جامعة بيرزيت

BIRZEIT UNIVERSITY

Faculty of Pharmacy, Nursing and Professions Health

PHARM D PROGRAM

Industrial Pharmacy Lab. Manual

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Laboratory Design Guide

- **Lab 1**: Introduction: Behavior in the pharmaceutical industries.
- **Lab 2**: How to write a report – Tour in the industry.
- **Lab 3**: Weighing – Experiment (1).
- **Lab 4**: Granulation – Experiment (1).
- **Lab 5**: Mixing – Experiment (2).
- **Lab 6 + 7**: QC tests (Bulk density + Tab density + Angle of repose + Sieve analysis) – Experiment (3, 4, 5).
- **Lab 8**: Compression – Experiment 6.
- **Lab 9**: Coating – Experiment 7.
- **Lab 10 + 11**: QC tests (Hardness + Friability + Dissolution test + Disintegration Test + Weight uniformity) Experiment (8, 9, 10, 11, 12).

Introduction

This is the third pharmaceutical laboratory for Pharm D students at Birzeit University. It is designed to give the students a clear idea about the pharmaceutical dosage forms and their preparation techniques.

Introducing this lab in this stage of the student's professional academic life will let them appreciate the pharmaceutical and industrial field. It will also provide them with a clear idea of the impact of drug formulations and compounding processes on drug prescription.

This lab will feed the students with a hand experience on prescription practice. Students will also carry out preparations that are similar to what are prepared in the pharmaceutical industries and drug manufacturing companies.

Students will learn the different procedures, techniques, and ethics of preparing, labeling, filling and storage conditions for the different drug formulas represented by the different dosage forms. They will also learn how to counsel patients on these dosage forms. Pharmacists must check the correct dose first, fitness of the prescription to the patient age, weight and gender, as well as the clinical validity of the prescription for the disease or condition in a simulated patient-pharmacist interaction. In addition, students have to report the methods and techniques used in both preparation and counseling.

By the end of this lab, students will accumulate a good knowledge about the necessary techniques and procedures of drug compounding that they might need in their pharmacy practice in their future. This include but not limited to; calculations, solubility determination, solvent mixture selection and preparation, expiry date and stability studies, and storage conditions. The student will also accumulate a good knowledge about quality control tests needed for the different dosage forms such as friability test, weight variation, dissolution test, hardness test and disintegration test.

LABORATORY OBJECTIVES

I. To learn the preparation method of tablets by wet granulation and dry granulation.
II. To learn how to use Mixing machine, granulator, roller compactor, tableting machine and coating machine.
III. To learn and discover the quality control tests for tablets.

جامعة بيرزيت

Samih Darwazeh Institute of Industrial Pharmacy

Your life is ... Our Passion

Quality System

Visitor Pre-gowning

Kindly follow these steps for the correct pre-gowning procedure:

Set on the bench and keep foot on dirty side

Place blue shoe-cover on one foot

Move covered foot over bench to clean area

Repeat the same procedure for the other foot

5

Push door open and step into corridor ensuring door closes behind you.

Gowning

The process of wearing special garments in order to control particulate contamination

- **Employees and students gowning**

➢ **Replace the old shoes/shoe covers as Following:**

1

Set in the bench and take off the old shoe cover

2

Place blue shoe-cover on one foot

3

Move covered foot over bench to clean area

4

Repeat the same procedure for the other foot

5

Move to the clean area

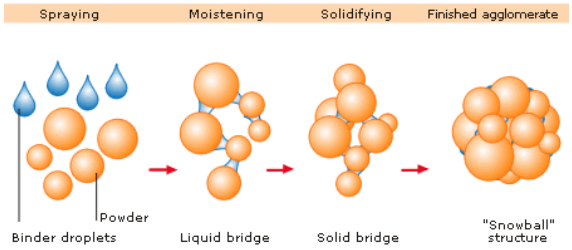
➢ **Place the head cover as follow ensuring covering hair**

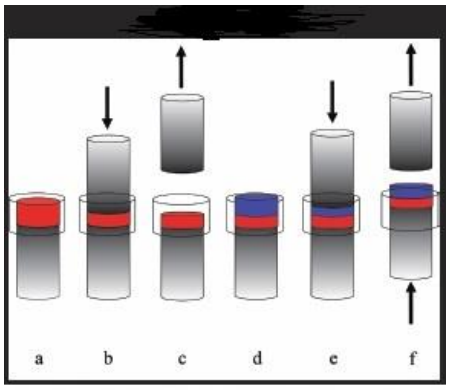
6

➢ **Place the lab coat as follow**

7

1. GRANULATION





Tablet is an important solid dosage form, which is usually prepared with the aid of suitable pharmaceutical excipients. Tablets may vary in size, shape, weight, hardness, thickness, disintegration and dissolution characteristics and in other aspects, depending on their intended use and method of manufacture.

Compressed tablets may be manufactured by three basic methods: wet granulation, dry granulation, and direct compression.

1.1 Introduction to granulation

Pharmaceutical granulations are used primarily for the preparation of materials for tableting and or encapsulation. The main objectives of granulation are to improve the flow properties and, in the case of tableting, the compression characteristics of the mix, and to prevent aggregation of the constituents during the tableting process. In this laboratory exercise, wet granulation will be carried out on both low shear and Fluid Bed Dryer granulator also dry granulation will be carried out on roller compactor. The difference in granule properties due to process differences will be evaluated from the following parameters:

i. Powder flow
ii. Particle size
iii. Bulk density data

1.2 Reasons for Granulation:

The reasons why granulation is often necessary are as follows:

1. To prevent segregation of the constituents of the powder mix
2. To improve the flow properties / fluidity of the mix
3. To improve the compaction characteristics of the mix
4. Avoid dustiness
5. Materials which are slightly hygroscopic may adhere and form a cake if stored as a powder
6. Granules, being denser than the parent powder mix, occupy less volume per unit weight
7. Improve appearance, mixing properties in general to either eliminate undesirable properties or to improve the physical and chemical properties of fine powders.

1.3 Granulation methods can be divided into two main types:

- ✓ Dry methods in which no liquid is utilized
- ✓ Wet methods which utilize a liquid in the process

1.3.1 Dry methods

Granulation is a process in which powder particles are made to adhere to each other, resulting in larger, multi-particle entities, so called granules. If such a process is performed without adding liquids, this is called dry granulation.
Since the dry granulation process does not involve the use of liquid, it is primarily used as a mean of granulation for moisture sensitive or heat sensitive drugs. In this process, dry powder particles are brought together mechanically by compression into slugs or by roller compaction. The compacts thus obtained are called briquettes, flakes or ribbons.
In order to obtain the desired granules, the compaction process is followed by a milling step.
Principally there are two methods to obtain the compacts when using dry granulation: slugging and roller compaction.

1.3.1.1 Slugging

If a tablet press is used for the compaction process, the term slugging is used. But since particles with a small particle size do not flow well into the die of a tablet press, the results are weight differences from one tablet (slug) to another. This in turn causes large fluctuations in the forces applied onto the individual slugs, with translates in variations of the slug's mechanical strength. Therefore, the properties of these granulates obtained by milling the slugs cannot be controlled well either.
This is one of the main reasons why slugging is hardly used any more as a dry granulation method.

1.3.1.2 Roller Compaction

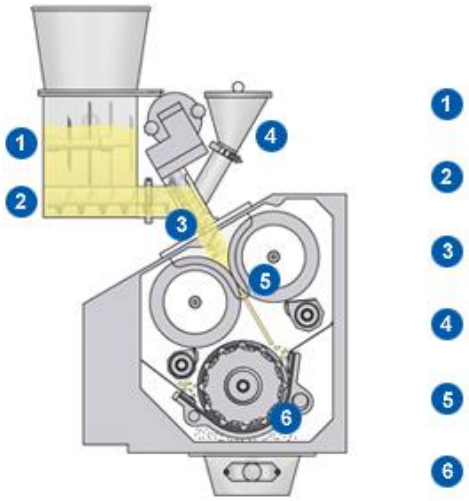
Roller compactor generally consist of three major units:

1. A **feeding system**, which conveys the powder to the compaction area between the rolls
2. A **compaction unit**, where powder is compacted between two counter rotating rolls to a ribbon by applying a force
3. A **size reduction unit**, for milling the ribbons to the desired particle size.

Process Parameters

The powder is compacted between two rolls by applying a force, which is the most important parameter in the dry granulation process. The applied force is expressed in kN/cm, being the force per cm roll width. Occasionally the press force is also indicated in bar. This, however, merely represents the pressure within the hydraulic system, and is in fact not an appropriate measuring unit for the force applied onto the powder.

At a given force, depending on the amount of powder conveyed to the rolls, the powder will be compacted to a predefined ribbon thickness. A precise process control is essential to obtain equal granules properties from a homogenous ribbon.



1. Inlet funnel with agitator
2. Feed auger
3. Tamp auger
4. Small quantity inlet funnel
5. Press rolllers with ribbon
6. Rotor with desired granules

Fig 1: Roller compactor

1.3.2 Wet methods

Wet granulation can be divided into three main processes of low shear, high shear, and fluid bed granulation. Additionally there is a drive towards continuous wet granulation for improvement in manufacturing efficiency. Each process has its advantages and disadvantages which may be useful for different formulations, but in practice a formulator may not have the choice of which process to use for a particular product, the selection being determined by equipment availability and company preference.

1.3.2.1 Low shear granulator

This is the traditional means of granulation employing low speed planetary or trough mixers in which the drug and intragranular excipients are granulated with a binder solution; the resulting wet mass is screened to form discrete granules which are typically dried in a tray drier. The dried granules are rescreened or milled to the required size, blended with extragranular excipients, lubricated and compressed.

