# COURSE SPECIFICATIONS

# Faculty of Pharmacy

## Fifth Year – Elective Courses

## 2018-2019

# CONTENTS:

# COURSE SPECIFICATIONS

# Clinical Nutrition

## Fifth Year- Elective Courses
## 2018-2019

# Course Specifications of Clinical Nutrition 2018-2019

**University: Zagazig Faculty: Pharmacy**

## A- Course specifications:

Program(s) on which the course is given: Bachelor of Pharmacy.

Major or Minor element of programs: Major

Department offering the program: -------

Department offering the course: Biochemistry Department

Academic year/Level: 2018-2019, Fifth year/Second term

Date of specification approval: 27/8/2018

## B- Basic information:

Title: Clinical Nutrition Code: EL 250

Credit Hours:

- Lectures : 1 h/week
- Practical: 1 h/week
- Tutorials: ---
- Total: 2 hrs/week

## C- Professional information:

### 1-Overall Aims of the Course:

On completion of the course, students will be able to explain the principles of clinical nutrition, pathophysiology, diet therapy and management of different diseases.

## 2-Intended Learning Outcomes of Clinical Nutrition (lLOs):

| | |
|---|---|
| **A- Knowledge and Understanding** | |
| a1 | Outline the principles of clinical nutrition and types of nutrients. |
| a2 | Illustrate the body energetics, electrolytes, pH in health and disease state. |
| a3 | Demonstrate the etiology and clinical features of obesity, diabetes, hypertension, cardiovascular diseases, electrolytes and acid base imbalances. |
| a4 | Discuss the principles of diet therapy and management of different diseases. |
| a5 | Illustrate drug-food interaction and food allergies |
| **B- Professional and Practical skills** | |
| b1 | Specify therapeutic and dietary interventions of obesity, diabetes, hypertension, cardiovascular diseases, electrolytes and acid base imbalances. |
| b2 | Recommend laboratory tests for diagnosis of different diseases. |
| b3 | Advise patients about balanced diet to promote the efficiency of medication. |
| **C- Intellectual skills** | |
| c1 | Suggest life style modifications to prevent obesity, diabetes, hypertension, cardiovascular diseases, electrolytes and acid base imbalances. |
| c2 | Select the appropriate drugs and dietary regimens for various disease conditions. |
| **D- General and Transferable skills** | |
| d1 | Develop communications skills with public, patients and other health care professionals. |
| d2 | Work effectively as a member of a team. |
| d3 | Use numeracy and computation in determination of body mass index, body weight and atherogenic index. |
| d4 | Practice independent learning needed for continuous professional development. |
| d5 | Write and present reports. |
| d6 | Implement critical thinking and decision making skills. |

## D- Contents:

| Week No. | Lecture (1 h/ week) | Practical session (1 h/week) |
|---|---|---|
| 1 | - Types of nutrients of balanced diet (macronutrients, micronutrients) | - Introduction to clinical nutrition<br>- Calculation of BMR- TEE |
| 2 | - Energy requirement and energy expenditure<br>- Diet and therapy<br>- Nutritional assessment and food pyramids | - Obesity<br>- Case studies for obesity |
| 3 | - Obesity (Definition, assessment, factors affecting obesity) | - Determination of body mass index<br>- Suggestion of life style modification |
| 4 | - Management of obesity<br>- Drugs of choice for treatment of obesity | - Metabolic syndrome<br>- Case study<br>- Calculation of atherogenic index |
| 5 | - Diabetes mellitus (DM)<br>-Nutrition therapy and recommendation for DM<br>- Drug of choice for treatment of DM | **- Activity (report)**<br>Nutrition and anemia |
| 6 | - Definition and types of cardiovascular diseases (CVD)<br>- Risk factors for CVD<br>- Drug of choice for treatment of CVD | - Diabetes<br>- Case study |
| 7 | - Management of CVD<br>- Diet for hypertensive patients<br>- Drugs of choice for treatment of hypertension | - Electrolytes<br>- Case study for electrolytes imbalance |
| 8 | - Electrolytes importance<br>- Sodium (functions, homeostasis) | - Case study for acid base imbalance |
| 9 | -Sodium imbalances:<br>Hypernatremia (signs , symptoms, Pathophysiology, diagnosis, treatment, management)<br>Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, management) | - Case study for hyoertension |
| 10 | - Potassium imbalances (hyperkalemia, hypokalemia) | - Case study for myocardial infarction |
| 11 | - Calcium imbalances (hypercalcemia, hypocalcemia) | - Collective case studies |

| | | |
|---|---|---|
| | - Magnesium imbalances (hypermagnesemia, hypomagnesemia) | |
| **12** | - The body and pH<br>- pH control (control of acids, control of bases)<br>- Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | **- Revision** |
| **13** | - Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | **- Activity (report)**<br>Nutrition and pregnancy |
| **14** | - Revision& Open discussion | **- Practical exam** |
| **15** | - Final exam | |

