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

Aim:

To demonstrate the dissolution 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 166 – 168

Apparatus and Materials Required :

Capsules and dissolution apparatus.

Theory :

The dissolution rate of a solid drug plays an important role in the absorption and physiological availability of the drug in the blood stream.

Therefore, determination of dissolution rate of any solid drug is very necessary

The apparatus for dissolution test (figure 15) consists of:

1) A cylindrical stainless steel basket is attached to the end of the stirrer shaft.
2) A 1000ml vessel made up of glass or other inert, transparent material fitted with a cover having 4 holes; one for the shaft of the stirrer, second for placing the thermometer, and remaining two for removing the samples.
3) A variable speed motor driven stirrer which can rotate at a speed of 25-150 rpm.

4) A thermostatically controlled water bath to maintain the dissolution medium at 37+0.5°C temperature

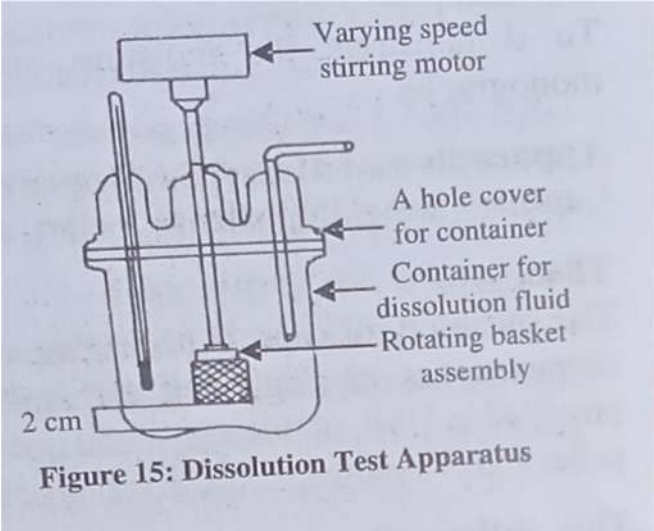


Figure 15: Dissolution Test Apparatus

Procedure :

1) In this test, a stated volume of the dissolution medium is placed inside the vessel.
2) The parts of apparatus are assembled and the dissolution medium is maintained at 37±0.5°C temperature.
3) A single capsule is placed in the apparatus, allowing exclusion of air bubbles from its surface.
4) The apparatus is operated at a specified speed.
5) At definite time intervals, specimens are withdrawn from a midway zone between dissolution medium surface and the top of the rotating basket or blade, not less than Icm from the vessel wall.
6) At each withdrawal, same amount of fresh dissolution medium (maintained at 37°C temperature) is added.
7) The vessel is kept covered during the test and the temperature of dissolution medium is checked at specific times.
8) The analysis is performed using a proper assay method as specified in the individual monographs.
9) The test is repeated with more capsules

10) In accordance with BP. USP. PhEur, Phint and JP, the specified requirements are met if the quantitics of API dissolved from the tested capsules comply with the acceptance criteria presented in table 8.

Table 8: BP, USP, phEur, phint and JP Acceptance Criteria for Dissolution Test of Capsule

Table 8: BP, USP, phEur, phInt and JP Acceptance Criteria for Dissolution Test of Capsule

S1	6	Each unit is not less than Q + 5%.
S2	6	Average of 12 units (S1 + S2) is equal to or greater than Q, and no unit is less than Q – 15%.
S3	12	Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, not more than 2 units are less than Q – 15%, and no unit is less than Q – 25%.

The capsules are continuously tested for 3 stages until the test results confirm at either S1 or 52 The quantity (Q) presents the definite quantity of dissolved APL, stated as a percentage of the labelled content. The 5%, 15%, and 25% values in the capsule are percentages of the labelled content so that these values and Q are in the same terms

Result :

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