The main disadvantages of this process are the open nature of the equipment and the manual transfer of the materials being processed, the long drying times, potential for migration of soluble components during tray drying and the general lack of instrumentation for in process control

Planetary Low Shear Mixer

kneader type mixer

Fig 2 : Low shear mixer/granulator

Variables Occur in Low Shear Mixer/Granulator

- **Process variables that affect granulation process are as follow:**

- Impeller rotation speed
- Load of the mixer
- Liquid addition rate
- Wet-massing time (subsequent of liquid addition time)
- Granulation time

- **Product variables that affect granulation process are as follow:**

- Amount of liquid binder
- Characteristics of liquid binder
    1. Surface tension
    2. Viscosity
    3. Adhesiveness

- **Characteristics of the feed materials**

    1. Particle size and size distribution
    2. Particle specific surface area
    3. Solubility in the liquid binder
    4. Wettability
    5. Packing properties

- **Apparatus Variables : The instrumental variables affecting the granulation characteristics are:**

- Size and shape of mixing chamber
- Size and shape of impeller

1.3.3.2 High-speed or high shear mixer/granulator

High-speed or high shear mixer/granulator is used extensively in pharmaceutics. This machine has a stainless steel mixing bowl containing a three-bladed main impeller, which revolves in the horizontal plane, and a three-bladed auxiliary chopper (breaker blade), which revolves either in the vertical or the horizontal plane.
The high shear mixers have been applied for high speed dispersion of dry powders, aqueous or solvent granulations, wet granulation, melt granulation, effervescent products and melt pelletization.

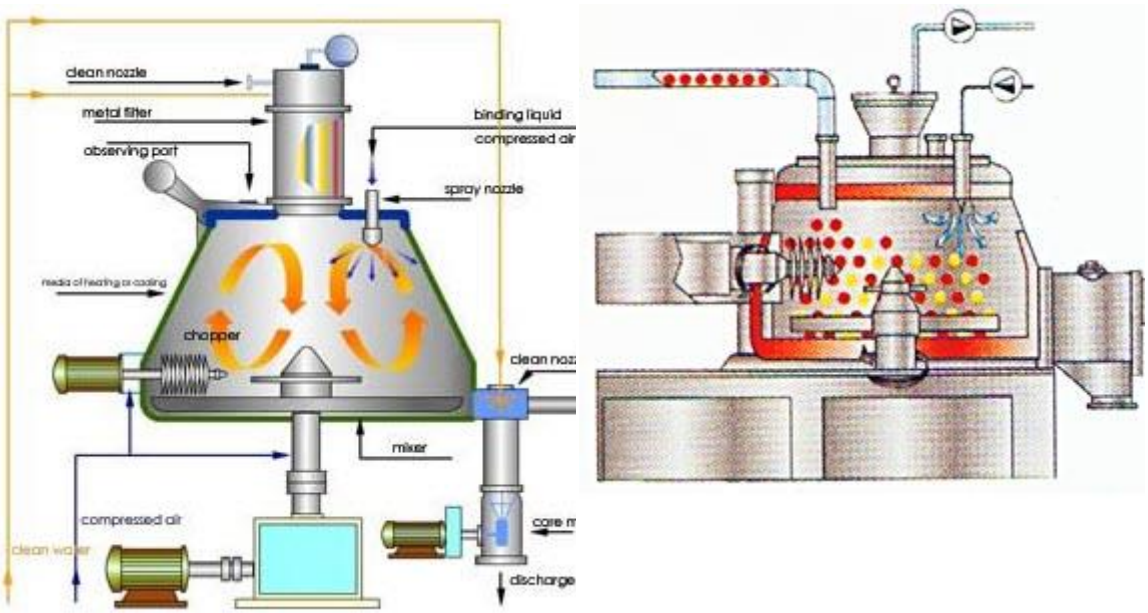


Fig 3: high shear mixer/granulator

The granulation is conventionally performed in the following process steps:

1. The unmixed dry powders are placed in the bowl then the dry material is mixed at high impeller speeds
2. Addition of liquid binder (Granulating liquid) by pouring via a port in the lid of the granulator onto the powder, while impeller are running at a low speed
3. The chopper is usually switched on when the moist mass is formed, as its function is to break up the wet mass to produce a bed of granular material.
4. Wet massing with both agitators running at high speed
5. Once a satisfactory granule has been produced, the granular product is discharged, passing through a wire mesh which breaks up any large aggregates, into the bowl of a fluidized-bed drier.
6. Dry the granules.
7. Dry sieving the granulate

Variables Occur in High Shear Mixer/Granulator

- **Process variables that affect granulation process are as follow:**

- Impeller rotation speed
- Chopper rotation speed
- Liquid flow rate
- Load of the mixer
- Liquid addition method
- Wet-massing time (subsequent of liquid addition time)

- **Product variables that affect granulation process are as follow:**

1. Amount of liquid binder
2. Characteristics of liquid binder
3. Surface tension
4. Viscosity
5. Adhesiveness
6. Characteristics of the feed materials
7. Particle size and size distribution
8. Particle specific surface area
9. Solubility in the liquid binder
10. Wettability
11. Packing properties

- **Apparatus Variables: The instrumental variables affecting the granulation characteristics are:**

- Size and shape of mixing chamber
- Size and shape of impeller
- Size and shape of chopper

1.3.3.3 Fluidized-bed granulator dryer

In the Fluidized-bed granulators Heated and filtered air is blown or sucked through the bed of unmixed powders to fluidize the particles and mix the powders; fluidization is very efficient mixing process. Granulating fluid is pumped from a reservoir through a spray

nozzle positioned over the bed of particles. The fluid causes the primary powder particles to adhere when the droplets and powders collide. Escape of material from the granulation chamber is prevented by exhaust filters, which are periodically agitated to reintroduce the collected material into the fluidized bed. Sufficient liquid is sprayed to produce granules of the required size, at which point the spray is turned off but the fluidizing air continued. The wet granules are then dried in the heated fluidizing airstream.

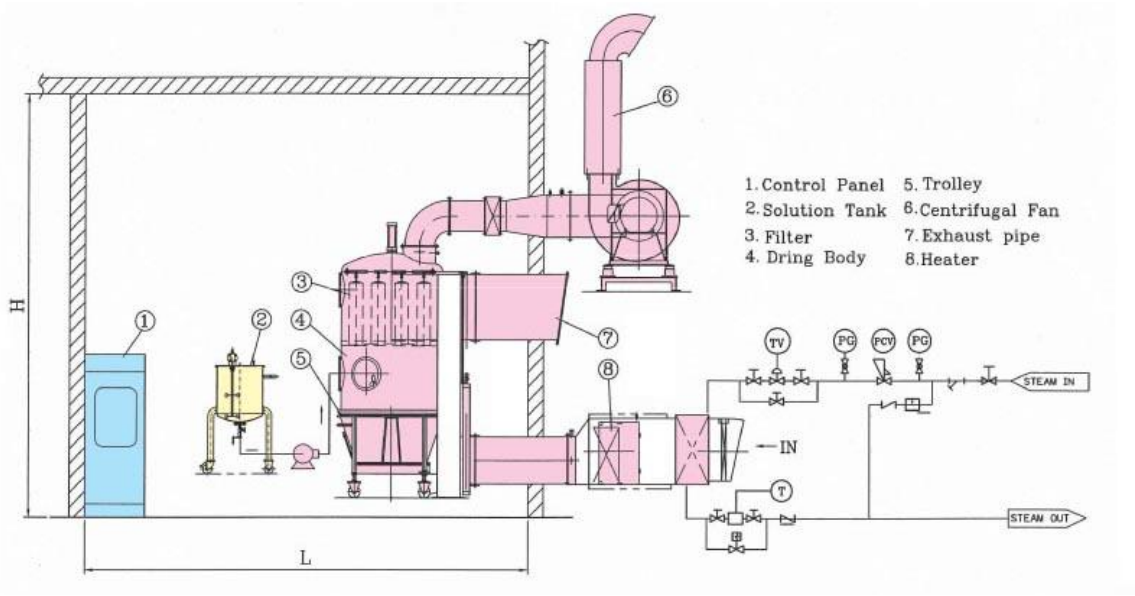


Fig 4 : Fluidized-bed dryer and granulators

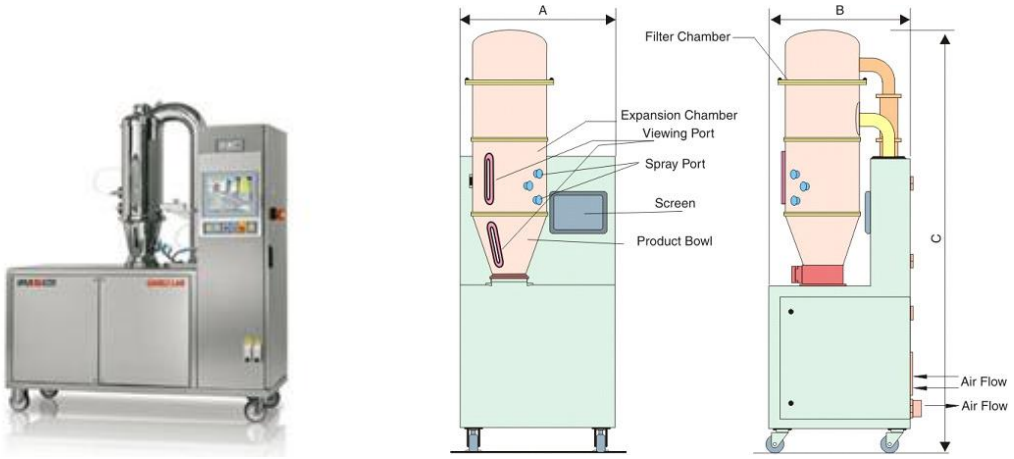


Fig 5 : Fluidized-bed dryer and granulators

There are numerous apparatus, process and product parameters that affect the quality of the final granule. Each formulation presents its own individual development problems, has led to fluidized-bed granulation not reaching its full potential in pharmaceutical production.

