

Program Name : Diploma in Chemical Engineering
Program Code : CH
Semester : Sixth
Course Title : Pharmaceutical Technology (Elective-III)
Course Code : 22614

1. RATIONALE

To acquire a deep-rooted theoretical and practical knowledge of the fundamental principles in pharmaceutical formulation. This course provides learning about pharmaceutics, the tools used to prepare pharmaceutical drug and the manufacturing processes used in pharmaceutical production. To acquire a comprehensive understanding of how pharmaceutical dosage forms are developed, manufactured and controlled. The chemical technologists will be able to handle various equipment used in pharmaceutical industries.

2. COMPETENCY

The aim of this course is to help the student to attain the following industry identified competency through various teaching learning experiences:

- Use relevant equipment safely to produce pharmaceutical products.

3. COURSE OUTCOMES (COs)

The theory, practical experiences and relevant soft skills associated with this course are to be taught and implemented, so that the student demonstrates the following industry oriented COs associated with the above mentioned competency:

- Apply good manufacturing practices in Pharmaceutical Industry.
- Use relevant Extraction processes in Pharmaceutical Industry.
- Undertake Emulsification and Homogenization process.
- Use relevant filtration processes for the desired pharmaceutical product.
- Use relevant sterilizer for the process.
- Use different Active Pharmaceutical Ingredients in pharmaceutical processes.

4. TEACHING AND EXAMINATION SCHEME

| Teaching Scheme | | | Credit (L+T+P) | Examination Scheme | | | | | | | | | | | | |
|-----------------|---|---|----------------|--------------------|-----|-----|-----|-----|-------|-----------|-----|-----|-----|-----|-------|----|
| L | T | P | | Theory | | | | | | Practical | | | | | | |
| | | | | Paper Hrs. | ESE | | PA | | Total | | ESE | | PA | | Total | |
| | | | | Max | Min | Max | Min | Max | Min | Max | Min | Max | Min | Max | Min | |
| 3 | - | 2 | 5 | 3 | 70 | 28 | 30* | 00 | 100 | 40 | 25@ | 10 | 25 | 10 | 50 | 20 |

(*): Under the theory PA; Out of 30 marks, 10 marks of theory PA is for micro-project assessment to facilitate attainment of COs and the remaining 20 marks is for tests and assignments given by the teacher.

Legends: L-Lecture; T – Tutorial/Teacher Guided Theory Practice; P - Practical; C – Credit, ESE - End Semester Examination; PA - Progressive Assessment.

5. COURSE MAP (with sample COs, Learning Outcomes i.e. LOs and topics)

This course map illustrates an overview of the flow and linkages of the topics at various levels of outcomes (details in subsequent sections) to be attained by the student by the end of the course, in all domains of learning in terms of the industry/employer identified competency depicted at the centre of this map.



