اتزلوا التجربة
بتبلش تحت

The Hashemite University
The Faculty of Pharmaceutical Science
Department of Pharmacy

Laboratory Manual

Course code: 1117014107

Course Name: Industrial Pharmacy (I) practical

Prepared by: M.Sc. Marwa Abu-Hassan
Updated by: M.Sc. Fajlat Abu-alkebir
M.Sc. Ola Jaber

Preface

There are a lot of rules and guidelines that accompany working in laboratory, since there are chemicals, equipment and experiments involved, safety is the main thing, since the security, that we will face from entry the of laboratory through and afterwards.

Little review of the specific hazards and protect yourself accordingly:

1. Think about the exercise as a whole (Read first, and know the of dangers and precautions before) Rule:

2. Dress for lab: Lab is a working, dirty place for chemistry, where you have to run experiments, in the environment of chemicals.

The laboratory has been designed to allow you to complete the basics of the Formulation, manufacturing, characterization and evaluation of solid dosage forms.

The manual will guide you to learn the fundamental principles of industrial pharmacy. Although the experiments are performed in small scale, the principles and the results of the successful experiments are on a completely comparable to those found on a full scale.

To make learning easier, you should do the following prior to attending the lab:

1. Read the experiment from the manual
2. Revisit the associated lecture notes or the ppt.
3. Learn how to perform the necessary calculations.

If you find any mistake, typo, or comments in the manual, leave it difficult to follow, ask the instructor to fix it. Please keep notes on any changes to the manual for future edition.

Introduction

Course Description

This course is designed to provide the essential principles, skills, and professional attitudes with the particular emphasis on the methods, materials and working procedures associated with the pharmaceutical industry and production of medicines.

Experiments illustrate the the operations of powders, sieving and milling of powders, wet and dry granulation methods, powder packed over capsules, tablet tooling technology, Tablets coating and tablets quality control.

Course Objectives

By the end of this course the student will be able to:

1. To recognize various processes and equipment used in manufacture solid dosage forms: powder mixing, granulation, tablet compression, and coating.
2. To understand the relationship between the of the dosage forms and the processes of which they are made.
3. To recognize various manufacturing methods for solid dosage forms.
4. To understand the principles of the operations involved in the manufacture of solid dosage forms.
5. To understand the problems associated with the manufacturing of solid dosage forms.
6. To understand the problems associated with the manufacturing of solid dosage forms.

To prepare the order and to be part of the the manual preparing is that of course, underwent the exercise of the course, **reading** assignments **done** on the laboratory notebook **Blackboard**, attention also concentrated that are needed to pass or fail a practical **Exam**. **The laboratory does not allow**:

Attendance

Attendance is mandatory and of importance. Attendance will be recorded at every the lab. You are expected to be available, and attend every other period as a non-scheduled demo. In some circumstances, the instructor may require you to attend a lecture, a video, a seminar, or other to prepare, research, and be good with the lab.

Dress

Dress appropriately for the lab. **Tie hair**, **No jewelry**, **dressed light** wear, **safety glasses**, **face mask and gloves**.

Wear a lab, **Apron** and **Gloves** **Sandals** are not permitted in the laboratory. **Dress** should be **kept** in **order**.

Food

Food will not be allowed in **order** the lab **food** and **drink**, **dress** shoes or not long **dress**

Introduction

Pharmacy is a profession concerned by various reports, the practical report will include both aspects of the experimental procedure and results.

Pharmacy is a profession concerned with the health and well-being of people. In the case of solid dosage forms, you will be asked to attempt to facilitate the relative contribution to the pharmacy profession, and the production of solid dosage forms, and the evaluation of the tablets and tablets contributions. If you do not provide the conclusions, then all attempts of the group will be given the same mark, which will then be mentioned according to the results of the assessment of individual contribution and effort.

