

INTERSHIP REPORT



SATHYABAMA

Institute of Science and Technology
(DEEMED TO BE UNIVERSITY)

Accredited by NAAC / 12B Status by UGC / Approved by AICTE

A Report Submitted in partial Fulfillment Of the requirement
for the award of degree of
BACHELOR OF SCIENCE

IN
CHEMISTRY

BY

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Ms.SOWBIYA H**, Reg No. 41030020, student of BSc Chemistry from "Sathyabama Institute of Science and Technology, Chennai", has undergone industrial with our organisation in the Quality Control Department from 25/05/2023 to 10/06/2023, for the period of 15 days. During her training period we found her sincere and Hardworking

For GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED.


HR Manager.



ACKNOWLEDGEMENT:

I want to thank my advisers and everyone at the company for their patience and assistance during my on-site training. Thanks to their guidance, I was able to develop my industrial skills and learn about ~~XRF~~ ^{Testing} ~~An~~ ^{spectroscopy} Dissolution analysis these skills will help me to expand my resume and advance my career.

ABOUT COMPANY:

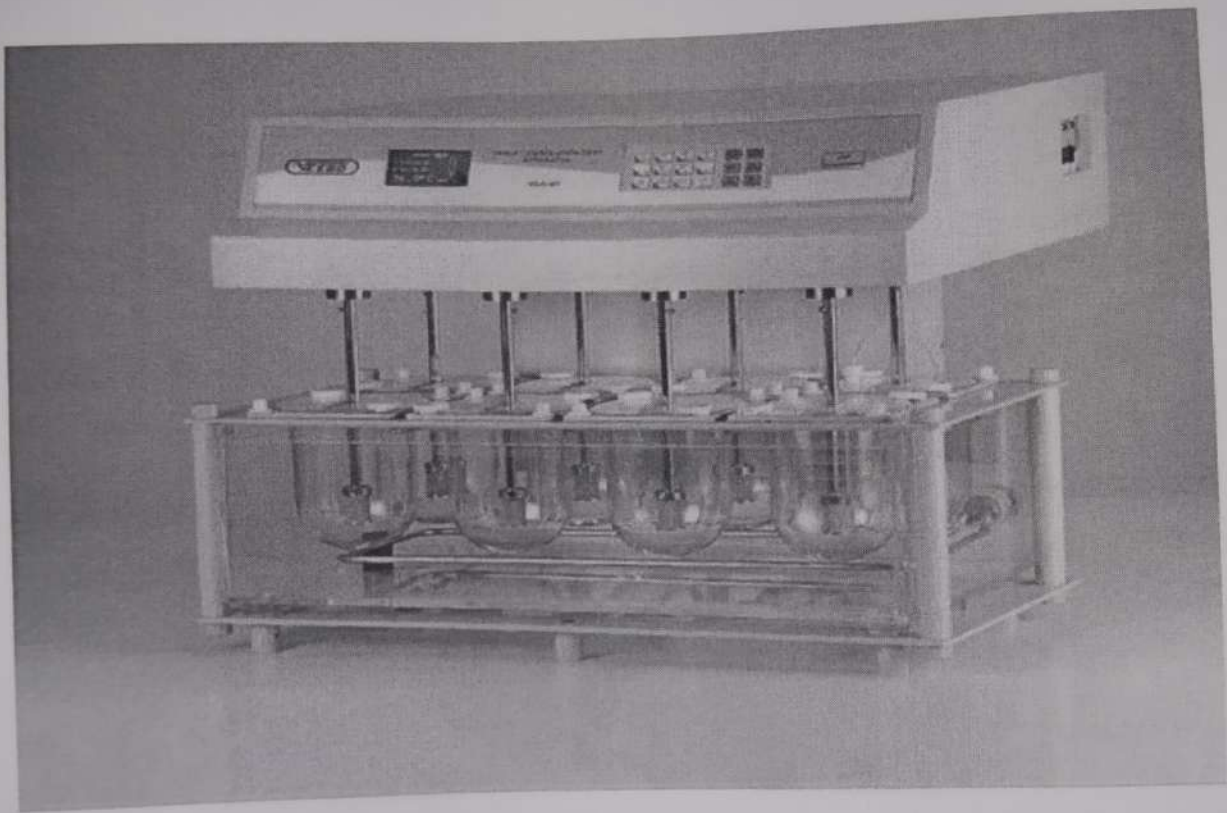
Global Pharma is a pharmaceutical company dedicated to ensuring the health and wellbeing of communities around the world. Our commitment to quality, innovation, and customer service has allowed our company to thrive. For in more than two decades, we have been providing a wide range of pharmaceutical formulations in several therapeutic forms to a variety of markets in Southeast Asia, Central America, LATAM, CIS, and Africa.

