CLASSIFICATION OF SEMICONDUCTOR PREPARATIONS BY THE EUROPEAN

PHARMACOPEIA

• Ointments,

Creams,

• Gels,

- Pastes,
- Poultices,
- Medicated Plasters







CONTROLS IN SEMI-SOLID PREPARATIONS

- Determination of quantity of active substance
- Homogeneity
- Examination of liquor properties
- Water content
- Rheological controls

- Stability tests
- Microbiological controls
- Sterility control
- Particle content
- Features of releasing active substance

ORGANOLEPTIC AND PHYSICAL STABILITY PARAMETERS

- Appearance
- Smell
- Color
- Homogeneity (phase separation, crystal growth, drying due to water loss, separation of water-bleeding, puddle when applied)
- pH
- Consistency, viscosity
- Particle size distribution

CHEMICAL AND MICROBIOLOGICAL STABILITY PARAMETERS

- Particle size distribution
- Determination of quantity, identification of impurities
- Preservative and anti-oxidant
- Microbiological determinations
- Weight loss

FEATURES OF STABLE SEMI SOLID PREPARATIONS

- A stable ointment should keep the cream homogenous throughout its shelf life.
- The most common stability problem in ointments

- bleeding
- depending on whether the temperature increases or changes.
- ➤ 'Bleeding' is the first step in the preparation of the ointment, in which the liquid components such as mineral oils dissolve and are visibly discernible. This is not an acceptable event and 'bleeding' may not be predictable.

VISCOSITY AND DENSITY

- The viscosity and density of the semi-solid preparations should be within a certain interval.
- Difficulty of using the patient for too low, too easy
- Extremely high, difficult to extrude and apply from the tube