Table 1: Parameters for Fluidized-bed granulator dryer

Apparatus parameters	**Process Parameters**	**Product Parameters**
Air distribution plate	Bed load	Type of binder
Shape of granulator body	Fluidizing air flow rate	Quantity of binder
Nozzle height	Fluidizing air temperature	Binder solvent
Positive or negative operation	Fluidizing air humidity	Concentration of granulating solution
Scale-up	Atomization : Nozzle type, Spray angel, spraying regime, Liquid flow rate, Atomizing air flow rate, Atomizing air pressure, Droplet size	Temperature of granulation solution
		Starting materials : Fluidization and Powder hydrophobicity

Experiment ONE:

Granulation

Preparation of Acetaminophen tablets using Wet Granulation Method.

Formula for Acetaminophen tablets **(B.No.PT01)** total weight of tablet 800mg

Table 2: Formula for Acetaminophen tablet

Ingredient	Composition
Acetaminophen	6.25%
Starch	23.25%
Lactose	20%
Mannitol Powder	15%
Avicel PH101	18%
Povidone K 30	8%
Use one of the following materials : Polyplasdone XL Croscarmellose Sodium (*Ac-Di-Sol)* Sodium starch glycolate	8%
Magnesium Stearate	1.5%
Total Tablet Weight	100%

- ✓ **Calculate the quantity to prepare 1000 Tablets**
- ✓ **Find the function of each ingredient (B.No.PT01)**

Table 3: Formula for Acetaminophen tablet

Ingredient	Composition PT01	Quantity per Tab.(mg)	Quantity per Batch(g)	Function
Acetaminophen	6.25%			
Starch	23.25%			
Lactose	20%			
Mannitol Powder	15%			
Avicel PH101	9%			
Avicel PH101	9%			
Polyplasdone XL Croscarmellose Sodium (*Ac-Di-Sol)* Sodium starch glycolate	8%			
PVP K30	8%			
Magnesium Stearate	1.5%			
Total Tablet Weight	100%	800 mg		

Procedure:

1. Weight the actual quantity of each excipient for the experiment

2. Mix the following ingredients using plastic sack and then Screen the mixture from sieve 20 mesh :

Material	Quantity
Acetaminophen	
Starch	
Lactose	
Mannitol Powder	
One part of Avicel PH101	

3. Transfer the above mixture to the bowl and mixed for 15 min at impeller speeds ( )

Take sample and measure Moisture contents (1.5gr)

4. Prepare the granulating solution by adding the PVP K30 to purified water (28% w\w PVP K30 in P.W.) and mix until the PVP K30 dissolved. (Granulating liquid)

5. Add the liquid binder (Granulating liquid) to the powder by pouring it via a port in the lid of the granulator, while impeller are running at a low speed…….

6. Once a satisfactory granule has been produced, the granular product is discharged, passing through a wire mesh #10 which breaks up any large aggregates.

7. Transfer the granules on stainless steel trays to the oven and dry until you reach the initial moisture content

Take sample and measure Moisture contents (Loss on Drying (LOD))

8. Discharge the stainless steel trays into plastic bags and transfer them to the storage area.

Experiment TWO

Mixing (B.No. PT01)

1. Transfer the granules from experiment 1 to the Mixing area
2. Make sure that the Mixing machine is clean and ready to be used
3. Transfer the granules to the bowl or to the cube mixer
4. Mix for 5 min
5. Add to the bowl the following materials :

Material	Quantity
Polyplasdone XL	
Second part of Avicel PH101	

6. Mix for 10 min
7. Add to the cube mixer Magnesium Stearate , ……. gr
8. Mix for 3 min
9. ***Take sample (150 gr)***
10. Discharge the cube mixer into plastic bag and transfer them to the storage area.

Data and Calculation (Check the next topic to complete these measurements)

Question: (should be answered on your report paper)

Q1: Why the mixing time after adding magnesium Stearate is only 3 min?

Q2: Why was Mg. Stearate mixed manually or in Cube mixer, not in the low shear mixer?

Q2: Why was PVP used as a solution and not as a powder? Why was PVP dissolved in water not in alcohol?

2. POWDER AND GRANULES PROPERTIES

The purpose of this lab is to determine the powder and granules properties such as densities, porosities flow and particle size distribution.

2.1 Particle Size Distribution

A good powder formulation has a uniform particle size distribution. If the particle size distribution is not uniform, the powder can segregate according to the different particle sizes, which may result in inaccurate dosing or inconsistent performance. A uniform particle size distribution insures uniform dissolution rate if the powder is to dissolve, an uniform sedimentation rate if the powder is used in a suspension, and minimizes stratification when powders are stored or transported.

The primary function of precision particle analysis is to obtain quantitative data about the size and size distribution of particles in the material. There is a wide range of instrumental and other methods of particle size analysis available.

Methods for Determining Particle Size:

- Microscopy
- Sieving
- Sedimentation techniques
- Optical and electrical sensing zone method
- Laser light scattering techniques
- Surface area measurement technique

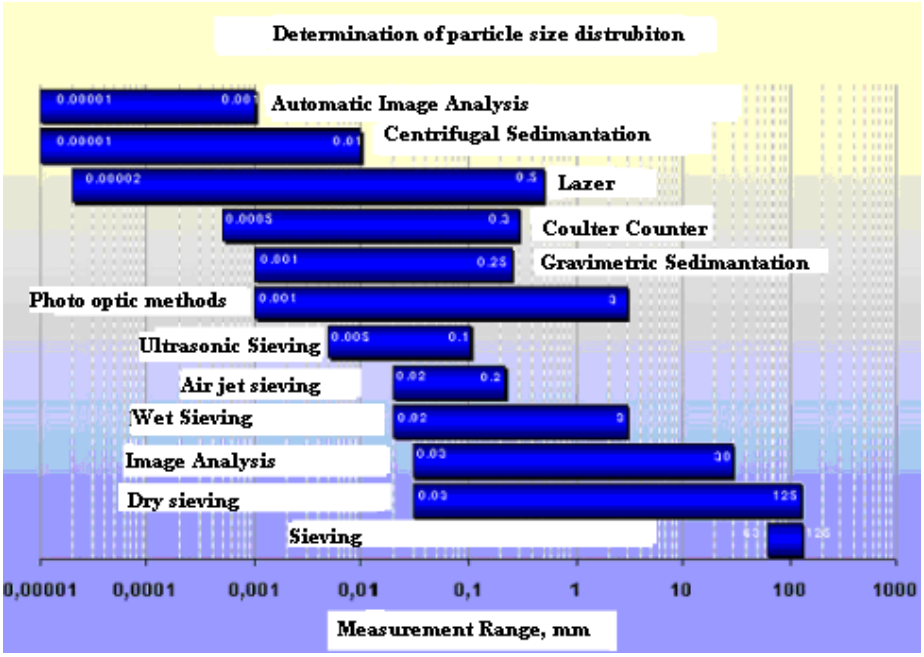


Fig 6: Methods of particle size analysis

2.1.1 SIEVE ANALYSIS

Sieving is one of the oldest methods of classifying powders and granules by particle size distribution. When using a woven sieve cloth, the sieving will essentially sort the particles by their intermediate size dimension (i.e., breadth or width). Mechanical sieving is most suitable where the majority of the particles are larger than about 75 µm.

In pharmaceutical terms, sieving is usually the method of choice for classification of the coarser grades of single powders or granules. It is a particularly attractive method in that powders and granules are classified only on the basis of particle size, and in most cases the analysis can be carried out in the dry state.

Sieve analysis is accomplished by passing a known weight of sample material successively through finer sieves and weighing the amount collected on each sieve to determine the percentage weight in each size fraction. Sieving is carried out with wet or dry materials and the sieves are usually shacked manually or automatically.

- **Manual Sieving**: Suitable for coarser particles than 0.038 mm. Sieves are used one by one starting from the largest size.
- **Automatic Sieving**: Most often practiced for particle sizes ranged between 6 mm – 0.038. A standard series of 6 sieves are put together and shacked on a automatic sieve shaker device for 5-20 minutes.
- **Dry Sieving**: Suitable for non-sticky and non-clay samples.
- **Wet Sieving**: Practiced for finer size particles containing clay which have hard nature for dry screening.

Dry Sieving: This method is intended for estimation of the total particle size distribution of a single material.

Estimate the particle size distribution as described under *Dry Sieving Method,* unless otherwise specified in the individual monograph. Where difficulty is experienced in reaching the endpoint (i.e., material does not readily pass through the sieves) or when it is necessary to use the finer end of the sieving range (below 75 µm), serious consideration should be given to the use of an alternative particle-sizing method.

Sieving should be carried out under conditions that do not cause the test sample to gain or lose moisture. The relative humidity of the environment in which the sieving is carried out should be controlled to prevent moisture uptake or loss by the sample. In the absence of evidence to the contrary, analytical test sieving is normally carried out at ambient humidity.

Sieve analysis is performed using a nest or stack of sieves where each lower sieve has a smaller aperture size than that of the above sieve

Sieves can be referred to either by their aperture size = mesh size = sieve number (BP, PhEur) above it.

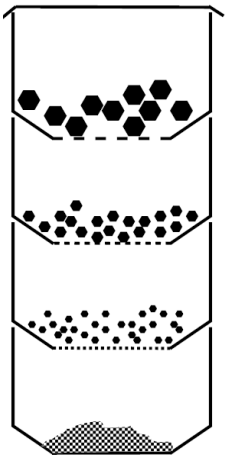


Fig 7: Sieve analysis

A **mesh number** denotes the size of the apertures in each sieve. The mesh number is the number of wire strands (of constant diameter) per inch used to weave the square mesh pattern. The side length of the aperture in microns is inversely related to the mesh number.

