UNIT VI

OINTMENTS

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OINTMENTS

“OINTMENTS ARE SEMISOLID DOSAGE FORMS INTENDED FOR EXTERNAL APPLICATION TO SKIN OR MUCOUS MEMBRANE”

• EITHER MEDICATED OR NON MEDICATED
• **MEDICATED**
  EITHER DISSOLVED OR DISPERSED IN A VEHICLE AS FINE POWDER e.g STEROIDS.

• **UNMEDICATED**
  UNMEDICATED OINTMENTS ARE USED FOR PHYSICAL EFFECTS SUCH AS PROTECTANTS or LUBRICANTS
OINTMENT BASES ARE CLASSIFIED INTO FOUR GENERAL GROUPS.

- OLEAGINOUS BASES.
- ABSORPTION BASES.
- WATER-REMOVABLE BASES.
- WATER-SOLUBLE BASES.
OLEAGINOUS BASES
(HYDROCARBON BASES)

- ON APPLICATION TO SKIN THEY HAVE AN EMOLLIENT EFFECT.
- PROTECT AGAINST ESCAPE OF MOISTURE.
- THEY ARE EFFECTIVE AS OCCLUSIVE DRESSINGS.
- IMMISCIBLE WITH WATER AND DIFFICULT TO WASH OFF.
- THEY CAN REMAIN ON SKIN FOR LONGER PERIODS WITHOUT DRYING OUT.
- WATER AND AQUEOUS SOLUTIONS IN SMALL AMOUNTS CAN BE INCORPORATED WITH SMALL DIFFICULTY.
- WHEN POWDERED SUBSTANCES ARE TO BE INCORPORATED LIQUID PETROLATUM IS USED AS LEVIGATING AGENT.
- THEY INCLUDE:
- PETROLATUM
- WHITE PETROLATUM
- YELLOW OINTMENT
- WHITE OINTMENT
**ABSORPTION BASES**

- **TWO TYPES**
- **THOSE THAT PERMIT INCORPORATION OF AQUEOUS SOLUTIONS RESULTING IN FORMATION OF W/O EMULSIONS**
- **THOSE THAT ARE ALREADY W/O EMULSIONS AND PERMIT INCORPORATION OF ADDITIONAL QUANTITY OF AQUEOUS SOLUTION**
PROPERTIES OF ABSORPTION BASES

- THESE BASES MAY BE USED AS EMOLLIENT
- THEY DO NOT PROVIDE DEGREE OF OCCLUSION
- THESE BASES ARE NOT EASY TO REMOVE FROM SKIN SINCE THE EXTERNAL PHASE OF EMULSION IS OLEAGINOUS
- DIFFICULT TO WATER WASHING
- THEY PERMIT INCORPORATION OF AQUEOUS SOLUTION RESULTING IN FORMATION OF W/O EMULSION.

- THOSE THAT ARE ALREADY W/O EMULSION, THEY PERMIT SMALL QUANTITIES OF AQUEOUS SOLUTION TO BE INCORPORATED.

- THEY FORM A GREASY FILM ON SKIN SURFACE
THEY INCLUDE:
- LANOLIN
- ANHYDROUS LANOLIN
- COLD CREAM
WATER REMOVABLE BASES
(EMULSIFYING BASES)

- THEY ARE OIL IN WATER EMULSIONS HAVING AN EMULSIFIER WHICH MAKES THEM READILY MISCIBLE WITH WATER.

- THEY MAY BE DILUTED WITH WATER OR AQUEOUS SOLUTIONS.

- BECAUSE OF THEIR SURFACE ACTIVE PROPERTY THEY FACILITATE CONTACT b/w SKIN AND MEDICAMENT
- READILY WATER WASHABLE
- THEY INCLUDE:
  - HYDROPHILLIC OINTMENTS
  - VANISHING CREAMS
WATER SOLUBLE BASES
(GREASELESS BASES)

■ UNLIKE OTHER BASES THEY CONTAIN ONLY WATER SOLUBLE COMPONENTS

■ THEY ARE COMPLETELY WATER WASHABLE

■ AQUEOUS SOLUTIONS CAN NOT BE INCORPORATED EFFICIENTLY BECAUSE THEY SOFTEN GREATLY WITH WATER ADDITION
- THEY MOSTLY ARE USED FOR INCORPORATION OF SOLID SUBSTANCES
- THESE BASES ARE USED FOR LOCAL ANAESTHETICS AND ARE USED WHEN EASY WASHING FROM SKIN IS REQUIRED