Dissolution testing

Analysis

Introduction

In the pharmaceutical industry, drug for both quality control purposes, i.e., to assess batch-to-batch consistency of solid oral dosage forms such as tablets, and drug development, i.e., to predict in vivo drug release profiles.^[1] There are *dissolution testing* is routinely used to provide critical in vitro drug release information three typical situations where dissolution testing plays a vital role: (i) formulation and optimization decisions: during product development, for products where dissolution performance is a critical quality attribute, both the product formulation and the manufacturing process are optimized based on achieving specific dissolution targets. (ii) Equivalence decisions: during generic product development, and also when implementing post-approval process or formulation changes, similarity of in vitro dissolution profiles between the reference product and its generic or modified version are one of the key requirements for regulatory approval decisions. (iii) Product compliance and release decisions: during routine manufacturing, dissolution outcomes are very often one of the criteria used to make product release decisions.^{[2][3][4]}

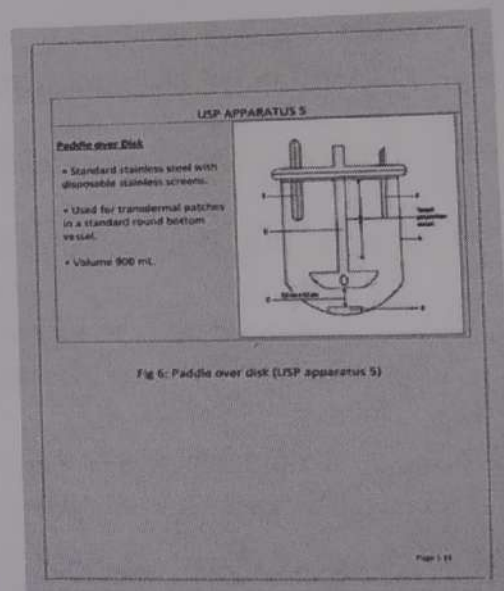


Definition :

Dissolution testing measures the extent and rate of solution formation from a dosage form, such as tablet, capsule, ointment, etc. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. Dissolution and drug release are terms used interchangeably.

Purpose of dissolution testing:

In early phase drug development, dissolution testing aids formulation design and drug delivery optimization. It is primarily carried out to assess product stability, monitor formulation changes over time, and establish in-vitro–in-vivo correlations.



Advantages of dissolution testing:

- ❖ The major advantage of dissolution testing is that the rate of release and the extent of absorption of a drug is determined by the dissolution of the dosage form.
- ❖ The dissolution test apparatus is robust and simple to use, requiring no specialist to handle.
- ❖ It is well standardized and sufficiently flexible to allow perform testing for a broad range of oral solid dosage forms.
- ❖ Dissolution testing is used to determine the quality of pharmaceutical products (tablets/capsules) based on the characteristics of in vitro release of the products.
- ❖ Dissolution testing is used to establish the quality of pharmaceutical products, mostly tablets and capsules, based on the in vitro drug release characteristics of these products.

Disadvantages of dissolution testing:

- ❖ The major disadvantage of the dissolution process is that the amount of media required to be maintained at each interval time, which feels the analyst uncomfortable.
- ❖ The results depend on other instruments, the sample of dissolution needs to be analyzed in UV/VIS spectrophotometer or high-performance liquid chromatography (HPLC).
- ❖ Dissolution requires large amounts of media and takes longer to prepare and adjust the pH of the buffer.
- ❖ Liquid dosage forms are not tested using this process; it is suitable only for solid dosage forms.
- ❖ Between the processes, it is often difficult to change the pH/media.
- ❖ Each drug and product has different properties, so in some cases, there is a problem of sticking and floating.

Dissolution testing methods

At each of the times stated, withdraw a specimen from a zone midway between the surface of the dissolution medium and the top of the rotating blade or basket, not less than 10 mm from the wall of the vessel.

For each of the tablet or capsule tested, calculate the amount of dissolved active ingredient in solution as a percentage of the stated amount.

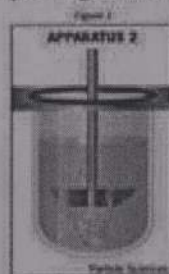
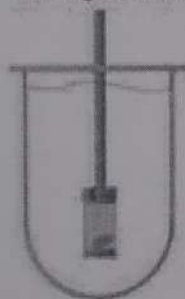


Figure 1