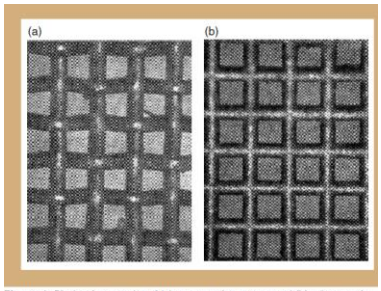


Figure 1: Photomicrographs of (a) woven-wire screen and (b) micromesh screen.

Fig 8: Sieve mesh number

Table 5: US Sieve size

	Mesh Opening Size	
Mesh Size Number	**millimeters**	**microns**
2	9.52	9520
4	4.76	4760
8	2.38	2380
10	2.00	2000
12	1.70	1700
14	1.40	1400
16	1.18	1180
18	1.00	1000
20	0.84	840
30	0.59	590
40	0.42	420
50	0.297	297
60	0.250	250
70	0.210	210
80	0.177	177
100	0.149	149
120	0.125	125
200	0.074	74

Table 6: The USP 24/NF19 uses descriptive terms to define powder fineness.

The table below shows the correlation their classification

Description Term	Mesh Opening Size (microns)	Mesh Size Number
Very Coarse	> 1000	2 – 10
Coarse	355 -1000	20 – 40
Moderately Coarse	180 – 355	40 – 80
Fine	125 – 180	80 – 120
Very Fine	90 - 125	120 - 200

Advantages of Sieve analysis

– Easy to perform

– Wide size range

– Inexpensive

Disadvantages of Sieve analysis

– Known problems of reproducibility

– Wear/damage in use or cleaning

– Irregular/agglomerated particles

– Rod-like particles: overestimate of under-size

Experiment THREE: SIEVE ANALYSIS

***USP* General Test _786_ Method I.**

USP General Test 786_Method I gives the procedure to be followed when conducting the sieving analysis of dry powdered solids. The steps are as follows:

● Tare each test sieve to the nearest 0.1 g.

● Place an accurately weighed quantity of test specimen on the top (coarsest) sieve and replace the lid.

● Agitate the nest of sieves for 5 min.

● Carefully, remove each sieve from the nest without losing material.

● Reweigh each sieve and determine the weight of material on each sieve.

● Determine the weight of material in the collecting pan in a similar manner.

● Reassemble the nest of sieves and agitate it for 5 min.

● Remove and weigh each sieve as previously described.

● Repeat these steps until the end point criteria are met (the weight on any of the test sieves does not change by more than 5% of the previous weight on that sieve).

When the analysis is completed, the analyst reconciles the weights of material. The total losses must not exceed 5% of the weight of the original test specimen. If particles retained on any sieve are aggregates (rather than single particles), then the use of dry sieving is not likely to be an easily reproducible method. At that point, the analyst could consider the use of Method II as an alternate technique.

- **Procedure :(See Fig 9)**

1. Record the weight of each empty sieve and the collection pan.
2. Arrange the sieves in a sequential nest: smallest mesh number (largest aperture) at the top, largest mesh number (smallest aperture) at the bottom. Add the collection pan to the bottom of the nest. (Record the mesh number of each sieve)
3. Weigh accurately about 100 gm of the supplied powder or granules
4. Add the weighed powder or granules to the top sieve, and cover with the rubber cap.
5. Agitate the nest of sieves for 5 min
6. Carefully remove each sieve from the nest without losing material.
7. Reweigh each sieve and determine the weight of material on each sieve.
8. Determine the weight of material in the collecting pan in a similar manner

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Fig 9: Steps of sieve analysis

GRAPH & CALCULATIONS

Calculate: (See Table)

1. Percent of Mass Retained
2. Cumulative Percent Retained
3. Percent Finer
4. ***Plot the mass on sieve gr (retained) vs. Opening Size.***
5. ***Plot the Cumulative % of sample passing through each sieve vs. Opening Size.***
6. Calculate D_{10}, D_{50}, D_{90} .
7. Loss during sieving

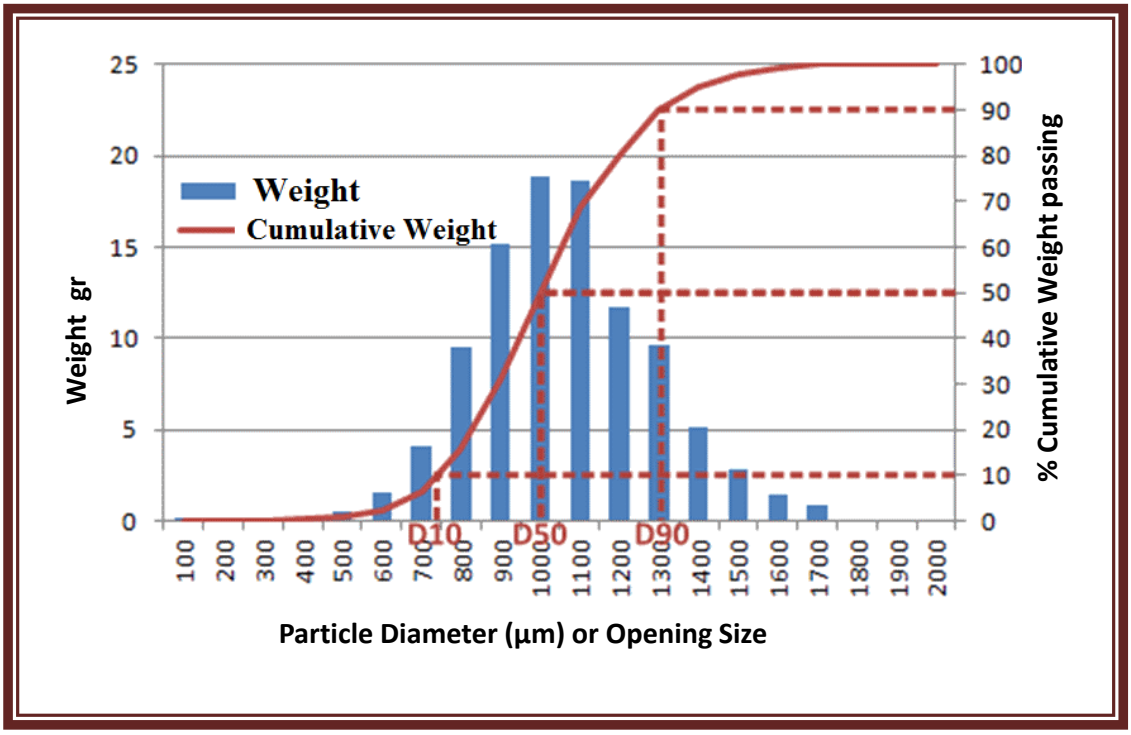
$$\%\boldsymbol{Loss\ during\ sieving} = \frac{\boldsymbol{W_S - \Sigma W_n}}{\boldsymbol{W_S}}$$

W_S : initial weight of the sample

W_n : Weight Retained on each sieve

Table 7: Lab measurement data for particles size analysis

W_S original sample (g) _____



Sieve No.	Opening Size (µm)	Sieve Weight (g)	Material + Sieve Weight W_T (g)	Weight Retained on each sieve W_n (g)	% Weight of sample retained on each sieve	Cumulative % of sample retained on each sieve	Cumulative % of sample passing through each sieve
Pan							
Total							

Question: (should be answered on your report paper)

Questions:

1. Describe as many limitations as you can think of for particle size determination by sieving. What types of particles could not be sized by sieving.
2. If a large percentage of powder were deposited on the top sieve or the bottom pan, is the particle size you determined representative of the powder sample? Justify your answer
3. Would you expect to get the same mean sieved diameter if you performed the experiment described above, but made the following changes? Justify your answer.

a. Increased the sieving time to 10 minutes.

b. Increased the sample quantity.

4. What are the other methods that can be used to identify the size of particle rather than sieving process?
5. What are the importance of size particles analysis in formulation?

2.1.2 Bulk Density

Bulk density: is the mass of powder per unit of bulk volume, which consists of the void volume and the true volume occupied by the particles. Although there is no direct linear relationship between the potential flowability of a powder and its bulk density, other properties of the substance can affect the bulk density and flowability. By comparing both the initial and final bulk volumes of powder subjected to tapped compression, Carr defined the compressibility index

The purpose of this experiment is to determine the densities and porosities of ingredients in a bulk powder prescription.

The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume including the contribution of the interparticulate void volume. The bulk density is expressed in grams per milliliter (g/mL) although the international unit is kilogram per cubic meter (1 g/mL = 1000 kg/m3) because the measurements are made using cylinders. It may also be expressed in grams per cubic centimeter (g/cm3).

Bulk density p_b = Weight of powder / Volume of powder (V_{bulk})

The tapped density: is an increased bulk density attained after mechanically tapping a container containing the powder sample. The bulk density is expressed in grams per milliliter (g/mL) although the international unit is kilogram per cubic meter (1 g/mL = 1000 kg/m3) because the measurements are made using cylinders. It may also be expressed in grams per cubic centimeter (g/cm3).

Tapped density p_p = Weight of powder / minimum volume of powder (V_{tap})

The true volume, **V**, of a powder is the space occupied by the powder exclusive of spaces greater than the intramolecular space.