- THEY INCLUDE:
  - PEG OINTMENT
SELECTION OF APPROPRIATE BASE

- Depends upon purpose for which ointment is going to be applied
- Desired release of drug substance from ointment base
- Desirability of topical absorption
- Desirability of occlusion of moisture from skin
- Stability of drug in ointment base
- Desirability of surface to which it is to be applied
- Equally efficient on dry and oily skin
- Should have a suitable pH
- No dehydrating effect
- Non irritant and non sensitising
- Compatible with a large number of drugs
- Miscible with skin secretions and excretions e.g. sebum, sweat etc.
TWO GENERAL METHODS DEPENDING PRIMARILY ON NATURE OF INGREDIENTS AND PHYSICAL PROPERTIES OF CONSTITUENTS OF BASE

- INCORPORATION

- FUSION
INCORPORATION OF SOLIDS

INCORPORATION OF LIQUIDS
INCORPORATION
(INCORPORATION OF SOLID)

- THE COMPONENTS ARE MIXED UNTIL A UNIFORM PREPARATION IS ATTAINED.
- ON SMALL SCALE AS IN EXTEMPORANEOUS COMPOUNDING THE COMPONENTS ARE MIXED USING PESTLE AND MORTAR OR SPATULA MAY BE USED TO RUB INGREDIENTS ON AN OINTMENT SLAB.
- MEDICAMENT IS MIXED WITH SMALL AMOUNT OF BASE AND REMAINDER IS MIXED GRADUALLY AND TRITURATED CONTINUOUSLY.
- IF MATERIAL TO BE INCORPORATED IS SOLID THEN FIRST SOLID IS TRITURATED TO FINE POWDER AND THEN SHOULD BE INCORPORATED.
IT IS OFTEN DESIRABLE TO REDUCE PARTICLE SIZE OF CRYSTALLINE MATERIAL SO THAT FINAL PRODUCT WILL NOT BE GRITTY

THIS IS DONE BY LEVIGATING OR MIXING SUBSTANCE IN A VEHICLE IN WHICH IT IS INSOLUBLE SO THAT A SMOOTH DISPERSION IS FORMED

LEVIGATING AGENT SHOULD BE IN EQUAL VOLUME TO SOLID MATERIAL

IF MATERIAL TO BE INCORPORATED IS SOLUBLE IN ONE OF INGREDIENTS OF BASE, FIRST DISSOLVE IN THAT INGREDIENT AND THEN INCORPORATE

TWIN-ROLLER MILLS ARE AVAILABLE FOR PREPARATION OF SMALL QUANTITIES OF OINTMENTS BY HAND

IF INGREDIENTS OF OINTMENTS ARE REACTIVE WITH STAINLESS STEEL SPATULA (AS DOES IODINE FOR EXAMPLE) HARD RUBBER SPATULA MAY BE USED
INCORPORATION
(INCORPORATION OF LIQUID)

- Liquids are added only after due consideration of an ointment base capacity to accept volume required.
- Only small amount of aqueous solution is incorporated into oleaginous ointment.
- Hydrophillic ointments readily accept large volumes.
- When it is necessary to add aqueous preparation to hydrophobic base, solution first may be incorporated into minimum amount of hydrophillic base and then added to hydrophobic base.
- All liquids have their limits to retain liquids beyond which they become too soft or semisolid.
FUSION

- MEDICATED OINTMENTS AND OINTMENT BASES CONTAINING COMPONENTS SUCH AS BEESWAX, PARAFFIN, STEARYL ALCOHOL AND HIGH M.W PEGs WHICH DO NOT LEND THEMSELVES WELL TO MIXTURE BY INCORPORATION ARE PREPARED BY FUSION

- OINTMENTS CONTAINING INGREDIENTS WHICH ARE QUITE SOLID AT ROOM TEMPERATURE ARE PREPARED BY MELTING INGREDIENTS IN A PORCELAIN DISH OVER WATER BATH

- THE USUAL METHOD IS TO MELT SUBSTANCE WITH HIGHEST MELTING POINT FIRST, AND THEN ADD INGREDIENTS IN ORDER OF THEIR MELTING POINTS

- STIRRING SHOULD BE CONTINUOUS UNTIL OINTMENT IS HOMOGENEOUS AND REACHES TO CONGEALING POINT
AN INSOLUBLE SUBSTANCE IS INCORPORATED AFTER LEVIGATING WITH OIL

ON LARGE SCALE FUSION IS CARRIED OUT IN STEAM JACKETED KETTLES
TOPICAL APPLICATIONS ARE NOT REQUIRED TO BE STERILE, HOWEVER CONSIDERATION MUST BE GIVEN TO INFECTIOUS RESPONSE CAUSED BY CERTAIN MICROORGANISMS.

- BASES HAVING HIGH WATER CONTENT SUPPORT MICROBIAL GROWTH.