## E- Teaching and Learning Methods:

- Lectures
- Practical sessions
- Case study
- Self learning (activity, reports, internet search, group discussion…) about nutrition and anemia and nutrition and pregnancy.

## F- Student Assessment Methods:

1- Written exam to assess a1, a2, a3, a4,a5, c1, c2, d3, d6

2- Practical exam to assess b1, b2, b3, d1, d2, d3, d6

3- Activities to assess d4, d5

## Assessment schedule:

| | |
|---|---|
| **Assessment (1):** Written exam | Week 15 |
| **Assessment (2):** Practical exam | Week 14 |
| **Assessment (3):** Activity | Week 5,13 |

## Weighing of Assessment:

| Assessment method | Marks | Percentage |
|---|---|---|
| Written exam | 40 | 80% |
| Practical exam and activities | 10 | 20% |
| TOTAL | 50 | 100% |

## G- Facilities Required for Teaching and Learning:

- Black (white) board, Data show, laboratory equipments and chemicals.

## H- List of References:

### 1- Course Notes:

- Student book of Clinical Nutrition approved by biochemistry department 2018-2019.
- Practical notes of Clinical Nutrition approved by biochemistry department 2018-2019.

### 2- Essential books:

- Advanced Human Nutrition, Denis M Medeiros, Robert E.C. Wildman, 4th edition, 2018
- Public health nutrition, Buttriss, Judith; Kearney, John M.; Lanham-New, Susan; Welch, Ailsa, 2018
- Food and Nutrition : What Everyone Needs to Know, P. K. Newby, 2018

### 3- Recommended books:

- Integrative Nutrition: A Whole-Life Approach to Health and Happines, Joshua Rosenthal, 2018
- Nutrition in the prevention and treatment of abdominal obesity, Ronald Watson, 2018
- Nutrition in Lifestyle Medicine, James M. Rippe, 2017

### 4- Periodicals and websites:

- Egyptian J. of biochem. and molecular biology.
- British J. of nutrition
- Arab J. of Laboratory Medicine,

- J. of Cardiovascular diseases.
- www.Pubmed.Com
- www.sciencedirect.com.

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**Course Coordinators:** **Prof. Dr. Hoda Elsayed**
**Head of Department:** **Prof. Dr. Sahar Elswefy**
**Date:** **تم مناقشة و إعتماد توصيف المقرر من مجلس القسم بتاريخ 2018-8-27**

