Suppositories

Evaluation of suppositories

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Suppositories are solid dosage forms intended for insertion into body orifices where they melt, soften, or dissolve and exert localized or systemic effects.

TESTS FOR SUPPOSITORIES

Appropriate test methods and specifications are developed, which are capable of guaranteeing that the purpose for which suppositories are used will be fulfilled.

1. Test of Appearance
2. Uniformity of weight
3. Breakage Test (Test of physical strength)
4. Content uniformity test
5. Disintegration Test
6. Test of Dissolution Rate
7. Test of Melting Range or Melting point determination test
8. Liquefaction time (softening)
9. Assay of active contents
10. Test of drug uptake/ absorption in to blood stream
11. Stability Problems of Suppositories

1. Test of Appearance

All the suppositories should be uniform in size and shape.

They should have an elegant appearance.

When cut longitudinally, the internal and external surface should be same.

Individual suppositories should be examined for cracks and pits due to the entrapment of air in the molten mass.

2. Uniformity of weight

Weigh 20 suppositories individually.

Determine their average weight.

Not more than two of individual weights should deviate from the average weight more than 5% and none deviates by more than 10%.

3. Breakage Test (Test of physical strength)

The tensile strength of suppositories is measured in this test to assess their ability to withstand the rigors of normal handling.

Tensile strength indicates the maximum force which the suppository can withstand during production, packing, and handling.

Large tensile strength indicates less tendency to fracture.

4. Content uniformity test

This test is to assess the uniformity of the mixed suppository mass.

All the suppositories should contain the same labeled quantity of the drug.

Different suppositories are assayed for the drug.

5. Disintegration Test

It is the amount of dosage form that gets dissolved in body fluid in unit time.

It is a measure of drug release from the suppository.

Disintegration is complete when molded suppositories are
1.Completely dissolved.

2.Dispersed into its components

3.Have become soft

Disintegration occurs in not more than 30 minutes for fat based suppositories and for water soluble suppositories disintegration occurs in not more than 60 minutes.

6. Test of Dissolution Rate:

It is the amount of dosage form that gets dissolved in body fluid in unit time.

It is a measure of the rate of drug release from the suppository.

7. Test of Melting Range or Melting point determination test:

The temperature at which partially melted substance begins to rise in the tube is regarded as the melting point.

The melting point of suppositories should not rise more than that given in the monograph.

8. Liquefaction time (softening):

The temperature at which the glass rods just come down was noted, which represents the **liquefaction temperature**.

The time at which the glass rod reaches to narrow end after complete melting of suppositories represents the **liquefaction time**.

9. Assay of active contents:

Official limit for the active contents is **95- 105%.**

10. Test of drug uptake/ absorption in to blood stream

Both in-vitro and in-vivo tests should be conducted to assess the amount of drug absorbed into the systemic circulation.

11. Stability Problems of Suppositories:

Blooming: During storage cocoa butter suppositories sometimes show deposition of white powder on the surface. This results in suppositories of disagreeable appearance.

Hardening: During storage, the suppositories made of fatty bases become hard. Hardening is occurred due to the crystallization of bases. This also affects the melting and rate of absorption of drugs.

THANK YOU