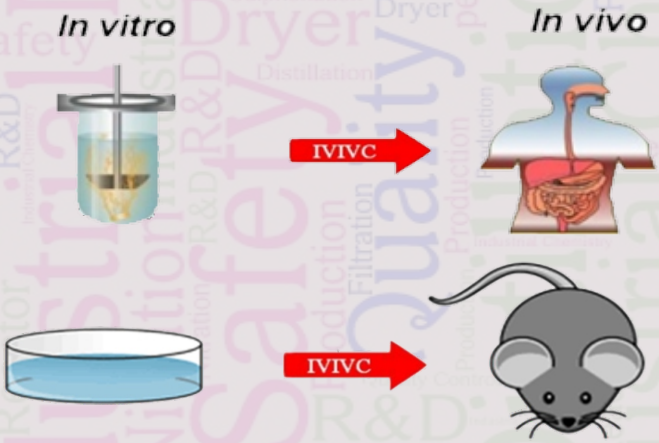
THE FINAL WORD
The official e-newsletter of Industrial chemistry(IC) department, V.V.Nagar, Anand, Gujarat

# IN-VITRO STUDIES

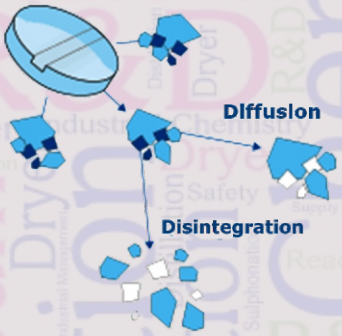
- In vitro (meaning: in the glass) studies are performed with microorganisms, cells, or biological molecules outside their normal biological context.
- Colloquially called "test-tube experiments", these studies in biology and its sub disciplines are traditionally done in lab ware such as test tubes, flasks, Petri dishes, and micro titer plates.

## IN VITRO IN VIVO CORRELATION




## TABLET OR CAPSULE DISINTEGRATION

- An in vitro technique for testing the disintegration and dissolution of tablets and capsules was developed and evaluated.
- The apparatus consists of a beaker with a cylindrical well in the bottom into which is placed a platform containing the dosage form to be tested.
- A phenylpropanolamine hydrochloride capsule formulated with a high level of magnesium stearate was shown to release drug more slowly in vitro and in vivo.
- The effects of capsule formulation factors such as type and level of lubricant and disintegrate as well as the presence of a surfactant were determined.
- It was found that the use of magnesium stearate and hydrogenated vegetable oil as lubricants significantly prolonged the in vitro disintegration time of hard gelatin capsules.




## DISINTEGRATION TEST FOR TABLETS AND CAPSULES

- This test is provided to determine whether tablets or capsules disintegrate within the prescribed time.
- when placed in a liquid medium under the experimental conditions presented below.
- For the purposes of this test disintegration does not imply complete dissolution of the unit or even of its active constituent
- Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the discs, if used, is a soft mass having no palpably 18 firm core.

## INSTRUMENTAL METHOD OF ANALYSIS

- The purpose of this chapter is to describe the analytical methods that are available for detecting, measuring, and/or monitoring cobalt, its metabolites, and other biomarkers of exposure and effect to cobalt.
- Many of the analytical methods used for environmental samples are the methods approved by federal agencies and organizations such as EPA and the National Institute for Occupational Safety and Health (NIOSH).
- Additionally, analytical methods are included that modify previously used methods to obtain lower detection limits and/or to improve accuracy and precision.

## DISSOLUTION RATE TEST

- Dissolution is a process in which a solid substance solubilizes in a given solvent to yield a solution i.e. mass transfer from the solid surface to the liquid phase.
- It depends on the affinity between the solid substance and solvent.

## RATE OF DISSOLUTION

- It quantifies the speed of the dissolution process.
- It depends on
  - → Chemical natures of the solvent and solute.
  - → Temperature (and possibly to a small degree, the pressure).
  - → Degree of under saturation.
  - → Presence of a means of mixing.
  - → Interfacial surface area.