Grading Pharmacy Profile

Pharmacy practice
Pharmacy organization
Pharmacy ethics
Information science and analysis
Pharmaceutical sciences of dosage
Research writing

Reading list / references

	READING LIST
1	Aulton M, Taylor Kevin (eds), Aulton's Pharmaceutics The design and manufacture of medicines, Elsevier Ltd, 2018
2	Rubin Jay, Farb Harvey (eds), Pharmaceutical Calculations, Lippincott Williams & Wilkins, 2011
3	Rowe Raymond C, Sheskey Paul J, Quinn Marian E (eds), Handbook of Pharmaceutical Excipients, Pharmaceutical Press and the American Pharmacists Association, 6th edition, 2009
4	Remington The Science and Practice of Pharmacy, LIPPINCOTT WILLIAMS & WILKINS, 21st edition

Course Outline:

Week	Topic Items	Lab and Lecture Hours	Instructor
1	Introduction, General Principles and Computing Tablet Parts	3	M.Sc. Marwa Abu-Hassan
2	Powder Characterization Methods Part Physical Properties	3	M.Sc. Marwa Abu-Hassan
3	Sieving	3	M.Sc. Marwa Abu-Hassan
4	Powder Mixing	3	M.Sc. Fajlat Abu-alkebir
5	Granulation Methods	3	M.Sc. Fajlat Abu-alkebir
6	Granulation of Powders and Powder	3	M.Sc. Fajlat Abu-alkebir
7	Effect of Additives On the Physical Properties of Tablets Granules	3	M.Sc. Fajlat Abu-alkebir
8	Compression and Characteristics of Tablets	3	M.Sc. Fajlat Abu-alkebir
9	Tablet Coating	3	M.Sc. Fajlat Abu-alkebir
10	Quality Control of Tablets, part I	3	M.Sc. Fajlat Abu-alkebir
11	Quality Control of Tablets, part II	3	M.Sc. Fajlat Abu-alkebir

Marks:

Assessment Method	% of Final Mark	Due Date
Laboratory Reports	20%	To be announced
Practical Exam (Lab Practical)	20%	To be announced
Quiz (Lab Quiz)	10%	To be announced
Practical Midterm Exam	20%	To be announced
Theoretical Exam	30%	To be announced

EXPERIMENT 1

SIZE REDUCTION OF PATERIAL

PATHOMOLOGY TEETH:

1. **Size Reduction** of powder is performed in many different industries and is often an essential step in the production of a wide variety of products, including food, cosmetics, and pharmaceuticals.
2. **Size Reduction** of solids is defined as and is carried out and used in two distinctive purposes, the first one is to increase the surface area of the solid dosage forms and the second purpose.

Why do we grind the dry materials?

1. In combination, to ensure that the dosage or quantity and distribution of specific surface area are different **Size Reduction** of pharmaceuticals and other materials **Grinding**. In other words, changes in the surface area of the solid dosage forms affect the rate of dissolution and absorption of the drug. Therefore, **Size Reduction** of pharmaceuticals **Solid Dosage Forms** affects the **bioavailability** of the drug. Also, **Size Reduction** of pharmaceuticals **Solid Dosage Forms** affects the **bioavailability** of the drug. Also, **Size Reduction** of pharmaceuticals **Solid Dosage Forms** affects the **bioavailability** of the drug.
2. **Size Reduction** of pharmaceuticals **Solid Dosage Forms** affects the **bioavailability** of the drug.
3. **Size Reduction** of pharmaceuticals **Solid Dosage Forms** affects the **bioavailability** of the drug.

Mechanism of size reduction

- Impaction
- Attrition
- Cutting
- Shearing
- Compression

The choice of milling equipment will be dependent upon the particle properties, the size distribution of the raw material and the size expected for the product, after milling.

