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

Aim:

To demonstrate the dissolution test of the tablets 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 144 – 148

Apparatus and Materials Required :

Tablets and dissolution test 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 14) 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.

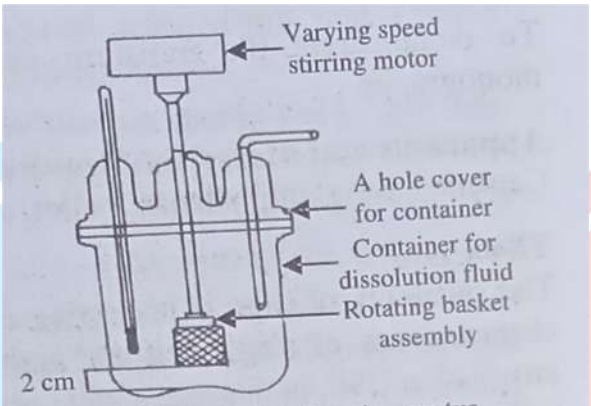

Figure 15: Dissolution Test Apparatus

Procedure :

For performing the test, a suitable volume of dissolution medium (e.g., distilled water, hydrochloric acid, or phosphate buffer at a pH of 7.3) is filled in the glass vessel which is submerged in the water bath maintained at 37°C. The tablet to be tested is introduced in the basket. The motor is started and its revolutions are adjusted as specified in the monograph.

The samples are withdrawn at specified intervals and filtered immediately through a suitable filler medium. About 5ml of sample is withdrawn cach time and replaced with 5ml of medium in order to maintain a constant volume in the vessel. The samples are tested by chemical analysis for the proportion of drug dissolved which should meet the requirements as stated in the monograph

The commonly used dissolution apparatus are :

1) **Apparatus-1 (Basket Type):** A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor The basket is immersed in a dissolution medium

tas specified in monograph) contained in a 1000ml cylindrical flask with a hemispherical bottom In the flask the temperature of the medium is maintained at 3740 5°C by a constant temperature bath. The motor is adjusted to turn the shaft at the specified speed, and samples of fluid are withdrawn at intervals to determine the amount of drug in the solution.

2) **Apparatus-2 (Paddle Type):** It is same as apparatus-1, except that the basket is replaced with a paddle The dosage form is allowed to sink to the bottom of the flask before stirring For dissolution test, USP specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft time lunit of the test, and the assay procedure.

Table 3 enlists the acceptance criteria for dissolution of different numbers of tablets:

Table 3: B.P., U.S.P., PhEur, J.P. and PhInt Acceptance Criteria for Dissolution Test of Tablets

Stage	No. of Tablet Tested	Acceptance Criteria
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%.

Result :

The dissolution test of the tablets as per the monographs was performed.