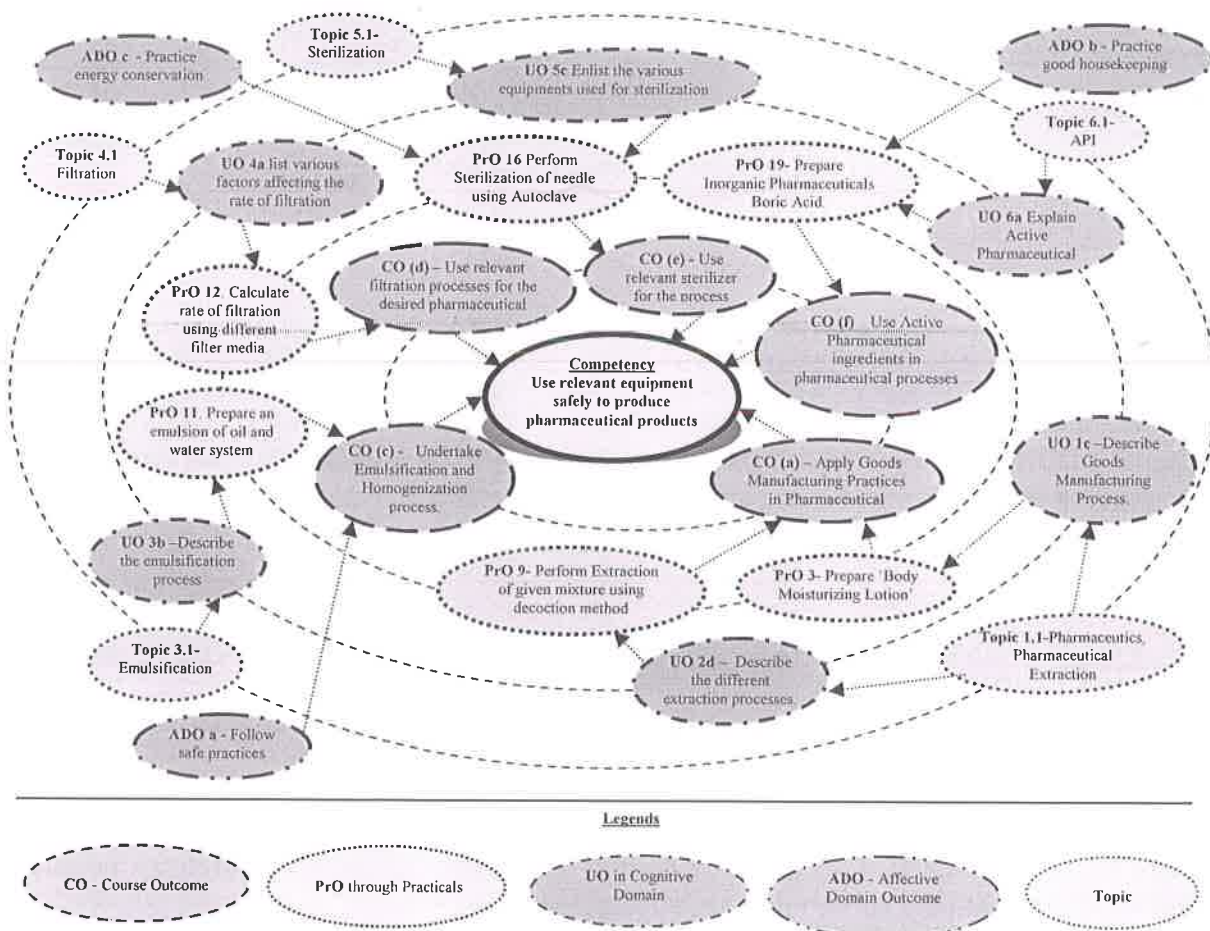


Figure 1 - Course Map

6. SUGGESTED PRACTICALS/ EXERCISES

The practicals in this section are PrOs (i.e. sub-components of the COs) to be developed and assessed in the student for the attainment of the competency.

| S. No. | Practical Outcomes (PrOs) | Unit No. | Approx. Hrs. Required |
|--------|--|----------|-----------------------|
| 1 | Perform Qualitative test of Protein for dosage form. | I | 02* |
| 2 | Perform Qualitative test of Amino Acids for dosage form. | I | 02 |
| 3 | Prepare 'Body Moisturizing Lotion' using provided Herbal Ingredients as per given instructions | I | 02* |
| 4 | Prepare 'Face Scrub' using provided Herbal Ingredients as per given instructions | I | 02* |
| 5 | Prepare 'Shampoo' using provided Herbal Ingredients as per given instructions. | I | 02* |
| 6 | Perform the selection test of solvent for extraction as per given instructions. | I | 02 |
| 7 | Perform Extraction of given mixture using mixer settler assembly. | I | 02 |
| 8 | Perform Extraction of given mixture using Hot Extraction Process. | I | 02 |
| 9 | Perform Extraction of given mixture using decoction method. | I | 02 |
| 10 | Use the Rotary Ball Mill Size reduction of Powder (Coarse Sucrose) | II | 02* |
| 11 | Prepare an emulsion of oil and water system and observe the effect of various Emulsifiers. | II | 02 |
| 12 | Use the different filter media to calculate rate of filtration. | III | 02 |



| S. No. | Practical Outcomes (PrOs) | Unit No. | Approx. Hrs. Required |
|--------------|---|----------|-----------------------|
| 13 | Use the Nutsche Filter to calculate rate of filtration. | III | 02 |
| 14 | Perform Qualitative Analysis of Glucose. | III | 02* |
| 15 | Perform Qualitative Analysis of Starch. | III | 02* |
| 16 | Perform sterilization of needle using Autoclave equipment. | IV | 02* |
| 17 | Perform Sterilization of hand gloves using Autoclave | IV | 02 |
| 18 | Use the hot air oven to calculate % of moisture removal of given sample using | IV | 02* |
| 19 | Prepare Inorganic Pharmaceuticals Boric Acid. | V | 02* |
| 20 | Prepare Inorganic Pharmaceuticals Potash Alum. | V | 02 |
| 21 | Perform Limit Test of Chloride contained in synthetic waste water | V | 02* |
| 22 | Perform Limit Test of Sulphate contained in synthetic waste water | V | 02* |
| Total | | | 44 |

