EXTEMPORANEOUS DISPENSING OF:

CREAMS

LEARNING OBJECTIVES

At the end of this topic, students will be able to:

- Define creams
- Discuss aqueous and oily creams
- Discuss the problems associated with diluting creams

CREAMS

- In pharmacy the term ‘cream’ is reserved for external preparations
- Creams are viscous semi-solid emulsions for external use
- Medicaments can be dissolved or suspended in creams
- A cream may be ‘water-in-oil’ or ‘oil-in-water’

CREAMS

- The possibility of microbial contamination of creams during preparation must be minimized since they provide suitable substrates for the growth of micro-organisms which may cause spoilage or pathogenicity.

- The preservative systems used are usually a compromise between clinical acceptability , formulation stability and efficacy and may be inadequate to cope with heavy microbial contamination
- Creams should therefore be prepared under conditions of strict hygiene or better still using aseptic technique

- As a minimum, all apparatus used in the preparation and the final containers should be thoroughly cleaned before use and rinsed with freshly boiled and cooled purified water before drying

Water-in-oil creams (oily creams) as bases

- These are produced by emulsifying agents of natural origin, e.g. beeswax, wool alcohols or wool fat.
- These bases have good emollient properties.
- They are creamy, white or translucent and rather stiff.

Wool alcohol (lanolin)

Oil-in-water creams (aqueous creams) as bases

- These are produced by synthetic waxes, e.g. macrogol and cetomacrogol.
- They are the best bases to use for rapid absorption and penetration of drugs.
- They are thin, white and smooth in consistency.

Cream: Oil-in-Water

Butter: Water-in-Oil

The preparation of a cream from first principles

1. As with other types of emulsion, hygiene is extremely important and all surfaces, spatulas and other equipment must be thoroughly cleaned with industrial denatured alcohol (IDA).
   - IDA is better than freshly boiled and cooled purified water as it will quickly evaporate, leaving no residue.

2. Always make an excess as it is never possible to transfer the entire cream into the final container.

3. Determine which of the ingredients are soluble in/miscible with the aqueous phase and which with the oily phase. Dissolve the water-soluble ingredients in the aqueous phase.

4. Melt the fatty bases in an evaporating dish over a water bath at the lowest possible temperature.

- Start with the base with the highest melting point.
- These should then be cooled to 60°C (overheating can denature the emulsifying agent and the stability of the product can be lost).

5. Substances that are soluble/miscible with the oily phase should then be stirred into the melt.

6.The temperature of the aqueous phase should then be adjusted to 60°C.

7.The disperse phase should then be added to the continuous phase at the same temperature.

8.Stir the resulting emulsion vigorously without incorporating air, until the product sets. Do not hasten cooling as this produces a poor product.

VIDEO

- https://www.youtube.com/watch?v=FxIoQd8NArE
- https://www.youtube.com/watch?v=-Gf6dj6F3k0

DILUTED CREAMS

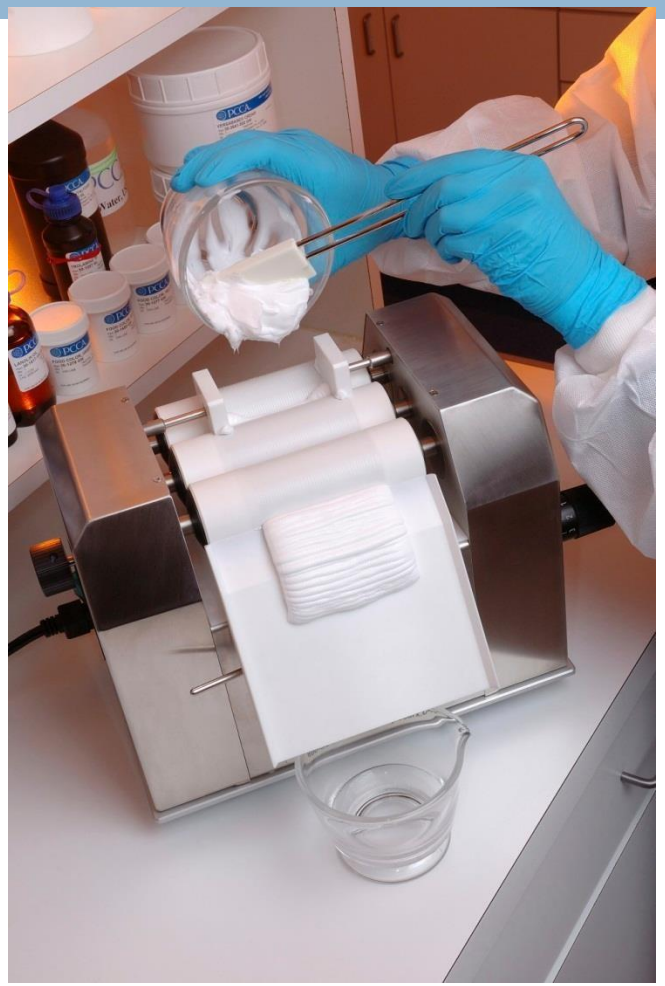
- The pharmacist may be asked to prepare extemporaneous dilutions of proprietary creams.
- Choice of the appropriate diluent is crucial since dilution may impair the preservative system in the cream and significantly affect the bioavailability of any active ingredients.
- The risk of microbial contamination is great and the practice should not be encouraged unless considered by the prescriber to be essential.

