AS PER PCI REGULATIONS

THIRD YEAR B. PHARM. SEMESTER-V

A PRACTICAL BOOK OF

INDUSTRIAL PHARMACY-I

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SANDIP M. HONMANE

NIRALI PRAKASHAN

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INDUSTRIAL PHARMACY - I

As Per PCI Regulations

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Semester - V

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Preface

Industrial Pharmacy is the branch of pharmacy that deals with scientific and technological aspects related to design and development of dosage forms. Pharmaceutical industry is made of hundreds of firms involved in discovery, development, and production and selling of drug products that meet regulatory requirements. The current curriculum implemented by Pharmacy Council of India New Delhi as Regulation 2014 has practical Industrial Pharmacy – I subject at Semester-V of Third Year of the B. Pharm. course. This practical book covers whole of the experimental component specified in the syllabus. The book has been divided in to six main chapters covering different pharmaceutical dosage forms like tablets, capsules, injections, eye drops, eye ointment and creams. Authors have made special attempts to cover all aspects ranging from preformulation studies, dosage form design, product manufacturing processes to facility design and management, packaging, evaluation, quality control and regulation. Taking this as an opportunity we have tried our level best to give detail insight of the subject expectations with respect to experiments on coating of solid dosage forms and testing of packaging materials. This book is first of its kind that it covers huge data compilation, methods of calculating raw material quantities, batch manufacturing record sheets and labels. Where ever required concepts are described in simple language and supported with suitable examples giving basic scientific reasons in most simple and lucid language so that an ordinary student can easily understand. This entire book has 13 experiments and each experiment is provided with the list of chemicals and equipments under requirements section. Every experiment is supplemented with theory/principle and its objectives. Efforts have been made to elaborate basic concepts of pharmaceutical manufacturing and are supported with flow diagrams, figures, equations and data tables. Each experiment is concluded with the necessary result to understand the appropriate outcome after completion. At the end of each experiment a review questions are given that well help the students to assess the knowledge gained after doing particular experiment.

As authors we would like to acknowledge our sincere students, fellow teacher colleagues and our teachers who always remained a force behind writing this book. Authors are thankful to the Management of Bharati Vidyapeeth Pune and Sant Dnyaneshwar Shikshan Sanstha, Islampur for their guidance, encouragement and support. We are highly thankful to our beloved family members for their sustained motivation and support.

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Authors

Syllabus

1. Preformulation studies on paracetamol/aspirin/or any other drug
2. Preparation and evaluation of Paracetamol Tablets
3. Preparation and evaluation of Aspirin Tablets
4. Coating of tablets- film coating of tablets/granules
5. Preparation and evaluation of Tetracycline Capsules
6. Preparation of Calcium Gluconate Injection
7. Preparation of Ascorbic Acid Injection
8. Quality control test of (as per I.P.) marketed tablets and capsules
9. Preparation of Eye Drops/ and Eye Ointments
10. Preparation of Creams (Cold Cream / Vanishing Cream)
11. Evaluation of Glass Containers (as per I.P.)

SCHEMES OF EXAMINATIONS AS PER PCI

Table- I: Schemes of Examinations

Course code	Name of course	Internal Assessment				End Semester Exam		Total Marks
		Continuous mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
BP502T	Industrial Pharmacy Theory	10	15	1 Hr.	25	75	3 Hrs.	100
BP506P	Industrial Pharmacy Practical	5	10	4 Hrs.	15	35	4 Hrs.	50

Table- II: Scheme for awarding internal assessment: Continuous mode

Practical	
Criteria	**Maximum Marks**
Attendance (Refer Table – III)	2
Based on Practical Records, Regular viva voce, etc.	3
Total	**5**

Table- III: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory Marks	Practical Marks
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

Sessional Exams:

Two sessional exams shall be conducted for each theory / practical course. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in Table - I. Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for practical sessional examinations (computed for 10 marks).

(I) Synopsis = 10
(II) Experiments = 25
(III) Viva voce = 05

Total = 40 marks

Question paper pattern for end semester practical examinations (35 marks)

(I) Synopsis = 05
(II) Experiments = 25
(III) Viva voce = 05

Total = 35 marks

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GENERAL LABORATORY INSTRUCTIONS AND WRITING PRACTICAL RECORD BOOK

GENERAL LABORATORY INSTRUCTIONS

(A) Personal Hygiene:

1. Personal hygiene is enormously important during working in pharmaceutical laboratory. Hygiene standards within a pharmaceutical environment should be high, because person engaging with the preparation of medicinal product which is being prepared for patients who may already be ill.
2. Personnel should be made well aware, trained and should practice good health habits.
3. Smoking, eating, drinking, chewing and the storage of food should be restricted to certain designated areas and separated from the laboratory areas.
4. Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should not engage in laboratory activities.