I**Note**

- i. A suggestive list of practical Los are given in the above table, more such practical Los can be added to attain the COs and competency. A judicious mix of minimum 12 or more practical/tutorials need to be performed, out of which, the practical marked as '*' are compulsory, so that the student reaches the 'Precision Level' of Dave's 'Psychomotor Domain Taxonomy' as generally required by the industry.
- ii. The 'Process' and 'Product' related skills associated with each PrO are to be assessed according to a suggested sample given below::

| S. No. | Performance Indicators | Weightage in % |
|--------------|---|----------------|
| 1 | Preparation of experimental set up | 20 |
| 2 | Setting and operation | 20 |
| 3 | Safety measures | 15 |
| 4 | Observations and recording | 15 |
| 5 | Interpretation of result and conclusion | 10 |
| 6 | Answer to sample questions | 10 |
| 7 | Submission of report in time | 10 |
| Total | | 100 |

The above PrOs also comprise of the following social skills/ attitudes which are Affective Domain Outcomes (ADOs) that are best developed through the laboratory/ field based experiences:

- a) Follow safety practices.
- b) Practice good housekeeping.
- c) Practice energy conservation.
- d) Work as a leader/a team member.
- e) Follow ethical Practices.

The ADOs are not specific to any one PrO, but are embedded in many PrOs. Hence, the acquisition of the ADOs takes place gradually in the student when s/he undertakes a series of practical experiences over a period of time. Moreover, the level of achievement of the ADOs according to Krathwohl's 'Affective Domain Taxonomy' should gradually increase as planned below:

- 'Valuing Level' in 1st year
- 'Organisation Level' in 2nd year
- 'Characterisation Level' in 3rd year.



7. MAJOR EQUIPMENT/ INSTRUMENTS REQUIRED

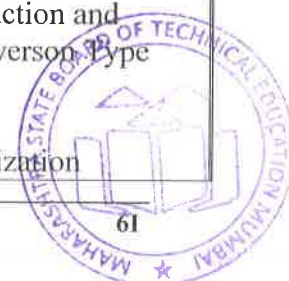
The major equipment with broad specification mentioned here will usher in uniformity in conduct of experiments, as well as aid to procure equipment by authorities concerned.

| S. No | Equipment Name with Broad Specifications | Pro. No. |
|-------|---|---------------------------------------|
| 1 | Beaker (250ml, 500ml), pipette (25ml), Test tube, Conical Flask (50ml), Burette(25ml), Measuring Cylinder (10ml, 50ml, 500ml) | 1,2,3,4,5,6,11, 12,14,15,19,20, 21,22 |
| 2 | Extraction Column- Pressure : 20-100psi, Material : SS, Alloys, Finishing : Mirror polishing, Matt polishing, Temperature : 0-300 Degree Celsius | 7,8,9 |
| 3 | Rotary Ball Mill - Voltage (V): 220, Capacity (kg): 5 to 10 kg, Frequency (Hz): 60 Hz, Automation Grade: Semi-Automatic | 10 |
| 4 | Nutsche Filter – Working Capacity: 170lit, Filtration area: 1.29m ² , Basket load : 200Kg, Motor Power: 10HP, Maximum Basket RPM: 1000 RPM | 13 |
| 5 | Plate and Frame Filter Press - Available Plate Size : 200x200mm, Plate Height – 13mm, Pressure Rating- 1-15 bar, Temperature Rating : -25°C to +65°C | 11 |
| 6 | Autoclave – Size: 200x200mm, Pressure Range:15-18psi, Voltage: 220V AC 50Hz Single Phase | 16,17 |
| 7 | Hot Air Oven – Size : 450x450x450, Temperature:50-200 ⁰ C, Voltage: 230V, 50Hz Single Phase | 18 |

8. UNDERPINNING THEORY COMPONENTS

The following topics are to be taught and assessed in order to develop the sample UOs given below for achieving the COs to attain the identified competency. More UOs could be added.