# Matrix I of Clinical Nutrition Course

| Course Contents | | ILOs of Clinical Nutrition Course | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Knowledge and understanding | | | | | Professional and practical skills | | | Intellectual skills | | General and transferable skills | | | | | |
| Lectures | | a1 | a2 | a3 | a4 | a5 | b1 | b2 | b3 | c1 | c2 | d1 | d2 | d3 | d4 | d5 | d6 |
| 1 | Types of nutrients of balanced diet (macronutrients, micronutrients) | x | | | | x | | | | | | | | | | | |
| 2 | Energy requirement and energy expenditure- Diet and therapy- Nutritional assessment and food pyramids | | x | | x | | | | | x | | | | x | | | x |
| 3 | Obesity (Definition, assessment, factors affecting obesity) | | | x | | | | | | | | | | x | | | |
| 4 | Management of obesity- Drugs of choice for treatment of obesity | | | | x | | | | | x | x | | | | | | |
| 5 | Diabetes mellitus (DM)-Nutrition therapy and recommendation for DM- Drug of choice for treatment of DM | | | x | x | | | | | x | x | | | | | | |
| 6 | Definition and types of cardiovascular diseases (CVD)- Risk factors for CVD- Drug of choice for treatment of CVD | | | x | x | | | | | | x | | | | | | |
| 7 | Management of CVD- Diet for hypertensive patients- Drugs of choice for treatment of hypertension | | | | x | | | | | x | x | | | | | | |
| 8 | Electrolytes importance- Sodium (functions, homeostasis) | | x | | | | | | | | | | | | | | |
| 9 | Sodium imbalances: Hypernatremia (signs, symptoms, pathophysiology)- Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, management) | | x | x | x | | | | | x | x | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 10 | Potassium imbalances (hyperkalemia, hypokalemia) | | x | x | | | | | | | | | | | | | |
| 11 | Calcium imbalances (hypercalcemia, hypocalcemia)- Magnesium imbalances (hypermagnesemia, hypomagnesemia) | | x | x | | | | | | | | | | | | | |
| 12 | The body and pH- pH control (control of acids, control of bases) | | x | | | | | | | | | | | | | | |
| 13 | Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | | x | x | x | | | | | x | x | | | | | | |
| 14 | Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | | x | x | x | | | | | x | x | | | | | | |
| 15 | Revision- Open discussion | | | | | | | | | | | | | | x | | |
| **Practical sessions** | | | | | | | | | | | | | | | | | |
| 1 | Introduction to clinical nutrition<br>Calculation of BMR - TEE | | | | | | x | | | | | | | x | | | |
| 2 | Obesity and cases | | | | | | | x | X | | | | | x | | | x |
| 3 | Determination of BMI<br>Suggestion of life style modification | | | | | | | x | X | | | | | x | | | |
| 4 | Metabolic syndrome and case study<br>Calculation of atherogenic index | | | | | | | x | X | | | | | x | | | |
| 5 | Activity (report) | | | | | | | | | | | x | x | | x | x | |
| 6 | Diabetes and case study | | | | | | | x | X | | | | | x | | | |
| 7 | Electrolyte and case study | | | | | | | x | X | | | | | x | | | |
| 8 | Case study for acid base imbalance | | | | | | | x | X | | | | | x | | | |
| 9 | Case study for hypertension | | | | | | | x | X | | | | | x | | | x |
| 10 | Case study for myocardial infarction | | | | | | | x | X | | | | | x | | | x |
| 11 | Collective case study | | | | | | | x | X | | | | | x | | | x |
| 12 | Revision | | | | | | x | x | X | | | x | x | x | | | x |

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| 13 | Activity (Report) | | | | | | | | | | | | | | X | x | | |

## Matrix II of Clinical Nutrition Course

| National Academic Reference Standards (NARS) | | Program ILOs | Course ILOs | Course contents | Sources | Teaching and learning methods | | | Method of assessment | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Lecture | Practical session | Self learning | Written exam | Practical exam | Periodical exam | Oral exam |
| 2.1 | Principles of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice. | A8 | a1 | Types of nutrients of balanced diet (macronutrients, micronutrients) | Student book Essential books | x | | | x | | x | x |
| 2.11 | Principles of body function in health and disease states as well as basis of | A24 A25 | a2 | Energy requirement and energy expenditure- Diet and therapy- Nutritional assessment and food pyramids | Student book Essential books | x | | | x | | x | x |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | genomic and different biochemical pathways regarding their correlation with different diseases. | | | Electrolytes importance- Sodium (functions, homeostasis) | Student book Essential books | x | | | x | | x | x |
| | | | | Sodium imbalances: Hypernatremia (signs, symptoms, pathophysiology)- Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, management) | Student book Essential books | x | | | x | | x | x |
| | | | | Potassium imbalances (hyperkalemia, hypokalemia) | Student book Essential books | x | | | x | | x | x |
| | | | | Calcium imbalances (hypercalcemia, hypocalcemia)- Magnesium imbalances (hypermagnesemia, hypomagnesemia) | Student book Essential books | x | | | x | | x | x |
| | | | | The body and pH- pH control (control of acids, control of bases) | Student book Essential books | x | | | x | | x | x |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | Student book Essential books | x | | | x | | x | x |
| | | | | Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | Student book Essential books | x | | | x | | x | x |
| 2.12 | Etiology, epidemiology, laboratory diagnosis and clinical features of different diseases and their pharmaco-therapeutic approaches | A27 A28 | a3 | Obesity (Definition, assessment, factors affecting obesity) | Student book Essential books | x | | | x | | | x |
| | | | | Diabetes mellitus (DM)- Nutrition therapy and recommendation for DM- Drug of choice for treatment of DM | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| | | | | Definition and types of cardiovascular diseases (CVD)- Risk factors for CVD- Drug of choice for treatment of CVD | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| | | | | Sodium imbalances: Hypernatremia (signs, symptoms, pathophysiology)- Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, | Student book Essential books Recommended books Internet | x | | x | x | | | x |

