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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment
To demonstrate the disintegration test of the capsules as per the monographs.

Aim:

To demonstrate the disintegration test of the capsules as per the monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 163 – 165

Apparatus and Materials Required :

Capsules and USP disintegration device.

Theory :

A drug in solution form is readily available to the body. Disintegration is the first important step involving the breakdown of tablet into smaller particles of granules. The U.S.P. disintegration device utilises 3 inches long 6 glass tubes which are open at the top and held against a 10 mesh screen at the bottom end of the basket rack assembly

The required specifications are only achieved if 16 out of 18 tested capsules disintegrate Table 7 displays the disintegration time of various capsules according to IP

Table 7. Disintegration Time of Various Capsules According to IP

Capsules	Disintegration Time (min)
Hard capsule	30
Soft capsule	60
Enteric capsule	60

As per the IP. disintegration test is not meant for modified-release capsules The requirements for disintegration are not applicable to capsules whose dissolution requirements are included in their monographs.

Procedure :

1) The USP device to test disintegration uses 3 inches long 6 glass tubes that are open at the top and held against a 10 mesh screen at the bottom end.
2) To test for disintegration time, a capsule is placed in each tube and the basket rack is placed in a beaker containing 1 It of water, simulated gastric fluid or simulated intestinal fluid maintained at 37±2°C temperature.
3) On moving upward the capsule should remain 2.5cm below the liquid surface and on downward movement it should remain 2.5cm above the bottom of the beaker.
4) The basket containing the capsule is moved up and down through a distance of 5-6cm at a frequency of 28-32 cycles per minute.
5) Floating of the capsules can be prevented by placing perforated plastic discs on each capsule.
6) These discs also impart an abrasive action.
7) The apparatus is operated for the time specified.
8) The capsule should disintegrate and all the particles should pass through the 10 mesh screen within the time specified
9) Any remaining residues should have a soft mass with no firm core.
10) In accordance with USP, this test is considered successful if all the capsules disintegrate completely.
11) Just in case, if 1 or 2 capsule fails to disintegrate the test needs to be performed again using 12 extra capsules.

Result :

The disintegration test of the capsules as per the monographs was studied.