| Unit | Unit Outcomes (in cognitive domain) | Topics and Sub-topics |
|--|--|--|
| Unit – I Pharmaceutic Dosage and Extraction | 1a. Explain Dosage form for the given type condition 1b. Describe Goods Manufacturing Practices for the given condition. 1c. Classify the given type of drugs. 1d. Describe the specified extraction processes. 1e. Select relevant extractor for the given process to maintain the purity of product with justification | 1.1 Pharmaceutics and Pharmacopeia:- 1.2 Dosage form: Definition and Types (Tablets, Capsules, Sugar Coated Tablet, Extended Relief Tablet, Immediate Relief Tablet) 1.3 Goods Manufacturing Practices (GMP) and Alternative system of medicine; 1.4 Overview of Galenical process:- definition and Process description 1.5 types of drugs -Stimulants, Depressants, Hallucinogens, Dissociative, Opioids, Inhalants, Cannabis. 1.6 Extraction: Infusion, decoction, maceration, percolation, hot extraction 1.7 Equipment used for large scale extraction : Principle, construction and working of Mono-stage centrifugal extractor, multi stage centrifugal extractor, mixer settler, decanter |
| Unit– II Emulsification and Homogenization. | 2a. Describe the features of the specified process. 2b. Explain with sketches the working of the specified process. 2c. Explain with sketches the given equipment. | 2.1 Definition and Process: Emulsification Homogenization 2.2 Equipment: Principle, construction and working of Colloid Mills, Silverson Type Homogenizer. 2.3 Industrial Applications of Emulsification and Homogenization |

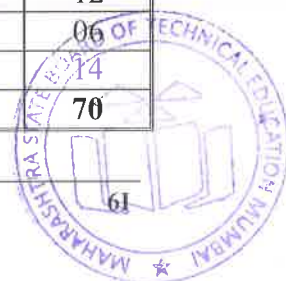


| Unit | Unit Outcomes (in cognitive domain) | Topics and Sub-topics |
|---|---|--|
| | 2d. List the relevant applications of specified process | processes. |
| Unit– III Filtration Processes | 3a. List the relevant factors affecting the rate of filtration with respect to the specified filter media. 3b. Classify the given filter media and filter aid used for filtration process. 3c. Explain with sketches the specified type of filtration equipment 3d. Describe the features of the specified type of air filtration units. | 3.1 Filtration : Factors influencing rate of filtration 3.2 Filter media: Types (Polymeric membrane, Ceramic, Charcoal, Synthetic woolen filter, Sand Filter) 3.3 Filtration Equipment: Principle, construction and working of Nutsche filter, Sparkler, Leaf filter, Sintered glass and membrane filter. 3.4 Filtration of air: Principle, construction and working of HEPA (high efficiency particulate air) filters, Carbon Air Filters, Ionic Air Filters, UV Light Air Filters |
| Unit –IV Sterilization | 4a. Describe the need for the specified type of Sterilization. 4b. State the specification of the specified equipment used for sterilization 4c. Explain with sketches the working of the specified equipment used for sterilization. | 4.1 Introduction of Disinfection. 4.2 Overview of Sterilization process. 4.3 Sterilization with moist heat: Autoclave 4.4 Dry heat sterilization: Incineration 4.5 Sterilization by radiation: Microwave 4.6 Sterilization by filtration: Vacuum or positive-pressure filtration |
| Unit –V Active Pharmaceutical Ingredient | 5a. Describe the properties of the given type of Active Pharmaceutical Ingredient. 5b. Draw the flow diagrams of the specified Pharmaceutical Products 5c. Describe the process of the given Pharmaceutical Products | 5.1 Introduction of Active Pharmaceutical Ingredients (API) 5.2 Pharmaceutical Products: Process Flow Diagram with Process description of Rantadine, Metformine, Atenolol, Amoxicillin trihydrate |

Note: To attain the COs and competency, above listed Learning Outcomes (LOs) need to be undertaken to achieve the 'Application Level' of Bloom's 'Cognitive Domain Taxonomy'.

9. SUGGESTED SPECIFICATION TABLE FOR QUESTION PAPER DESIGN

| Unit No. | Unit Title | Teaching Hours | Distribution of Theory Marks | | | |
|--------------|------------------------------------|----------------|------------------------------|-----------|-----------|-------------|
| | | | R Level | U Level | A Level | Total Marks |
| I | Pharmaceutic Dosage and Extraction | 18 | 06 | 10 | 10 | 26 |
| II | Emulsification and Homogenization. | 08 | 02 | 04 | 06 | 12 |
| III | Filtration Processes | 08 | 02 | 04 | 06 | 12 |
| IV | Sterilization | 04 | 00 | 02 | 04 | 06 |
| V | Active Pharmaceutical Ingredient | 10 | 04 | 04 | 06 | 14 |
| Total | | 48 | 14 | 24 | 32 | 70 |



Legends: R=Remember, U=Understand, A=Apply and above (Bloom's Revised taxonomy)

Note: This specification table provides general guidelines to assist students for their learning and to teachers to teach and assess students with respect to attainment of LOs. The actual distribution of marks at different taxonomy levels (of R, U and A) in the question paper may vary from above table.