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| | | | | management) | | | | | | | | |
| | | | | Potassium imbalances (hyperkalemia, hypokalemia) | Student book Essential books | x | | | x | | | x |
| | | | | Calcium imbalances (hypercalcemia, hypocalcemia)- Magnesium imbalances (hypermagnesemia, hypomagnesemia) | Student book Essential books | x | | | x | | | x |
| | | | | Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| | | | | Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| 2.15 | Basis of complementary and alternative medicine | A32 | a4 a5 | Energy requirement and energy expenditure- Diet and therapy- Nutritional assessment and food pyramids | Student book Essential books | x | | | x | | | x |
| | | | | Management of obesity- Drugs of choice for treatment of obesity | Student book Essential books Recommended | x | | X | x | | | x |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Diabetes mellitus (DM)- Nutrition therapy and recommendation for DM- Drug of choice for treatment of DM | books Internet | x | | X | x | | | x |
| | | | | Definition and types of cardiovascular diseases (CVD)- Risk factors for CVD- Drug of choice for treatment of CVD | | x | | X | x | | | x |
| | | | | Management of CVD- Diet for hypertensive patients- Drugs of choice for treatment of hypertension | | x | | X | x | | | x |
| | | | | Sodium imbalances: Hypernatremia (signs, symptoms, pathophysiology)- Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, management) | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| | | | | Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | Student book Essential books Recommended books Internet | x | | X | x | | | x |
| | | | | Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | Student book Essential books Recommended books Internet | x | | x | x | | | x |
| 3.5 | Select medicines | B8 | b1 | Case study for obesity | Practical notes | | x | | | x | | |

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| | based on understanding of etiology and pathophysiology of diseases | | | Case study for Diabetes mellitus | | | x | | | x | | |
| | | | | Case study for CVD | | | x | | | x | | |
| | | | | Case study for hypertension | | | x | | | x | | |
| | | | | Case study for electrolytes imbalance | | | x | | | x | | |
| | | | | Case study for acid-base imbalance | | | x | | | x | | |
| 3.10 | Advise patients and other health care professionals about safe and proper use of medicines. | B18 | b3 | Case study for obesity | Practical notes | | x | | | x | | |
| | | | | Case study for Diabetes mellitus | | | x | | | x | | |
| | | | | Case study for CVD | | | x | | | x | | |
| | | | | Case study for hypertension | | | x | | | x | | |
| | | | | Case study for electrolytes imbalance | | | x | | | x | | |
| | | | | Case study for acid-base imbalance | | | x | | | x | | |
| 4.9 | Utilize the pharmacological basis of therapeutics in the proper selection and use of drugs in various disease conditions. | C14 | c2 | Management of obesity- Drugs of choice for treatment of obesity | Student book Essential books Recommended books Internet | x | | x | x | | x | x |
| | | | | Diabetes mellitus (DM)- Nutrition therapy and recommendation for DM- Drug of choice for treatment of DM | | x | | x | x | | x | x |
| | | | | Definition and types of cardiovascular diseases (CVD)- Risk factors for CVD- Drug of choice for | | x | | x | x | | x | x |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | treatment of CVD | | | | | | | | |
| | | | | Management of CVD- Diet for hypertensive patients- Drugs of choice for treatment of hypertension | | x | | x | x | | x | x |
| | | | | Sodium imbalances: Hypernatremia (signs, symptoms, pathophysiology)- Hyponatremia (signs, symptoms, pathophysiology, diagnosis, treatment, management | Student book Essential books Recommended books Internet | x | | x | x | | x | x |
| | | | | Acidosis (respiratory acidosis, metabolic acidosis, signs, symptoms, compensation, treatment) | | x | | x | x | | x | x |
| | | | | Alkalosis (respiratory alkalosis, metabolic alkalosis , signs, symptoms, compensation, treatment) | | x | | x | x | | x | x |
| 5.1 | Communicate clearly by verbal and written means | D1 | d1 | Case study for obesity | Practical notes | | x | | | x | | |
| | | | | Case study for Diabetes mellitus | | | x | | | x | | |
| | | | | Case study for CVD | | | x | | | x | | |
| | | | | Case study for hypertension | | | x | | | x | | |
| | | | | Case study for electrolytes imbalance | | | x | | | x | | |
| | | | | Case study for acid-base | | | x | | | x | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | imbalance | | | | | | | | |
| 5.3 | Work effectively in a team | D3 | d2 | Activity | Practical notes | | x | | | x | | |
| | | | | | | | x | | | x | | |
| | | | | | | | x | | | x | | |
| 5.4 | Use numeracy, calculation and statistical methods as well as information technology tools | D4 | d3 | Energy needed (energy requirement and energy expenditure) | Student book Essential books | x | | | x | | x | x |
| | | | | Determination of body mass index | Practical notes | | x | | | x | | |
| | | | | | | | x | | | x | | |
| | | | | Calculation of athergenic index | | | x | | | x | | |
| 5.5 | Practice independent learning needed for continuous professional development | D6 | d4 | Revision- Open discussion | Student book Essential books Recommended books Internet | x | | x | | | | x |
| | | | | | | x | | x | | | | x |
| | | | | | | x | | x | | | | x |
| | | | | | | | | | | | | |
| | | | | Activity (report) | Recommended books Internet | | x | x | | x | | |
| 5.9 | Implement writing and presentation skills | D10 | d5 | Activity (report) | Recommended books Internet | | x | x | | x | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 5.1O | Implement writing and thinking, problem-solving and decision-making abilities. | D11 | d6 | Energy needed (energy requirement and energy expenditure) | Student book Essential books | x | | | x | | x | x |
| | | | | Case study for obesity | Practical notes | | x | | | x | | |
| | | | | Case study for Diabetes mellitus | Practical notes | | x | | | x | | |
| | | | | Case study for CVD | Practical notes | | x | | | x | | |
| | | | | Case study for hypertension | Practical notes | | x | | | x | | |
| | | | | Case study for electrolytes imbalance | Practical notes | | x | | | x | | |
| | | | | Case study for acid-base imbalance | Practical notes | | x | | | x | | |

