Quality Control of Capsules

**Capsules** are preparations with hard or soft shells, of various shapes and capacities, usually containing a single dose of medicament.

**Types of capsules**: hard, soft, enteric, and modified-release capsules.

***Quality Control Tests for Capsules:***

1. ***Standard for content of active ingredients in capsules:***

This test determines the amount of active ingredient by the method in the assay.

1. ***Disintegration:***

Disintegration is the state in which no residue except fragments of capsule shell, remains on the screen of the test apparatus or adheres to the lower surface of the disc. The disintegration test determines wither tablets or capsules disintegrate within a prescribed time when placed in a liquid medium under the prescribed experimental conditions.

**Method:**

*According to the B.P. and applies to hard and soft capsules.*

* Introduce one capsule into each tube and suspend the apparatus in a beaker containing 600 ml water @ 37oC.
* If hard capsules float on the surface of the water, the discs may be added.
* Operate the apparatus for 30 minutes; remove the assembly from the liquid.
* The capsules pass the test if
  + No residue remains on the screen of the apparatus or,
  + If a residue remains, it consists of fragments of shell or,
  + Is a soft mass with no palpable core.
  + If the disc is used, any residue remaining on its lower surface should only consist of fragments of shell.

1. ***Uniformity of Weight:***

This test applies to all types of capsules and it is to be done on 20 capsules.

**Method:**

* Weigh an intact capsule.
* Open the capsule without losing any part of the shell and remove the contents as completely as possible.
* Weigh the shell.
* The weight of the contents is the difference between the weighing.
* Repeat the procedure with a further 19 capsules selected at random.
* Determine the average weight.

**Limit:**

Not more than two of the individual weights deviate from the average weight by more than the percentage deviation shown in the table below, and none deviates by more than twice that percentage.

|  |  |
| --- | --- |
| Average Weight of Capsule Content | Percentage Deviation |
| Less than 300 mg | 10 |
| 300 mg or more | 7.5 |

**Results:**

1. ***Results of disintegration test:***
   1. Time recorded for the capsules to break into particles and pass to the liquid medium = ----------------- minutes.
   2. Comment:

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***Results of weight variation test:***

* Average weight of the contents = (total wt. of the contents / 20) =
* % deviation permitted (from the table) =
* Upper limit (at % deviation)=

=

* Lower limit (at % deviation)=

=

* Upper limit (at double %) =

=

* Lower limit (at double %) =

=

**Record your results in the following table:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Caps. No.* | *Wt. Of intact capsule* | *Wt. Of the empty shell* | *Wt. Of the content* | *Comparison at % deviation* | *Comparison at double % deviation* |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |
| 7 |  |  |  |  |  |
| 8 |  |  |  |  |  |
| 9 |  |  |  |  |  |
| 10 |  |  |  |  |  |
| 11 |  |  |  |  |  |
| 12 |  |  |  |  |  |
| 13 |  |  |  |  |  |
| 14 |  |  |  |  |  |
| 15 |  |  |  |  |  |
| 16 |  |  |  |  |  |
| 17 |  |  |  |  |  |
| 18 |  |  |  |  |  |
| 19 |  |  |  |  |  |
| 20 |  |  |  |  |  |
|  |  |  | Σ = |  |  |

* **Comment:**

Suppositories Evaluation

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1. *Uniformity of weight (weight Variation) (B.P. 1980):*
2. *Weigh* 20 suppositories *individually*. w1, w2, w3….w20
3. *Weigh all* the suppositories together = W.
4. Calculate the *average weight* = W/20.

*Limit*:

* Not more than 2 suppositories differ from the average weight by more than 5%,

 Upper limit = average weight + 

 Lower limit = average weight - 

* Not more than two of the suppositories differ from the average weight by more than the % ***error*** listed. If more than two suppositories are different from the average weight by 5%, calculate double the percent error as follows:

 Upper limit = average weight + 

 Upper limit = average weight - 

No suppository differs by more than double that percentage.



1. ***Hardness of Suppositories (Breaking Test)***
   * + 1. The suppository is placed in the instrument.
       2. Add 600 g; leave it for one min. (use a stop watch).
       3. If not broken, add 200 g every one min. until the suppository is broken.

***Calculations****:*

The hardness of the suppository is calculated by adding the weights together. But if the suppository is broken before the end of the last min. the last weight is canceled.

***Results:***

* Using polyethylene suppositories 🡪 H = 1.7 kg.
* Using Indocid suppositories 🡪 H = 4 kg.
* Using Glycerin suppositories 🡪 H = 1.4 kg.

1. *Disintegration test:*

The disintegration test determines whether suppositories soften or disintegrate within a prescribed time when placed in an immersion fluid.

***Disintegration is considered to be achieved when:***

* + dissolution is complete;
    - * the components of the suppositories have separated, e.g. melted fatty substances have collected on the surface of the liquid, insoluble powders have fallen to the bottom, and soluble components have dissolved;
      * there is softening of the test sample, usually accompanied by an appreciable change of shape without complete separation of the components. The softening process is such that a solid core no longer exists when pressure is applied with a glass rod.

**Method**

* Unless otherwise described in the individual monograph, use water maintained at a temperature of 36-37°C as the immersion fluid.

The test requires three suppositories and the procedure is applied to each of the suppositories.

* 1. Place the sample on the lower disc of the metal device and then insert it into the cylinder.
  2. Place the apparatus into the beaker and invert it every 10 minutes without removing it from the liquid. Repeat the operation with the remaining two suppositories.
  3. Record the time required for the disintegration of the suppositories.
* Unless otherwise stated in the individual monograph, for each of the three suppositories, examine the state of the sample after 30 minutes for fat-based suppositories and rectal capsules, and after 60 minutes for water-soluble suppositories.

1. ***Melting Range Test:***

* This test is also called the Macromelting range test and is a measure of the time it takes for the entire suppository to melt when immersed in a constant-temperature (37oC) water bath.
* The apparatus commonly used for measuring the melting range of the entire suppository is the USP Tablet Disintegration Apparatus.

**Method:**

The suppository is completely immersed in the constant temperature water bath, and the time for the entire suppository to melt or disperse in the surrounding water is measured.

The suppository is considered disintegrated when:

1. It is completely dissolved or
2. Dispersed into its component part.
3. Become soft “change in shape” with formation of core which is not resistant to pressure with glass rod.