10. SUGGESTED STUDENT ACTIVITIES

Other than the classroom and laboratory learning, following are the suggested student-related *co-curricular* activities which can be undertaken to accelerate the attainment of the various outcomes in this course:

- Prepare journals based on practical performed in laboratory.
- Follow the safety precautions.
- Prepare charts of processes flow diagrams used in Pharmaceutical Industries.
- Library /Internet survey of instruments used for various parameters
- Prepare power point presentation or animation for understanding different pharmaceutical processes.

11. SUGGESTED SPECIAL INSTRUCTIONAL STRATEGIES (if any)

These are sample strategies, which the teacher can use to accelerate the attainment of the various outcomes in this course:

- Massive open online courses (*MOOCs*) may be used to teach various topics/sub topics.
- 'L' in item No. 4 does not mean only the traditional lecture method, but different types of teaching methods and media that are to be employed to develop the outcomes.
- About **15-20% of the topics/sub-topics** which is relatively simpler or descriptive in nature is to be given to the students for *self-directed learning* and assess the development of the LOs/COs through classroom presentations (see implementation guideline for details).
- With respect to item No.10, teachers need to ensure to create opportunities and provisions for *co-curricular activities*.
- Use Flash/Animations to explain various instruments for measurement
- Guide student(s) in undertaking micro-projects

12. SUGGESTED MICRO-PROJECTS

Only one micro-project is planned to be undertaken by a student that needs to be assigned to him/her in the beginning of the semester. In the first four semesters, the micro-project are group-based. However, in the fifth and sixth semesters, it should be preferably be *individually* undertaken to build up the skill and confidence in every student to become problem solver so that s/he contributes to the projects of the industry. In special situations where groups have to be formed for micro-projects, the number of students in the group should **not exceed three**.

The micro-project could be industry application based, internet-based, workshop-based, laboratory-based or field-based. Each micro-project should encompass two or more COs which are in fact, an integration of PrOs, UOs and ADOs. Each student will have to maintain dated work diary consisting of individual contribution in the project work and give a seminar presentation of it before submission. The total duration of the micro-project should not be less than **16 (sixteen) student engagement hours** during the course. The student ought to submit micro-project by the end of the semester to develop the industry oriented COs.

A suggestive list of micro-projects are given here. Similar micro-projects could be added by the concerned faculty:

- Prepare report on the profile of Pharmacy and Pharmaceutical industries in India.
- Prepare a list of different types of drugs produced in Pharmaceutical industries in India using internet and industries web sites.



- c) Prepare model of colloidal mill using suitable material.
- d) Prepare a chart of different filter media and filter aid used in different filters.
- e) Visit nearby industry to observe different units and operations of sterilization processes.
- f) Select any one medicine / pharmaceutical product and draw process flow diagram for identified product.

13. SUGGESTED LEARNING RESOURCES

| S. No. | Title of Book | Author | Publication |
|--------|---|---|---|
| 1 | Pharmaceutical Dosage Form and drug delivery systems | Howard C. Ansel, Nicholas G., Popovich, Lord V. Alien | B.I. Waverly Pvt. Ltd., New Delhi, 2015, ISBN: 9780781746120 |
| 2 | Perry's Chemical Engineer's Handbook | Perry Robert H. Green Don W. | McGraw Hill New Delhi 2009 ISBN- 13: 9780070498419 |
| 3 | Introduction to Chemical Engineering | Walter L. Badger, Julius T. Banchero | McGraw Hill, New Delhi, 2010, ISBN: 978-0070850279 |
| 4 | Process Chemistry in Pharmaceutical Industry | Kumar Gadamasetti | CRC Press, First Edition 2007 ISBN 13: 9780824719814 |
| 5 | Principle of Process Research and Chemical Development in Pharmaceutical Industry | O. Ropic | John Wiley & Sons. Inc Publication New York, ISBN: 0471165166 |
| 6 | Good Pharmaceutical Manufacturing Practice: Rationale and Compliance | Sharp John | CRC Press, First Edition 2004 ISBN 13: 9780849319945 |

14. SOFTWARE/LEARNING WEBSITES

- a) https://www.youtube.com/results?search_query=natural+way+to+prepare+shampoo
- b) e Library: <http://202.74.245.22:8080/xmlui/handle/123456789/292>
- c) <https://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM397228.pdf>
- d) https://www.lsu.edu/studentorgs/ispe/Welcome_files/PHARMACEUTICAL%20ENGINEERING.pdf
- e) https://www.youtube.com/results?search_query=natural+way+to+prepare+lotion



