمَصْفُوعَةَ بِالرَّابِعَةِ الْحَرَارَةِ صَبْرَةً لِالانابيبِ مَعَ الْحَذَرِ لِسَوْفَ تَرْتَبِعُهَا أَوْ فَضْلَ الْهَكَوَارِ)
- On a small scale, as in the extemporaneous filling of an ointment in the pharmacy, the tube may be filled manually or with a small-scale filling machine (يَمْتَنُ تَعْبِئَةُ الْانابيبِ يَدَوِيًّا أَوْ بِتَقْدِيمِ آتَمَةِ تَعْبِئَةِ لِهَيْئَةِ الْحَمِّ)

Fusion method



Observing formulations for evidence of instability

- Instability of various dermatological formulations can be identified by :

- A separation of components مفصل المكونات
- Discoloration تغير اللون
- Development of rancid odor ظهور رائحة فاسدة
- Dryness جفاف
- Crystal growth
- Shrinkage انكماش
- Microbial contamination

- Additional instability signs for ointments: كميات كبيرة

- Excessive bleeding (i.e. separation of excessive amounts of liquids) زهم زائد

- Formation of granules or grittiness تكوّن حبيبات أو صرّة

Observing formulations for evidence of instability

التوكيدات المائية

- Anhydrous formulations tend to be more stable than hydrous products
- Anhydrous formulation can have a 6 month beyond use date if incorporated drug is stable for that period
- For formulations containing water it is recommended that no more than a 2 week supply be dispensed if no preservative is used

يُوصى بتوفير كمية لا تتجاوز أسبوعين إذا لم تستخدم مواد حافظة.

Ophthalmic ointments

- Ophthalmic ointments are semisolids for application to the

eye

اصيافات خاصة

- Special precautions must be taken in the preparation of ophthalmic ointments. They are manufactured from sterilized ingredients under rigidly aseptic conditions, must meet the requirements under Sterility Tests and must be free of large particles.

لازم تحققوا لاصتبار العظامه

- The medicinal agent is added to the ointment base either as a solution or as a micronized powder.

يضاف الدواء النشط الى قاعدة المرهم

اما كحلولا او مسحوق

Ophthalmic ointments

- The USP directs that ophthalmic ointments must be packaged in collapsible ointment tubes.
النايب قابلة للطي
- These tubes have an elongated narrow tip to facilitate application of a narrow band of ointment to the eye.
مرف حويل و صيفه حتر يوا صيفه
- The patient should be advised that blurred vision will occur as the ointment spreads over the eye and not to be alarmed.
انه المرؤية قد تتأثر يتم ايهي
- If the ointment is to be administered only once daily, it is often preferable to do so at bedtime, when vision impairment will be inconsequential.
انه المرؤية قد تتأثر

لذا اذا كانه للتطبيق يومياً مرة واحدة، يُفضل الصيام به عن النوم لانه تأسيب
الرؤية الحسية له تكره مشكلة.

الثقافة والسلامة:

Ophthalmic ointments

لازم تأكد مع المريض انه سوف المعاملة مع المنتجات الصيدية مع يوديا الى تلوثها بكتريا بسبب عدم

- It is important to emphasize to the patient that ocular products if handled improperly can become contaminated by bacteria that cause ocular infections, which may lead to serious consequences.
- Thus every effort must be made to avoid touching the tip of the tube to the eye, eyelid, fingertip, or any other surface, and the ointment should be used by only one person.

مع لازم يستخدم المنتج فقط واحد.

Summary

- Differences in emollient and occlusive effects and ease of application and removal between products is a factor of the base used and product type.
- As noted earlier, oleaginous bases provide greater occlusion and emollient effects than do hydrophilic or water-washable bases.
- Pastes offer even greater occlusion and are more effective than ointments at absorbing serous discharge.
- Creams, usually oil-in-water emulsions, spread more easily than ointments and are easier to remove.
- Water-soluble bases are nongreasy and are easily removed.

zero lipids

السابق (زِيَا حاشيًا) كثير سهل ومعد فإله شاء الله بئله باليه.

بالتوفيق لوله شاء الله - دعواتكم

فأنا أفلا يارب.