Factors that affect the milling process:

1. Hardness of the material
2. Moisture content
3. Temperature
4. Fineness of the product
5. Contamination of the product
6. Explosion hazard
7. Toxicity of the material

Types of Mills:

1. Hammer Mill
2. Ball Mill
3. Fluid Energy Mill
4. Colloid Mill
5. Roller Mill

Hammer Mill:

- Hammer Mill is a general purpose machine for powders and granules. It consists of a rotor with a number of hammers or blades, which rotate at high speed within a chamber. The material to be milled is fed into the top of the chamber, where it is struck by the hammers and thrown against the chamber walls. The material remains in the chamber until it is small enough to pass through the screen at the bottom of the chamber. The size of the material which can be accepted into the chamber depends on the size of the feed material, the speed of the rotor and the size of the hammers.

Advantages of Hammer Mill:

1. **Wide range of applications:** Hammer mills are used in a wide range of applications, including the grinding of food, pharmaceuticals, and chemicals.
2. **Efficiency:** Hammer mills are efficient and can process large amounts of material in a short time.
3. **Ease of maintenance:** Hammer mills are easy to maintain and can be serviced by a single operator.
4. **Versatility:** Hammer mills can be used to grind a variety of materials, including hard, soft, and fibrous materials.

Disadvantages of Hammer Mill:

1. **Wear and tear:** The hammers and other components of the mill can wear out over time, requiring regular maintenance and replacement.
2. **Noise and vibration:** Hammer mills can generate a lot of noise and vibration, which can be a nuisance in the workplace.
3. **Dust generation:** The grinding process can generate a lot of dust, which can be a health hazard if not properly controlled.

Ball Mill:

- Ball Mill is a cylinder with a number of balls inside. The material to be milled is placed in the cylinder and the cylinder is rotated. The balls are lifted by the rotation of the cylinder and then fall back down, striking the material to be milled and breaking it into smaller particles. The size of the material which can be accepted into the cylinder depends on the size of the balls and the speed of the cylinder.

Advantages of Ball Mill:

1. **Wide range of applications:** Ball mills are used in a wide range of applications, including the grinding of ceramics, minerals, and chemicals.
2. **Efficiency:** Ball mills are efficient and can process large amounts of material in a short time.
3. **Ease of maintenance:** Ball mills are easy to maintain and can be serviced by a single operator.
4. **Versatility:** Ball mills can be used to grind a variety of materials, including hard, soft, and fibrous materials.

Disadvantages of Ball Mill:

1. **Wear and tear:** The balls and other components of the mill can wear out over time, requiring regular maintenance and replacement.
2. **Noise and vibration:** Ball mills can generate a lot of noise and vibration, which can be a nuisance in the workplace.
3. **Dust generation:** The grinding process can generate a lot of dust, which can be a health hazard if not properly controlled.

Fluid Energy Mill:

- Fluid Energy Mill is a type of mill that uses a high-speed jet of air or other gas to grind the material to be milled into smaller particles. The material to be milled is fed into the mill and the jet of air or other gas is used to break the material into smaller particles. The size of the material which can be accepted into the mill depends on the size of the jet of air or other gas and the speed of the mill.

Advantages of Fluid Energy Mill:

1. **Wide range of applications:** Fluid Energy Mills are used in a wide range of applications, including the grinding of pharmaceuticals, chemicals, and food products.
2. **Efficiency:** Fluid Energy Mills are efficient and can process large amounts of material in a short time.
3. **Ease of maintenance:** Fluid Energy Mills are easy to maintain and can be serviced by a single operator.
4. **Versatility:** Fluid Energy Mills can be used to grind a variety of materials, including hard, soft, and fibrous materials.

Disadvantages of Fluid Energy Mill:

1. **Wear and tear:** The jet of air or other gas and the mill can wear out over time, requiring regular maintenance and replacement.
2. **Noise and vibration:** Fluid Energy Mills can generate a lot of noise and vibration, which can be a nuisance in the workplace.
3. **Dust generation:** The grinding process can generate a lot of dust, which can be a health hazard if not properly controlled.