The true density p_t = Weight of powder / The true volume of powder (V)

Carr's index is a measure of interparticulate forces. If the interparticulate forces are high, powders will have a low bulk density because bridging will occur between particles. This results in a large Carr's index and a large change in volume caused by tapping. If the interparticulate forces are low, particles will have little affinity for one another, and will compact spontaneously. Under these circumstances, Carr's index is small and little change in apparent density is induced by tapping

Carr's index (%) = [(Tapped density – bulk density)/tapped density] * 100

Carr's index= $(p_p - p_b) / p_p$

Table 8: Standards for Carr's Index

Carr's Index	Flow
5 – 15	Excellent
12 - 16	Good
18 – 21	Fair
23 – 35	Poor
35 – 38	Very poor
More than 40	Extremely poor

Porosity: is the volume ratio occupied by air spaces (voids) between particles of a powder sample.

Porosity = $(p_t - p_b) / p_t$ (bulk)

Porosity = $(p_t - p_p) / p_t$ (Tapped)

Experiment FOUR: BULK + TAB Density

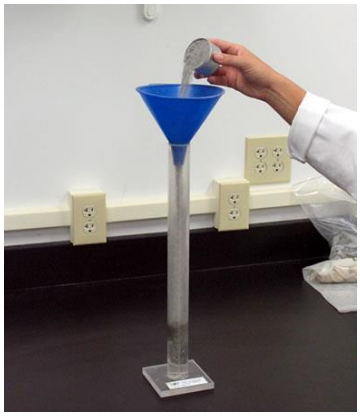
Procedure (see Fig 10)

1. Weigh out the quantity of the powder sample and the granule sample
2. Determine the weight of a 100 ml graduated cylinder. Without tapping, use a powder funnel to fill the cylinder to 100 ml with powder A. Record the weight of the cylinder and powder.
3. Using an automated tap density apparatus. Tap the filled cylinder 100 taps
4. Record the volume occupied by the sample after 100 taps.
5. Repeat Steps 3 and 4 for three times and record the final volume .

   (The true density of the powder can be found in the literature)

Step 1

Step 2



Step 3

Step 4

Fig 10 : Steps for bulk density measurement

Data and Calculation Sheet

Table 9: Lab measurement data for Bulk Density

	Powder	Granules
True Density		
Bulk Volume ml		
Tapped Volume ml		
Bulk density p_b		
Tapped density p_p		
Porosity Bulk		
Porosity Tapped		
Carr's index		

Questions:

1. A granulation has been prepared with a bulk density of 0.73 g /ml. If the granulation is tableted with 10 mm diameter, flat faced tooling (circular), and the lower punch drops to a depth of 8 mm in the die cavity, what will be the theoretical weight of the resulting tablet?
2. Give reasons why the actual tablets weight might deviate from the theoretical weight.

2.1.3 POWDER FLOW PROPERTIES (Angle of Repose)

During many pharmaceutical production processes it is necessary to transfer large quantities of powder from one location to another in a controlled manner. For example:

- Powder blending
- Powder filling into containers (e.g. dusting powders)
- Powder flow into capsules
- Powder filling into the dies of a tablet press

One method of assessing flow properties is the **Angle of Repose**.

Angle of Repose

The angle of repose has been used in several branches of science to characterize the flow properties of solids. Angle of repose is a characteristic related to interparticulate friction or resistance to movement between particles. Angle of repose results are reported to be very dependent upon the method used. Experimental difficulties arise as a result of segregation of material and consolidation or aeration of the powder as the cone is formed. Despite its difficulties, the method continues to be used in the pharmaceutical industry, and a number of examples demonstrating its value in predicting manufacturing problems appear in the literature. When bulk granular material or powder is poured on a horizontal surface of conical pile, it will form the internal angle between the surface of the pile and the horizontal surface is known as angle of repose. Angle of repose or the critical angle of repose is the steepest angle of descent or dip of the slope relative to the horizontal plane when material on the slope face is on the verge of sliding. This angle is in the range 0°–90°.

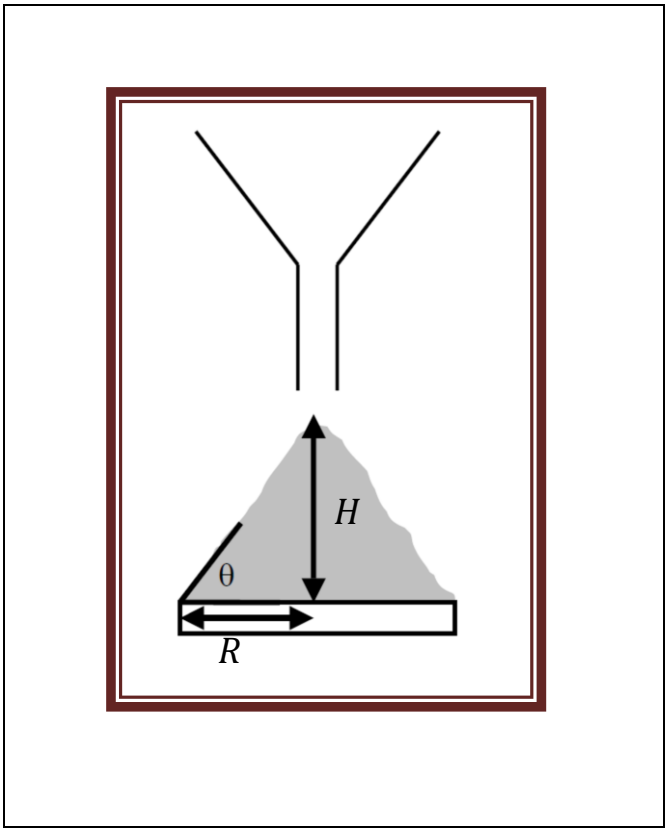


Fig 11 : Angle of Repose measurement method

$$\boldsymbol{Tan\,\Theta = \frac{H}{R}} \quad , \quad \boldsymbol{Where\ \Theta = Angle\ of\ Repose}$$

The Table below indicates the flow properties associated with corresponding Angles of Repose.

Table 10: Flow Properties & Angle of Repose

Flow Property	Angle of Repose
Excellent	25 - 30
Good	31 - 35
Fair - aid not needed	36 - 40
Passable - may hang up	41 - 45
Poor - must agitate, vibrate	56 - 55
Very poor	56 - 65
Very, very poor	> 66

Recommended Procedure for Angle of Repose (USP)

Form the angle of repose on a fixed base with a retaining lip to retain a layer of powder on the base. The base should be free of vibration. Vary the height of the funnel to carefully build up a symmetrical cone of powder. Care should be taken to prevent vibration as the funnel is moved. The funnel height should be maintained approximately 5 cm from the top of the powder pile as it is being formed in order to minimize the impact of falling powder on the tip of the cone. If a symmetrical cone of powder cannot be successfully or reproducibly prepared, this method is not appropriate.

Experiment FIVE: Angle of repose

Procedure:

1- Make sure there is a piece of paper under the funnel so you can pick up the powder and record the diameter of the formed circle

2- Position the bottom of a funnel about 5 cm above the center of the piece of paper

3- Slowly pour the of powder or granules sample into the funnel, tapping the funnel as necessary to ensure that powder flows through the hole.

4- Mark the base of the formed circle.

5- Measure the height of the pile using a ruler.

6- Remove the powder.

7- Measure the diameter of the formed circle using a ruler

8- Repeat the process three times and calculate the average the Diameter D **(2R) and the Height (H)**

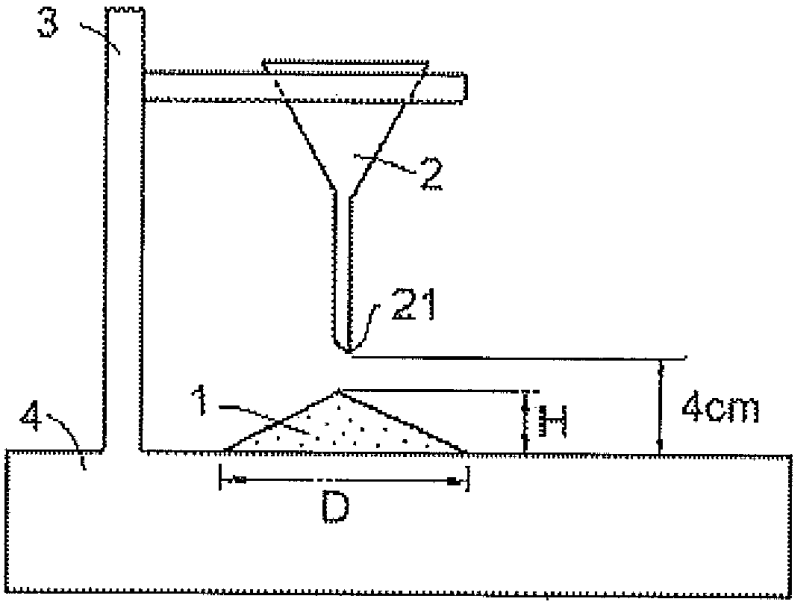


Fig 12 : Angle of Repose measurement method

$$\text{Angle of Repose}\,(\theta) = \tan^{-1}\left(\frac{h}{0.5\times D}\right)$$

Data and Calculation Sheet

Table 11: Lab measurement data for Angle of Repose

Powder/ Granules	Height (H)				Diameter D (2R)				Angle of Repose
	1	2	3	Mean	1	2	3	Mean	

Question: (should be answered on your report paper)

1- What factors will influence angle of repose for the materials?

2- What other method can be used to calculate the angle of repose for the materials?

3. Compression

Compressed tablets are one of the most popular dosage forms nowadays. Usually one considers a compressed tablet as an oral medication; however, tablets have many other uses. The sublingual tablet, the pellet, the wafer, the troche, and the vaginal insert are manufactured by the same procedure as an oral tablet.

Tablets contain active/s and other excipients selected to aid in the efficiency and safety in the dosage form.

