Evaluation of Suppositories

Should be Evaluated by ① Appearance
② physical Strength
③ Dissolution rate
③ Melting range
④ softening point
⑤ uniformity of drug content.

Appearance:

→ prepared Suppositories should be Evaluated for physical appearance - visually
→ Colour, shape should be Evaluated visually
→ Size should be Evaluated by using → vernier callipers
→ There should be no difference in Size or shapes among the Suppositories
→ should have a Elegant appearance
→ Cracks and pits can occur due to air Entrapment
→ Examine Each Suppository separately for Signs of air Entrapment

Physical Strength (Breakage test):

- The physical strength test used to classified as brittle or Elastic suppositories.
- Testing is conducted using an apparatus called as breaking test apparatus
- In this method it measures the mass in Kgs.
- that it can bear with out breaking (Good result is 1.8 to 2.0 Kg).
- Suppository is positioned in upright position
- increasing weight on it untill it loses its structures and collapses

Test for dissolution:

dissolution test is done by
- USP I (Basket)
- USP II (paddle)

- The test is carried out for testing the rate of invitro release of drug

Test for melting Range:

- Called as → macro melting range test used to measure → time it takes to melt

→ Immersed in a constant temperature 37°C water bath (should be melted with in 30 min)

Test for softening point (liquefication test)

→ It is also known as liquefication test.

→ also called as "Krowczynskis test"

→ It measures time required for suppository to liquefy under pressure same as pressure in body cavity in presence of water at 37°C

→ liquefaction should take no longer than about 30 minutes.

Test for uniformity of drug content

→ In order to Ensure content uniformity

→ 20 suppositories should be weighed and an average weight is calculated

→ Then each suppository is weighed individually and weight is noted

→ No suppository should deviate from the average weight by more than 5%.

→ 2 should not deviate by more than 7.5%.

→ The weight variation may result if some cavities are underfilled and other are

overfilled

Pharmaceutical Incompatibilities

→ when two or more ingredients are mixed together to prepare a medicine an undesired change takes place which affect the physical, chemical and therapeutic properties of medicament then the phenomenon is termed as Incompatability

→ Incompatabilities are usually unintentional

Incompatabilities may occur during

① Compounding
② Formulation
③ Manufacturing
④ packaging
⑤ Dispensing
⑥ storage
⑦ Administration

Incompatability Can Effect

① Safety of medicament
② Efficacy of product
③ Appearance of medicine
④ purpose of medicament