(B) Personal Protective Equipment (PPE):

1. A clean white coat (Apron) should be worn to protect the person from the product and conversely the product contamination from the person.
2. During the preparation and/or manufacturing process, safety equipment such as mouth masks, head cap, gloves, goggles etc. must be used. Similarly, long hairs should be tied back and properly covered with head cap to ensure any open cut be covered.
3. It is the responsibility of the individual to ensure that the correct safety equipment are used.
4. Personnel should avoid direct contact with intermediates or APIs.

(C) Clean Work Area:

1. The cleanliness of the work area and equipment used during the compounding/preparation of medicament is of paramount importance.
2. The risk of contaminating the final product with either dust, dirt or microorganisms from the surroundings or from other ingredients from a previous preparation can be considerable if attention is not paid to the cleanliness of the work area and equipment.
3. Before starting to compound a product, the work area and equipment should be cleaned with a suitable solution, which must be allowed to dry fully.
4. Never use apron outside the laboratory.

(D) Equipment Cleaning:

1. Equipment and utensils should be cleaned, stored, and where appropriate, sanitized or sterilized to prevent contamination or carry-over of a material that would alter the quality of the intermediate or API beyond the official or other established specifications.
2. In cases, where equipment is assigned to continuous preparation of successive batches of the same intermediate or API, equipment should be cleaned at appropriate intervals to prevent build-up and carry-over of contaminants (e.g. degradants or objectionable levels of micro-organisms).

(E) Label Preparation:

The label for any pharmaceutical intermediate or finished product must be prepared before starting the compounding/preparation procedure. This will enable the product to be labeled as soon as it has been manufactured and packaged. This will eliminate the product being mislabeled and given to the wrong patient.

(F) Weighing and Measuring Procedure:

1. During weighing use of clean balance pan as well as spatula helps to prevent mix-ups of different pharmaceutical ingredients as many ingredients resemble each other.
2. After weighing or measuring of each ingredient label each ingredient using paper piece or tag as soon as it has been weighed or measured.
3. Close the bottles/containers tightly after weighing and place at respective shelf/place after completion of weighing.

WRITING PRACTICAL RECORD BOOK

Left Hand Side Page	Right Hand Side Page
a) Calculations: b) Raw material weighing record: c) Batch manufacturing/Packing record (BMR/BPR): d) Evaluation table: e) Label:	a) Title: b) Aim: c) References: d) Theory: e) Requirements: f) Formula: g) Procedure: h) Category: i) Use: j) Dose: k) Storage: l) Direction: m) Advice to patients: n) Precautions: o) Result:

Chapter ... **1**

INTRODUCTION TO PHARMACY AND PHARMACEUTICAL INDUSTRY

1.1 INTRODUCTION

Pharmacy: Pharmacy is healthcare profession that relates the health sciences with the chemical sciences and it is deals with ensuring the safe and effective use of medication.

Pharmacy is the science of identification, selection, preservation, standardization, compounding, proper utilization and dispensing of medicinal substances.

Drug: It is defined as any substance used for the purpose of diagnosis, prevention, relief or cure of a disease in man or animals.

Drug substance: Drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient

Drug product: Drug product means a finished dosage form, for example, tablet, capsule, or solution that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Pharmaceutical Excipients: Excipients are pharmacologically inactive substances formulated alongside the active pharmaceutical ingredient of a medication.

Excipients are usually an inert substance added to the drug to give suitable consistency or definite form to the drug. It is also called pharmaceutical necessity or aid.

1.2 PHARMACEUTICAL INDUSTRY

The term pharmaceutical industry refers to the industrial scale manufacture of drugs based on the substance of vegetable, organic or synthetic origin. The pharmaceutical industry is made of hundreds of firms that discover, develop, produce and sell drug products. Health professionals to prevent and cure some diseases and relieve symptoms of other ailments use these products. Throughout the twentieth century and especially from 1940s

onwards, members of the industry have discovered new drugs, that cure previously incurable diseases, prevent diseases that are epidemic in nature and reduce the frequency and length of hospital stay, and increase life expectancy. It is the group of firms, manufacturing and distributing medicines in finished forms such as ointments, capsules, tablets and syrups.

The industry performs the manufacturing and processing activities, which includes:

(a) Bulk manufacturing of synthetic organic chemicals, such as vitamins, anti-histamines, diuretics and sulphonamides.

(b) Bulk manufacturing by fermentation, synthesis or both, for example, antibiotics such as penicillin and streptomycin, which are normally made by the culture of microorganisms.

(c) Preparation of sera and vaccines by microorganism culture.

(d) Production from naturally occurring animal or vegetable sources of drugs such as insulin, hormones and morphine.

(e) Processing of bulk drugs into finished forms such as capsules, tablets and ointments.