DILUTED CREAMS

- Diluent may impair the preservative system in the cream.
- May affect the bioavailability of the medicament.
- Incompatible with other ingredients.
- Increases the risk of microbial contamination.

DILUTED CREAMS

- Dilutions should be made only if the diluent to be used is stated in the manufacturer's data sheet.
- Diluted creams must be freshly prepared without the application of heat and with strict hygiene precautions.



SHELF-LIFE OF CREAMS

- Extemporaneously prepared creams should generally be given a short shelf-life unless freedom from micro-organisms can be assured.

- Diluted creams should be freshly prepared and should not be used for more than 2 weeks after issue.

CONTAINERS FOR CREAMS

- Wide-mouthed squat jars may be used for creams where the risk of contamination in use is considered to be minimal, e.g. oily creams.
- The containers must be well closed and prevent water evaporation.
- The mouth of the jar should be coveredwith a disc of greaseproof paper.

- Collapsible metal or flexible plastic tubes are to be preferred since these reduce the risk of contamination in use and most proprietary products are packed in tubes.

SPECIAL LABEL AND ADVICE FOR PATIENTS

STORE IN A COOL PLACE

- But do not allow to freeze
- The labels for collapsible tubes should be fixed to the upper (nozzle) end of the tube.

EXTEMPORANEOUS PREPARATION OF CREAM- VIDEO

- https://www.youtube.com/watch?v=vFkcAJBGXek

- Sterilized products should be labeled:

STERILE UNTIL OPENED

AQUEOUS CREAM BP

- 50 g aqueous cream

Ingredients	Master formula	For 55 g
Emulsifying ointment	300 g	16.5 g
Phenoxyethanol	10 g	0.55 g
Purified water, freshly boiled and cooled	690 g	37.95 g

ACTION & USES

- Aqueous cream is an emollient and can be used as a base for drugs.

Method

- The phenoxyethanol is dissolved in water warmed to 60°C
- Weigh the emulsifying ointment and melt it in an evaporating basin an a water bath or hot plate
- Ensure that both phases are close to 60°C, then mix both phases
- Remove from the heat and stir continuously until cold, taking care not to incorporate too much air
- Weigh 50g and pack in an ointment jar or collapsible tube

SHELF LIFE AND STORAGE

- The preparation should be stored in a cool place, but not allowed to freeze
- A shelf life of 2-3 weeks is appropriate because the preparation has not been made in the cleanest conditions

OILY CREAM BP

- 50g oily cream

Ingredients	Master formula	For 60 g
Wool alcohols ointment	500 g	30 g
Phenoxyethanol	10 g	0.6 g
Dried magnesium sulphate	5 g	0.3 g
Purified water, freshly boiled and cooled	485 g	29.1 g

Action & uses

- Oily cream is used as an emollient in treating dry conditions

Method of preparation

- All equipment should be thoroughly cleaned before use
- Dissolve the magnesium sulphate and phenoxyethanol in the water and warm to 60^{o}C on a water bath or hot plate
- Weigh the wool alcohol ointment, using a piece of paper, and melt it in an evaporating basin at 60^{o}C
- Check that two temperatures are the same

- Add the water, little by little, to the ointment stirring constantly until a smooth creamy mixture is produced, while maintaining the temperature at 60^{o}C
- When all the wateris added, remove from the heat and stir gently until the cream is at room temperature.
- Pack 50g in an ointment jar or collapsible tube

SHELF LIFE AND STORAGE

- Store in a cool place but do not allowed to freeze.
- If liquid separated on storage, stirring may reincorporate it.
- An expiry date of 4 weeks is appropriate.

EXAMPLES

- CHAPTER # 13 Pharmaceutical practice, Diana M. Collett

  - ✓ 13.5
  - ✓ 13.6
  - ✓ 13.12
  - ✓ 13.13
  - ✓ 13.14

REFERENCE

- CHAPTER # 13 Pharmaceutical practice, Diana M. Collett
  - Page # 116-117
- CHAPTER # 33 Pharmaceutical practice, 4th edition, A.J. Winfield
  - Page # 373-374
- Suggested reading:
  - http://www.preservearticles.com/2011122319146/here-is-your-short-essay-on-creams.html