

PHARMACEUTICS-I (BP103T)

UNIT: 4 (Suppositories, Pharmaceutical incompatibilities)

CLASS: 3

TOPIC: Displacement value

Definition: “The quantity of the drug which displaces one part of the base is known as displacement value.”

e.g. Determination the displacement value of a medicament in theobroma oil suppositories containing 40% medicament, prepared in 1 gm mould. The weight of 10 suppositories is 14.66 gm. Solution:

Wt.of 10 suppo. Cont. theobroma oil alone prepared in 1 gm capacity mould=1 x 10=10 gm

Wt.of 10 suppo. Cont. 40% of medicament = 14.66gm

Amt. of theobroma oil present = $60/100 \times 14.66 = 8.79$ gm

Amt. of medicament present = $40/100 \times 14.66 = 5.86$ gm

Amt. of theobroma oil displaced by 5.86 gm of medicament = $10 - 8.79 = 1.20$ gm

So, Displacement value of medicament = $5.86/1.20 = 5$ (Approx.)

Suppositories are usually packed in tin or aluminum, paper or plastic. Poorly packed suppositories may give rise to staining, breakage or deformation by melting. Both cocoa butter and glycerinated gelatin suppositories stored preferably in a refrigerator. Polyethylene glycol suppositories stored at usual room temperature without the requirement of refrigeration.

Evaluation

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%. Melting point determination test Both micro melting range and micro melting range are determined as follows:

(a) Macromelting range

It is a measure of the thermal stability of the suppository. It is the time taken by the entire suppository to melt in a constant temperature water bath. The test is conducted using the tablet disintegration apparatus. The suppository is immersed in a constant water bath. Finally, the melting range is recorded.

(b) Micromelting range

The melting range of the fatty base is measured in capillary tubes.

Liquefaction time (softening)

Softening time is the time for which the suppository melts completely at a definite temperature. This test measures the softening time of suppositories which indicates the hardness of the base.

A liquefaction temperature/time test was done using the fabricated instrument. A big pipette was taken having a narrow opening on one side and a broad opening on another side. The pipette was dipped in hot water maintained at $35 \pm 0.2^\circ\text{C}$ so that the narrow end faces towards hot water. The sample suppository was introduced from the top of the pipette through the broad end and carefully pushed down its length until it reaches the narrow end. A glass rod was then inserted so that it rests over the suppository. 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.

General appearance test
The suppository when cut longitudinally and examined with the naked eye the internal and external surfaces of the suppository should be uniform in appearance. [?]

Compliance with the standard indicates satisfactory subdivision and dispersion of suspended material. [?] Surface appearance and colour can be verified usually to assess absence of fissuring, absence of fissuring, absence of pitting, absence of exudation, absence of migration of the active ingredients.

Dissolution testing

Testing for the rate of in vitro release of drug substances from suppositories has always posed a difficult problem, owing to melting deformation, and dispersion in the dissolution medium. Early testing was carried out by simple placement in a beaker containing a medium.

2 MARKS QUESTIONS

1. Define displacement value.
2. Enlist the evaluation tests for suppositories.

5 MARKS QUESTIONS

1. What is displacement value? Determine the displacement value of a medicament in theobroma oil suppositories containing 40% medicament, prepared in 1 gm mould. The weight of 10 suppositories is 14.66 gm.