*Chapter ...***2**

PREFORMULATION

2.1 INTRODUCTION

Preformulation testing is the first step in the development of dosage forms of a drug substance before formulation. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients before the formulation. The overall objective of preformulation testing is to generate information useful to the formulator in developing stable and bioavailable dosage forms. Preformulation investigations are designed to deliver all necessary data especially physicochemical, physico-mechanical and bio-pharmaceutical properties of drug substances, excipients and packaging materials.

Objectives:

(i) To develop the elegant dosage forms (stable, effective and safe).

(ii) It is important to have an understanding of the physical description of a drug substance before dosage form development.

(iii) To obtain rational information about drugs and excipients for the development of dosage form before its development.

2.2 PREFORMULATION PARAMETERS

2.2.1 Organoleptic Properties

These properties include the physical description of the drug substance. The color, odor and taste of the new drug or excipients must be recorded using descriptive terminology. It is important to establish a standard terminology to describe these properties in order to avoid confusion among scientists using different terms to describe the same property.

2.2.2 Bulk Characteristics

(a) Assay Development:

Assay development is a function of molecular structure. The strength of a drug substance may be its concentration (quantity of the drug per unit measure) or its potency, or both. The potency of a drug is a measurable (quantitative) extent of the biological, physiological, pharmacological, or chemical activities of the drug per unit weight or volume of the drug preparation. No relevant physicochemical property can be measured without an assay and so development of a suitable assay is the first step of preformulation. At first, assay procedures should require minimal amounts of sample (as little as 50 mg). Ideally, experiments should

allow determination of multiple parameters. For instance, a saturated solution is prepared to determine aqueous solubility that may subsequently be re-used to determine a partition coefficient.

In assay development, actual content of active ingredient in given sample (percent purity-Assay) of drug is determined. In assay development, a particular method is developed for specific drug using UV spectrophotometer or for better accuracy, using high performance liquid chromatography (HPLC) and the percent purity of drug determined is compared with the specifications. The percent purity (assay) is a major part during formulation for preparing required strength of formulation. At this stage the determination of approximate values is not acceptable in order to make a 'go' or 'no go' decision in respect of a particular drug candidate, and so assays do not need to be as rigorously validated as they do later in formulation development, the assays that may be used to quantify them.

(b) Melting Point:

The melting point of a pure solid (drug or excipients) is defined as the temperature at which solid and liquid exist in equilibrium. The melting point is a particular temperature or range of temperature over which substance exists in equilibrium and can be used as an indicator of purity of drug substances. It can be determined from melting point test apparatus or characterized by very sharp melting peak in DSC. An altered peak or peak at different temperature may indicate an adulterated or impure drug. Melting point of a drug substance can be measured using three techniques:

(i) Capillary melting
(ii) Hot stage microscopy
(iii) Differential scanning calorimetry (thermal analysis)

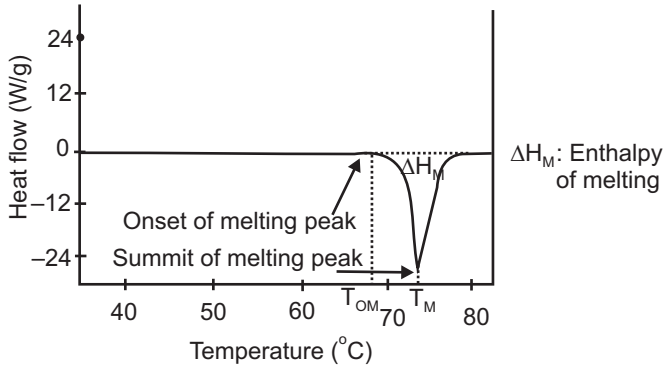
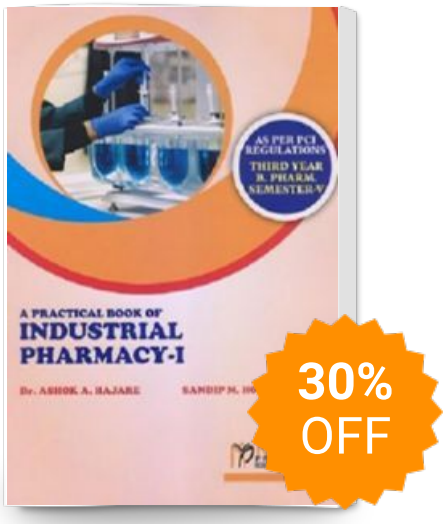


Fig. 2.1: Typical DSC Thermogram for Melting Point of Solid

(c) Solid State Characteristics:

Powders are masses of solid particles or granules surrounded by air (or other fluid) and are combination of solid and fluid that significantly affects the bulk properties of the powder. Physical characteristics of the particles, such as size, shape, angularity, size variability and hardness all affect flow properties. In addition, external factors such as humidity, conveying environment, vibration and perhaps most importantly aeration will compound the problem.

A Practical Book Of Industrial Pharmacy I



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