3.1.1 Tablet Excipients:

1. Fillers (Diluents): are used to increase the bulk of the tablet. It is generally not feasible to make tablets with a weight of less than about 50 mg. It is essential that fillers be inert and stable. The range of tablet fillers may vary from 5-80%. Fillers are also synonymously known as Diluents. Diluents are used to:

- ✓ To improve cohesion
- ✓ To allow direct compression manufacturing
- ✓ To enhance flow
- ✓ To adjust weight of tablet as per die capacity

Classification of Diluents Based On Their Solubility:

I. **Soluble fillers**: lactose , sucrose , mannitol , sorbitol .

II. **Insoluble fillers**: calcium sulfate, dicalcium phosphate, tricalcium phosphate, starch, calcium carbonate

Selection of the appropriate diluent should be done after considering properties of diluent such as:

- Compatibility
- Flowability
- Solubility
- Disintegration properties
- hygroscopicity
- Lubricity
- Stability

2. Binders: Binders are one of an important excipient to be added in tablet formulation. In simpler words, binders or adhesives are the substances that promote cohesiveness. It is utilized for converting powder into granules through a process known as granulation. They are either sugars, natural or polymeric materials. The type and the percentage of the binder in the formula depend on the API, the other excipients and the characteristics of the final product.

Table 11: Classification of Binders

Sugar	Natural Binders	Synthetic/Semisybthetic Polymer
Sucrose	Acacia	Methyl Cellulose
Liquid glucose	Tragacanth	Ethyl Cellulose
	Gelatin	Hydroxy Propyl Methyl Cellulose (HPMC)
	Starch Paste	Hydroxy Propyl Cellulose
	Pregelatinized Starch	Sodium Carboxy Methyl Cellulose
	Alginic Acid	Polyvinyl Pyrrolidone (PVP)
	Cellulose	Polyethylene Glycol (PEG)
		Polyvinyl Alcohols
		Polymethacrylates

3. **Lubricants:** Lubricants work by reducing friction by interposing an intermediate layer between the tablet constituents and the die and / or the punches wall during compression and ejection and also between particles during compression. Since primarily lubricants are required to act at the material interface, lubricants should be incorporated in the final mixing step, after granulation is complete. When hydrophobic lubricants are added to a granulation, they form a coat around the individual particles (granules), which may cause an increase in the disintegration time and a decrease in the drug dissolution rate. Presence of lubricants may

results in a less cohesive and mechanically weaker tablet because it may interfere with the particle – particle bonding (Lessen tensile strength).

Classification of Lubricants

Lubricant are classified (based on their water solubility) into two groups:

1. Water insoluble
2. Water-soluble

Water insoluble lubricants are most effective and used at lower concentration than water soluble lubricants.

Table 12: Water insoluble Lubricants

Insoluble Lubricants	Concentration	Comments
Stearates(Magnesium Stearate, Calcium Stearate, Sodium stearate)	0.25-1	Reduce tablet strength and prolong disintegration
Talc	1-2	Insoluble but not hydrophobic, moderately effective.
Sterotex	0.25-1	-
Waxes	1-5	-
Stearowet	1-5	-
Glyceryl behapate (Compritol 888)	1-5	Both lubricant and binder
Liquid paraffin	Up to 5	Dispersion problem, inferior to stearates

Stearic acid and its calcium and magnesium salts are very effective lubricants. Magnesium stearate is very popular as a lubricant and is preferred to calcium stearate. Both of these compounds are basics, thus should not be used with acidic drugs.

Water Soluble Lubricants

Water Soluble Lubricants are used when a tablet is completely soluble or when unique disintegration and dissolution characteristics are required. Tablet containing soluble lubricant shows higher dissolution rate than tablet with insoluble lubricants. Physical mixture of this lubricant are sodium lauryl sulfate or magnesium lauryl sulfate with stearates can lead to the best compromise in terms of lubricity, tablet strength and disintegration.

Table 13: Water soluble Lubricants

Water Soluble Lubricants	Concentration range (%w/w)
Boric acid	1
Sodium benzoate	5
Sodium oleate	5
Sodium acetate	5
Sodium lauryl sulfate (SLS)	1-5
Magnesium lauryl sulfate (MLS)	1-2

4. **Glidants:** Glidants are added to the formulation to improve the flow properties of the material, which is to be fed into the die cavity and aid in particle rearrangement within the die during the early stages of compression. If the flow properties are extremely poor then glidants are ineffective and consideration of force free mechanisms may be necessary. The effect of glidants on the flow of the granules depends on the shape and size of the particle of the glidant and the granule. The commonly used glidants are talcum, starch, colloidal silica silicates, stearates calcium phosphate
5. **Disintegrants:** Disintegrants are excipients which are added to the tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a

fluid environment. This is especially important for immediate release products where rapid release of drug substance is required. Disintegrants can be used with products that are wet granulated, dry granulated and direct compressed. In wet granulation formulations, the disintegrant is normally effective when incorporated into the granule (intragranularly). It may be more effective if added 50% intragranularly, and 50% extra-granularly..

Some of the commonly used disintegrant

1. **Croscarmellose Sodium (Explotab, Primogel)** : High swelling capacity with minimal gelling, effective at low concentrations (2.0% - 6.0%).
2. **Crospovidone (Polyplasdone XL, Kollidon CL)** : water insoluble and strongly hydrophilic. Rapidly disperses and swells in water, but does not gel even after prolonged exposure. Greatest rate of swelling compared to other disintegrants.
3. **L-HPC (Low-substituted hydroxypropyl cellulose)** : Insoluble in water. Rapidly swells in water. Grades LH-11 and LH-21 exhibit the greatest degree of swelling. Certain grades can also provide some binding properties while retaining disintegration capacity. Recommended concentration 1-5%. Sodium Starch Glycolate
4. **Modified Cellulose**- **Internally cross-linked form of Sodium carboxymethyl cellulose. (Accelerates Dissolution), Nymcel.** Wicking due to fibrous structure, swelling with minimal gelling. Effective Concentrations: 1-3% (Direct Compression), 2-4% (Wet Granulation)

3.1.2 Single-punch Tablet Machines

Tableting machines are commonly used in pharmaceutical industry. They are high-speed machines that create thousands of tablets in a small period. The compounding pharmacist uses a variation of these machines. It is called a single-punch tablet press and makes one tablet at a time. A "punch" has two pieces of castled tubular metal. The bottom metal piece has a small cavity in one end of the tube; the top metal piece has one end that is tapered into a small rod that will just fit into the small cavity in the other piece. The rod does not go all the way to the bottom of the cavity, but leaves a small gap. The punch is fitted into a press so that when the handle is depressed and released, the rod goes into and then comes out of the bottom piece. To make a tablet, the powder material is placed

into the bottom piece, and the handle is depressed and released. The powders are compressed and occupy the size of the gap designed in the punch.

Punches come in many sizes which allows the production of tablets of different sizes and compression strengths. But each punch is a matched set; it is not possible to interchange the top and bottom pieces of different punches.