Colloid Mill:

- Colloid Mill is a type of mill that uses a rotating disk and a stationary disk to grind the material to be milled into smaller particles. The material to be milled is fed into the mill and the rotating disk is used to break the material into smaller particles. The size of the material which can be accepted into the mill depends on the size of the rotating disk and the speed of the mill.

Advantages of Colloid Mill:

1. **Wide range of applications:** Colloid Mills are used in a wide range of applications, including the grinding of pharmaceuticals, chemicals, and food products.
2. **Efficiency:** Colloid Mills are efficient and can process large amounts of material in a short time.
3. **Ease of maintenance:** Colloid Mills are easy to maintain and can be serviced by a single operator.
4. **Versatility:** Colloid Mills can be used to grind a variety of materials, including hard, soft, and fibrous materials.

Disadvantages of Colloid Mill:

1. **Wear and tear:** The rotating disk and the stationary disk can wear out over time, requiring regular maintenance and replacement.
2. **Noise and vibration:** Colloid Mills can generate a lot of noise and vibration, which can be a nuisance in the workplace.
3. **Dust generation:** The grinding process can generate a lot of dust, which can be a health hazard if not properly controlled.

Roller Mill:

- Roller Mill is a type of mill that uses two rollers to grind the material to be milled into smaller particles. The material to be milled is fed into the mill and the rollers are used to break the material into smaller particles. The size of the material which can be accepted into the mill depends on the size of the rollers and the speed of the mill.

Advantages of Roller Mill:

1. **Wide range of applications:** Roller Mills are used in a wide range of applications, including the grinding of pharmaceuticals, chemicals, and food products.
2. **Efficiency:** Roller Mills are efficient and can process large amounts of material in a short time.
3. **Ease of maintenance:** Roller Mills are easy to maintain and can be serviced by a single operator.
4. **Versatility:** Roller Mills can be used to grind a variety of materials, including hard, soft, and fibrous materials.

Disadvantages of Roller Mill:

1. **Wear and tear:** The rollers and other components of the mill can wear out over time, requiring regular maintenance and replacement.
2. **Noise and vibration:** Roller Mills can generate a lot of noise and vibration, which can be a nuisance in the workplace.
3. **Dust generation:** The grinding process can generate a lot of dust, which can be a health hazard if not properly controlled.

PARTICLE SIZE ANALYSIS METHOD:

There are different methods used to determine particle size:

1. Microscopic measurement
2. Sieve measurement
3. Sedimentation
4. Electrical Sensing Zone Methods
5. Light Scattering
6. Sieving

Sieve Method:

- Sieving method is a simple and cost-effective method for separating and analyzing a mixture of particles of different sizes. The method involves passing the mixture of particles through a series of sieves with different mesh sizes, or openings, and measuring the amount of material that remains on each sieve. The size of the particles that remain on each sieve is then used to determine the size distribution of the mixture. The method is simple and cost-effective, but it may not be accurate for very small particles or for particles with irregular shapes.

The formula for calculating the sieve size:

- The formula for calculating the sieve size is: Sieve size = (Mesh size / 25.4) x 1000
- Mesh size is the number of openings per inch on the sieve.
- 25.4 is the conversion factor from inches to millimeters.
- 1000 is the conversion factor from millimeters to micrometers.

Example:

- If a sieve has a mesh size of 100, the sieve size in micrometers would be: Sieve size = (100 / 25.4) x 1000 = 3937.5 micrometers.

The formula for calculating the sieve size in micrometers:

- The formula for calculating the sieve size in micrometers is: Sieve size = (Mesh size / 25.4) x 1000 x 1000
- Mesh size is the number of openings per inch on the sieve.
- 25.4 is the conversion factor from inches to millimeters.
- 1000 is the conversion factor from millimeters to micrometers.
- The additional 1000 is the conversion factor from micrometers to nanometers.

Example:

- If a sieve has a mesh size of 100, the sieve size in micrometers would be: Sieve size = (100 / 25.4) x 1000 x 1000 = 3937.5 micrometers.