## APPLICATION OF DISSOLUTION STUDIES

- For optimization of formulation and quality control.
- To identify the manufacturing variable, like the binding agent effect, mixing effects, granulation procedure, coating parameters and comparative profile studies.
- To show that the release of drug from the tablet is close to 100%.
- To show that the rate of drug release is uniform batch to batch.
- To show that release is equivalent to those batches proven to be bioavailable and clinically effective.

FACTORS AFFECTING DISSOLUTION RATE

- Factors related to Physicochemical Properties of Drug.
- Factors related to Drug Product Formulation.
- Processing Factor.
- Factors Relating Dissolution Apparatus.
- Factors Relating Dissolution Test Parameters

## DISSOLUTION PROFILE

- It is graphical representation (in terms of concentration vs time) of complete release of drug from dosage form in an appropriate selected dissolution medium.

## IMPORTANCE OF DISSOLUTION PROFILE

- Dissolution profile of an A.P.I. reflects its release pattern under the selected condition sets. i.e. either sustained release or immediate release of the formulated formulas.
- For optimizing the dosage formula by comparing the dissolution profiles of various formulas of the same A.P.I.
- The most important application of the dissolution profile is that by knowing the dissolution profile of particular product of the BRAND LEADER, we can make appropriate necessary change in our formulation to achieve the same profile of the BRAND LEADER.

## IN GENERAL METHOD FOR IN VITRO PROCESS

- Pharmaceuticals involves three elements
  - → Fundamental biological research
  - → Method development
  - → Drug discovery and development

## IN VITRO SCREENING METHODS

- Toxicological screening should take place as soon as a group of molecule with particular pharmacological activity of interest has been identified.
- Purification & identification of macromolecular target sites, combined with powerful physical techniques, or homology molding, have allowed the molecular structure of the target sites to be determined.
- Interaction of drug with their target sites (DNA, enzymes, membrane raptors, etc.)
- In vitro methods are ideal when there is a specific dynamic effect or end-point can be measured. They provide an environment in which the variables can be controlled carefully and manipulated. the end-points can be pharmacological, biochemical or molecular, immunological, generic, physiological or pathological.

## ADVANTAGES

- In vitro methods are usually the methods of choice for large-scale production by the pharmaceutical industry because of the ease of culture for production, compared with use of animals, and because of economic considerations.
- In vitro methods avoid the need to submit animal protocols to IACUCs.
- In vitro methods avoid or decrease the need for laboratory personnel experienced in animal handling.

## DISADVANTAGES

- It should be noted that each of the items below pertains to only a fraction (3–5%) of hybridomas, but they indicate some of the difficulties associated with in vitro methods.
- The loss of proper glycosylation of the antibody (in contrast with in vivo production) might make the antibody product unsuitable for in vivo experiments because of increased immunogenicity, reduced binding affinity, changes in biologic functions, or accelerated clearance in vivo.
- Some hybridomas do not grow well in culture or are lost in culture.
- In vitro culture methods are generally more expensive than the ascites method for small-scale or medium-scale production of mAb.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# EXPERT TALK IN 'MY IC'

1. *'Chemical Engineering-An Extra Edge for an Industrial Chemist'*
   *Dt.:-23/07/2018*
   *Delivered by:-*
   *Dr. Tejal Patel*
   *Asso. Prof., G H Patel College of Engineering & Technology, VVN.*

2. *Process Development In Chemical Industry*
   *Dt.:-04/08/2018*
   *Delivered by:-*
   *Mr. Hemendra Pancholi*
   *(GM Deepak Nitrate, Nandesari)*

3. *Destiny by Desire or Default*
   *Dt.:-14/08/2018*
   *Delivered by:-*
   *Dr. Raju M. Rathod*
   *(Professor in G.H. Patel P.G. Institute of MBA Programme Sardar Patel University, Chairman of Indian Society for Training and Development, Anand)*



Designed By:-
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