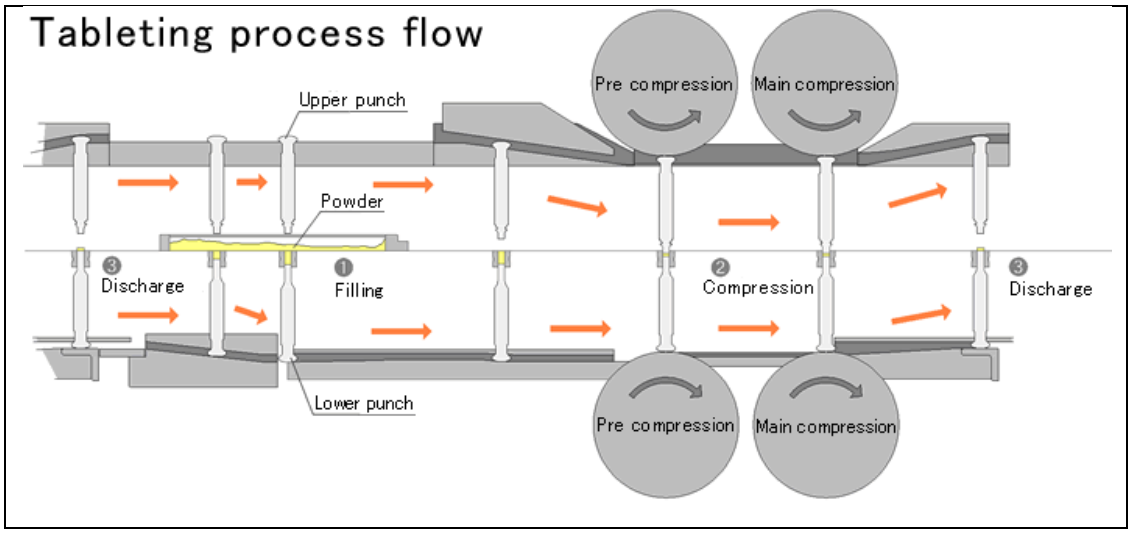


Fig 13: Compression process principles

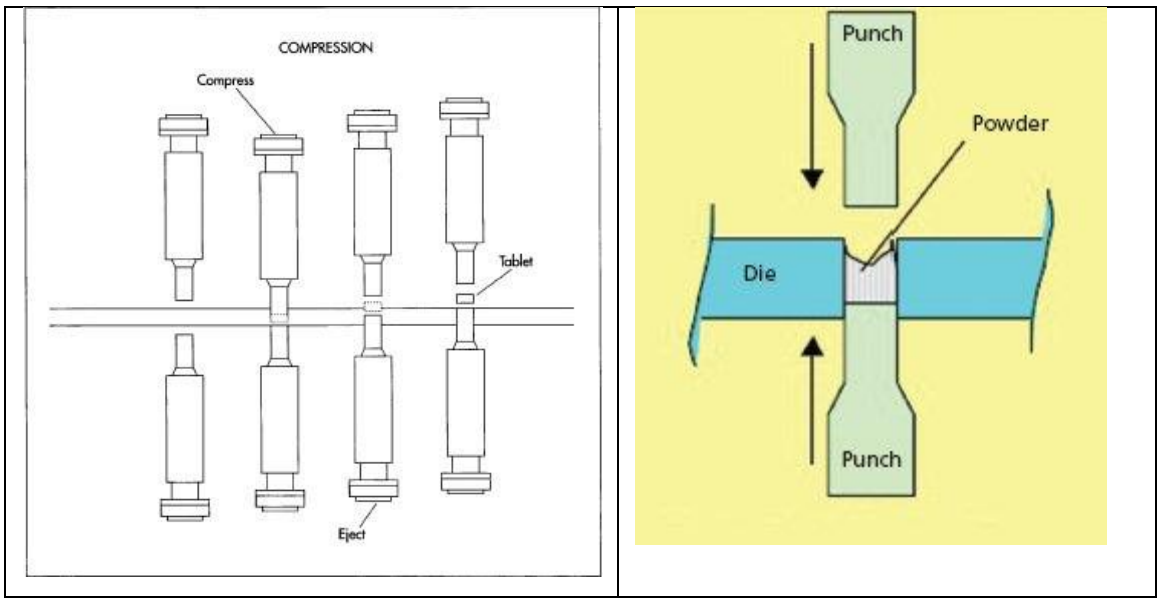


Fig 14 : Compression machine

Experiments SIX: Compression

1- Transfer the granules to the compression area
2- Make sure that the compression machine is clean and ready to be used
3- Fill the hoper of the machine with the granules
4- Adjust the weight of the tablet
5- Adjust the hardness of the tablets
6- Start compression with the supervision of the responsible person
7- Collect the tablets in plastic bags and transfer them to the storage area.

Sample collection

Take 2 samples of tablets with different compression force and keep the samples in well-closed container. (30 tablets for each sample)

Fill the following table for the compression process

Table 16: Lab data during compression process

Time	Main pressure		Pre pressure		Machine speed		Weight indicator	
	Set value	Actual value	Set value	Actual value	Set value	Actual value	Set value	Actual value

Quality control tests (Check the next topics)

Measure:

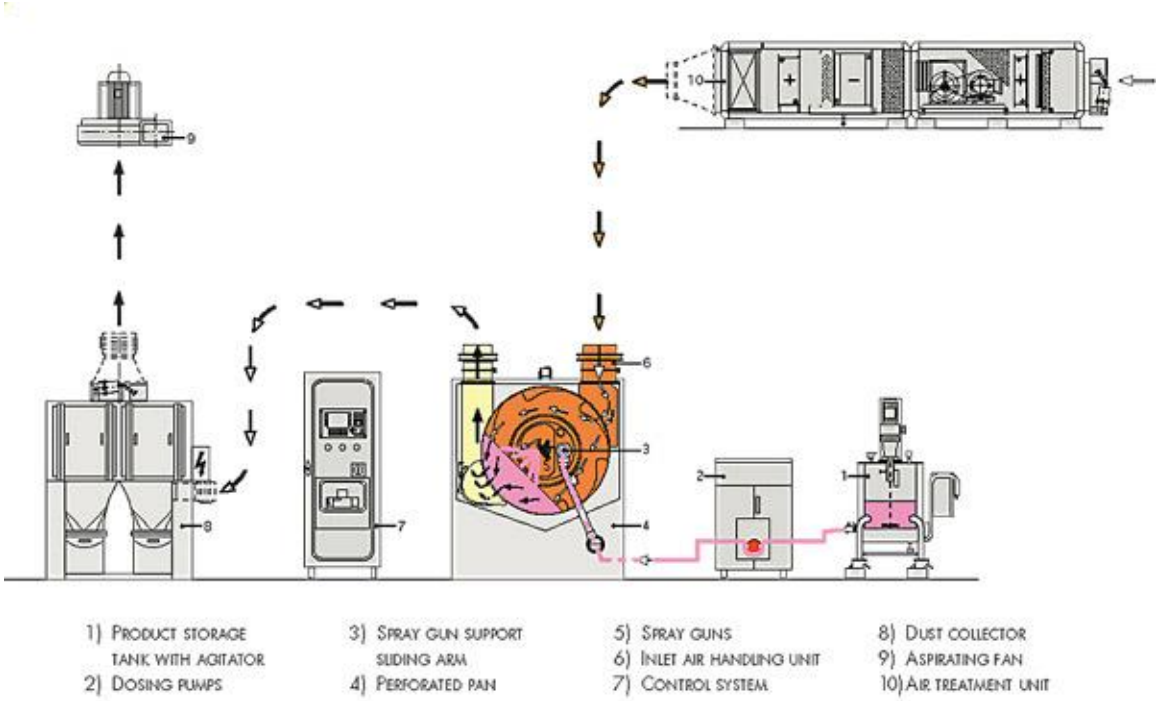
Tablet hardness

Tablet disintegration

Weight variation

Friability

4. Coating



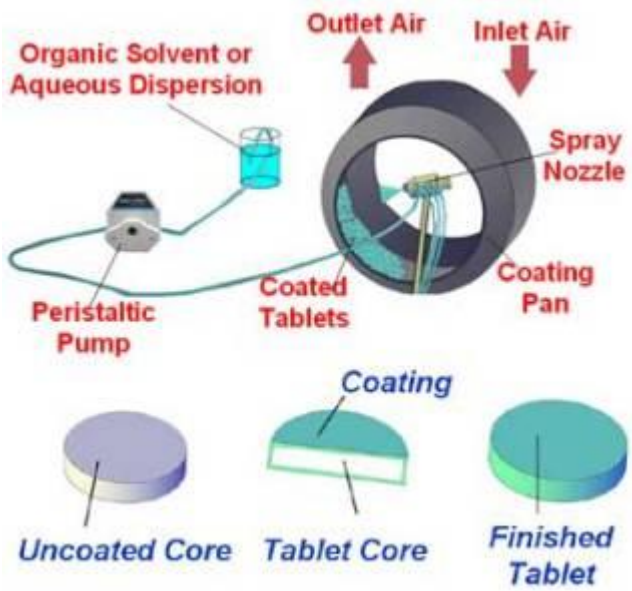


Fig 15: Coating machine & coating process

Experiments SEVEN: Coating

1. Transfer the tablets to the coating area
2. Make sure that the coating pan is clean and ready to used
3. Complete the table 17 before starting the coating process
4. Transfer the tablets to the coating pan
5. Adjust the parameter of the coating process
6. Prepare the coating suspension by adding the coating material (Opadry complete film coating) to purified water. The solution must be 15% Opadry in purified water and mix for 15 min using homogenized
7. Transfer the coating suspension to the coating machine container
8. Heat the tablets to reach the temperature 45^{o}C
9. Start the coating process by spraying the coating suspension solution to the powder (with the supervision of the responsible person)
10. Continue the coating process until the tablets take weight gain 3% (fill the table 17 to insure that the weight gain is 3%
11. ***Take samples (Sample 5)***
12. Discharge the coating ban to plastic bags and transfer them to the storage area

Table 17: weight of tablets before and after coat

No.	Weight of 10 tablets before coat	Weight of 10 tablets after coat
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Average weight		

Calculation and Sample collection

1. Calculate the quantity of coating material needed to coat the tablets (the tablets must take weight gain 3% coating material)
2. Weigh individually 10 Tablets before coating selected at random and calculate the average weight. Why?
3. Weigh individually 10 Tablets during the coating process selected at random and calculate the average weight. Why?
4. Weigh individually 10 Tablets at the end of coating process selected at random and calculate the average weight. Why?

Quality control tests (Check the next topics)

Measure:

Tablet hardness

Tablet disintegration

Weight variation

Friability

Quality control tests

- **Quality control**: the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical (WHO).

- **Quality control unit**: an organizational element designated by a firm to be responsible for the duties relating to quality control.

- **Quality control tests**: the process of striving to produce a quality product by a series of measures, requiring an organized effort in order to eliminate errors at every stage in the production.

Official and Non-official tests:

Official Tests: Weight variation, disintegration, dissolution, drug content.

Non-Official Tests: Hardness, friability

Hardness (crushing strength) test:

- Tablet Hardness: the force required to break a tablet along its diameter by applying compression loading.

Experiments EIGHT: Hardness

Test Description:

- A tablet is placed between two anvils, force is applied to the anvils, & the crushing strength that just causes the tablet to break is recorded (in kp).
- Minimum of 6 tablet samples should be tested then take the average hardness.
- Limit: Tablet hardness must be above 4 kp minimum.
- In general, if the tablet hardness is too high, we first check its disintegration before rejecting the patch. And if the disintegration is within limit, we accept the patch.

Data:

Tablet	1	2	3	4	5	6	7	8	9	10	**Avg. Hardness**
Hardness (Kp)											

Results & comments:

Friability (attrition-resistance) test:

Friability: Friction and shock are the forces that most often cause tablets to chip, cap or break. This may affect the elegance, appearance, consumer acceptance of the tablets. This will also lead to some weight variation or content uniformity problems.

The friability test is closely related to the hardness test and is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping.

Experiments NINE: Friability Test

Procedure:

1.Weigh tablets together = **W1**

For tablets with an average weight of 0.65 g or less take a sample of whole tablets corresponding to about 6.5 g and for tablets with an average weight of more than 0.65g take a sample of 10 whole tablets.

2. Dedust the tablets carefully and weigh accurately the required number of tablets. Place the tablets in the drum and rotate them 100 times.

3. Take the tablets out, and clean them with a brush and weigh them again = **W2**

(any broken or smashed tablets are not picked up. Normally, when capping occurs, friability values are not calculated. the sample fails the test.)