- DERMATOLOGIC PRODUCTS SHOULD BE FREE OF:
  - STAPHYLOCOCCUS AUREUS
  - PSEUDOMONAS AERUGINOSA
PRESERVATION
AMONG THE ANTIMICROBIAL PRESERVATIVES USED TO INHIBIT MICROBIAL GROWTH IN TOPICAL PREPARATIONS ARE:

- METHYL PARABEN
- PROPYL PARABEN
- BENZOIC ACID
- PHENOLS
- SORBIC ACID
FILLING OF OINTMENT
FILLING IS DONE BY TWO WAYS:

- HAND FILLING
- MECHANICAL FILLING
HAND FILLING:

- WEIGHTED AMOUNT OF OINTMENT IS PLACED IN A JAR WITH THE HELP OF FLEXIBLE SPATULA

- OINTMENT IS FORCED DOWN TO BOTTOM AND ALONG WALLS OF JAR TO AVOID AIR ENTRAPMENT
MECHANICAL FILLING:

- IN THIS METHOD OINTMENTS CAN BE FILLED IN TIN JARS AND POLYETHYLENE TUBES
- FILLING IS DONE BY PRESSURE FILLER WHICH CONSIST OF NOZEL AND PISTON FROM WHICH OINTMENT OOZES OUT ON APPLYING PRESSURE ON PISTON
- TUBES ARE FILLED FROM BACK SIDE AND THEN ARE SEALED
VACCUM FILLERS ARE ALSO AVAILABLE IN WHICH NOZEL IS ATTACHED TO VACCUM PUMP.

AN OINTMENT FILLER
Ointments should be packaged so that there are no air spaces in jar.

- Must be stored in well closed container to avoid contamination.
- Store at cool place to avoid softening and liquification of base.
IT SHOULD BE LABELLED AS:

“FOR EXTERNAL USE ONLY”
“VISCOUS LIQUID OR SEMISOLID EMULSIONS FOR APPLICATION ON SKIN AND MUCOUS MEMBRANE”

CREAMS MAY BE:

- MEDICATED
  - FOR SPECIFIC ACTION e.g. FOR APPLICATION ON BURNS
- NON-MEDICATED
  - EMOLLIENT
TWO TYPES:

WATER IN OIL OR OILY CREAMS:
CONTAIN W/O EMULSIFIER e.g. WOOL FATS AND WOOL ALCOHOL
EXAMPLES:
- COLD CREAM
- ZINC CREAM

OIL IN WATER OR AQUEOUS CREAMS:
CONTAIN O/W EMULSIFIER e.g. EMULSIFYING WAX ALKALI SALT OF A FATTY ACID
EXAMPLES:
- VANISHING CREAM
- HYDROCORTISONE CREAM
OIL IN WATER EMULSIONS CONTAIN LARGE PERCENTAGE OF WATER, STEARIC ACID AND OTHER OLEAGINOUS COMPONENTS

AFTER APPLICATION WATER EVAPORATES AND LEAVES BEHIND A THIN RESIDUE FILM OF STEARIC ACID AND OLEAGINOUS COMPONENT

SO IT IS PROTECTANT IN NATURE
PREPARATION OF CREAMS
CREAMS ARE PREPARED BY DISPERSING OR DISSOLVING MEDICINAL AGENTS IN EMULSION.

IN EXTEMPORANEIOUS PREPARATION, PESTLE AND MORTAR IS USED (A MECHANICAL BLENDER) TO PREPARE EMULSION

EMULSIFYING AGENT IS MIXED WITH OIL AND THEN WATER IS ADDED.

AFTER FORMATION OF EMULSION, MEDICINAL AGENTS OF CREAM ARE DISPERSED.
ADVANTAGES OVER OINTMENTS

AQUEOUS CREAMS ARE EASY TO WASH THAN ALL OINTMENTS

CREAMS ARE EASIER TO SPREAD THAN OINTMENTS
SAME PACKAGING AS OINTMENTS:

CREAMS SHOULD BE PACKAGED SO THAT THERE ARE NO AIR SPACES IN JAR

MUST BE STORED IN WELL CLOSED CONTAINER TO AVOID CONTAMINATION
PRESERVATION OF CREAMS
AMONG THE ANTIMICROBIAL PRESERVATIVES USED TO INHIBIT MICROBIAL GROWTH IN TOPICAL PREPARATIONS ARE:

- METHYLPARABEN
- PROPYLPARABEN
- BENZOIC ACID
- PHENOLS
- SORBIC ACID
SOURCES

→ ANSEL’S
PHARMACEUTICAL DOSAGE FORMS AND
DRUG DELIVERY SYSTEMS

→ NASIR HAYYAT  SIPRA

→ WWW.GOOGLE.COM

→ WWW.WIKIPEDIA.COM