4. **Calculate Friability (% loss) = [(W1-W2)/W1] *100%**

RESULTS: It must be ≤ **1%** but if more ***we do not reject the tablets*** as this test is non-official (USP).

- The test is run only once unless:
  1. The results are difficult to interpret
  2. or if the weight loss is greater than the targeted value, in which case, the test is repeated twice and the mean of the three tests is determined.

A maximum loss of weight (from a single test or from the mean of the three tests) not greater than 1.0 % is acceptable for most tablets. (USP)

Data:

Weight of tablets before processing	
Weight of tablets after processing	
Friability (%loss)	

Results& comment:

Experiments Ten: Weight Variation

Weight Variation (uniformity of weight) test:

- This test is not applicable to coated tablets other than film-coated tablets and to tablets that are required to comply with the test for *uniformity of content* for all active ingredients.

Procedure:

1. Weigh 10 tablets selected at random, each one individually . X1, X2, X3… Xz
2. Determine the average weight. X= (X1+X2 +X3+…+ Xz)/10
3. And % deviation for each Tablet
4. Calculate upper limit and lower limit :

Upper limit = average weight + (average weight * %error)

Lower limit = average weight - (average weight * %error)

5. Compare individual weight of each Tablet with the upper and lower limits.

- Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the table and none deviates by more than twice that percentage.

Average weight	% difference (%error)
130 mg or less	**±10%**
More than 130mg through 324mg	**±**7.5
More than 324mg	**±** 5

- **Accepted tablets**: Tablets pass the U.S.P. test if no more that 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

- **Suspected tablet:** not more than six tablets are outside the percentage limit and no tablet differs by more than two times the percentage limit according to the table.

- **Rejected tablets:** one Tablet differs by more than two times the percentage limit according to the table or if more than six tablets are outside the percentage limit.
- **Data:**

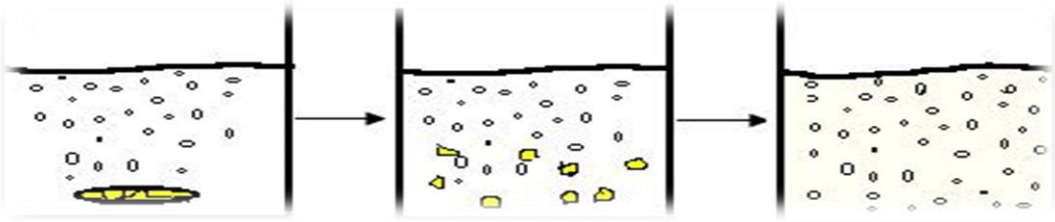
Tablet #	**Wight of Tablet**	Accepted Tablet or not
Tablet #1		
Tablet #2		
Tablet #3		
Tablet #4		
Tablet #5		
Tablet #6		
Tablet #7		
Tablet #8		
Tablet #9		
Tablet #10		
Average weight		
Upper-limit		
Lower-limit		

Results& Comments:

Experiments 11: Disintegration Test

Disintegration test:

It is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles.



Test description for coated & uncoated tablets:

- Place 1 dosage unit in each of the six tubes of the basket and, if necessary, add a disk.
- Operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37°C ± 2. At the end of the time limit specified in the monograph, lift the basket from the fluid, and observe the tablets.
- Disintegration time for uncoated and coated tablets are <15 min and <60 min, respectively.
- All of the tablets have to be disintegrated completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not less than 16 of the total of 18 tablets tested are disintegrated.

Data:

No. of tablets	Tablet #1	Tablet #2	Tablet #3	Tablet #4	Tablet #5	Tablet #6
Disintegration time						

Results & comments:

_____

Experiments 12: Dissolution Test

Dissolution test:

Dissolution is the process in which a solid substance solubilizes in a certain solvent. Whereas, dissolution rate is the amount of drug substance that transfer into a solution phase per unit time under standard conditions of temperature, PH and solvent.

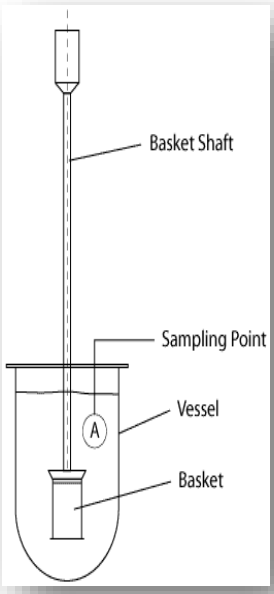
The goal of dissolution test is to check the percentage release of drug from the dosage form.

Advantages:

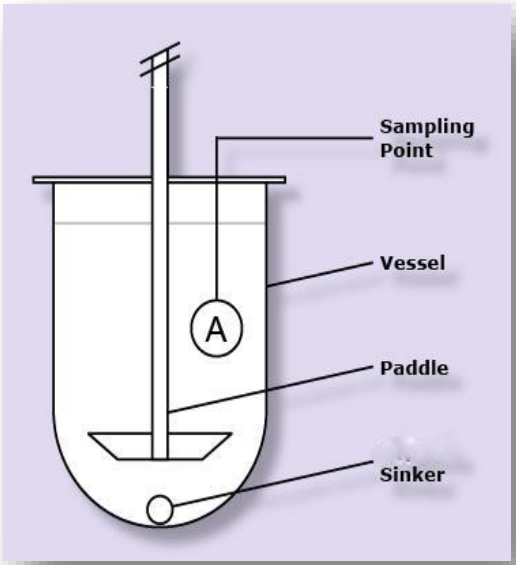
- Difficultly to perform in vivo studies for each manufactured batch, so in vitro dissolution test is used as indirect measure of drug bioavailability (in vitro-in vivo correlation, IVIVC)
- Dissolution pattern of a drug have a critical impact on its pharmacological activity.

Official USP dissolution apparatus:

Basket type



Paddle type



Procedure using basket type dissolution apparatus:

1) A dosage unit is placed in a dry basket at the beginning of the test.
2) The basket with the sample rotates freely in a vessel containing the dissolution medium.
3) The entire vessel is immersed in constant temperature bath (37 ± 0.5 C)
4) The rotating speed (most commonly 100rpm) and the position of the basket must meet USP specific requirements.
5) A sample is taken at specific intervals to determine the amount of drug in the solution.

Acceptance criteria:

Stage	Number Tested	Acceptance
S1	6	Each unit is not less than D* + 5% (Q)
S2	6	Average of 12 units (S1 +S2) is equal to or greater than D, and no unit is less than D -15%.
S3	12	Average of 24 units (S1+S2+S3), Is equal t or greater than D, not, More than 2 units are less than D - 15% and no unit is less than D - 25%

D* is the amount of dissolved active ingredient specified in the individual monograph

If the results do not conform to the requirements at stage S1, continue testing with additional tablets through stages S2 and S3 unless the result conform at stage S2.

Data:

Time / %Release	10 min	20min	30min	45min	60min
Tablet #1					
Tablet #2					
Tablet #3					
Tablet #4					
Tablet #5					
Tablet #6					

Results & comments:

Questions:

Q1- what is /are the important of the dissolution test ?

Q2- how the disintegrant affects the dissolution process?

Q2- describe the dissolution test for the following API (medium , type of apparatus , time ,and tolerance):

a-Ibuprofen immediate tablets.

b-Cefuroxime suspension.

c-Amoxicillin capsule .

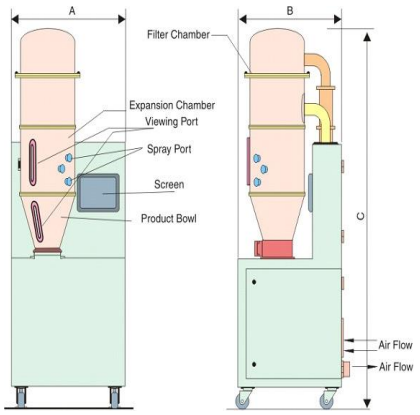
Faculty Of Pharmacy, Nursing And Health Professions

Program Of Doctor Of Pharmacy

Industrial Pharmacy PHAR 411

Lab Report

Lab Coordinator: Dr. Hani Shtaya



Student Name/ID#: …….

Product: …….

Batch #: …….

Experiment date: …….

Submission date: …….

Student signature: …….

Supervisor signature: ……..

Experiment No. : ……

Title: …….

Objectives :

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Abstract: (General overview about what was done in the experiment)

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Introduction: (General description of the whole experiment)

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Experimental

- **Procedure** (only reference the procedure introduced in the manual. Do not list the manual's working procedure unless there is a modification which should be mentioned clearly. Use your own words!).

- **Ingredients** (Mention each ingredient used in the experiment, its role, maximum daily intake for human or any remarkable information).

- **Machine / Instruments** (General information about the machine indicating the main purpose of it's use and any parameters that may be enrolled).

Results and Discussion (Display the results in a scheduled form (use tables). show any calculations if performed in details. Then make a discussion of all results obtained).

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Conclusion

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References (Indicate if used)**.**

Faculty Of Pharmacy, Nursing And Health Professions

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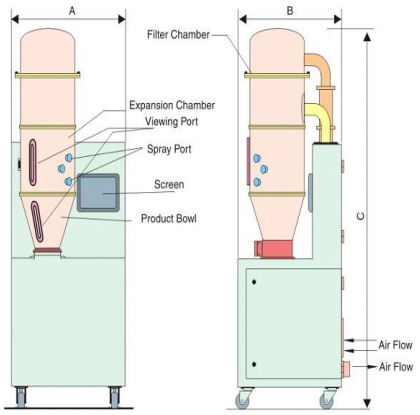
Lab Report

Lab Coordinator:



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Abstract:

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Experimental

- **Procedure**

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- **Ingredients**

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- **Machine / Instruments**

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- **Results and Discussion**

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References (Indicate if used)**.**

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