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**Course Coordinators:** **Prof. Dr. Hoda Elsayed**

**Head of Department:** **Prof. Dr. Sahar Elswefy**

**Date:** **2018-8-27 تم مناقشة و إعتماد توصيف المقرر من مجلس القسم بتاريخ**

# COURSE SPECIFICATIONS

# Advanced Pharmacology

## Fifth Year- Elective Courses
## 2018-2019

# COURSE SPECIFICATIONS

# Heterocyclic synthesis of drugs

## Fifth Year- Elective Courses
## 2018-2019

# COURSE SPECIFICATIONS

# Manufacturing and production of crude drugs of natural origin

## Fifth Year- Elective Courses
## 2018-2019

# COURSE SPECIFICATIONS

# Good manufacturing practice (GMP)

## Fifth Year- Elective Courses
## 2018-2019

# Course specification of Good Manufacturing Practice (GMP)

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**University: Zagazig** **Faculty: Pharmacy**

## A- Course specifications:

- Program (s) on which the course is given :Bachelor of pharmacy
- Major or minor element of programs : Major
- Department offering the course : Pharmaceutics
- Academic year level :Fifth year (Elective course: Good Manufacturing Practice (GMP))
- Date of specification approval : November 2018

## B- Basic information:

- Title : Good Manufacturing Practice (GMP)
- Credit Hours : --- Code : ---
- Lectures : 2 hr/ week
- Practical : 2 hr / week
- Tutorials : ---------
- Total : 4 hr/week

## C- Professional information:

### 1-Overall aim of the course

**On completion of the course, the student will be able to:**

- Describe the guidelines of manufacturing of dosage forms
- Determine the good practices that should be followed during sampling, packaging, storing and labeling of different dosage forms

## 2-Intended Learning Outcomes

**ILOs**

**A- Knowledge and Understanding:**

a1: Outline the history of GMP development within years

a2: Enumerate the minimum requirements for GMP

a3: Outline the guidelines for proper sampling, packaging, labeling and storage of pharmaceutical products

a4: Recognize the importance of qualification and validation of products during manufacturing process

**B- Professional and Practical skills:**

b1: Identify the required documentation during manufacturing process

b2: Demonstrate the good practices regarding cleaning of equipment and accessories and personal hygiene

**C- Intellectual skills:**

c1: Judge the good and bad manufacturing processes

**D-General and Transferable skills:**

d1: Develop critical thinking skills

| Week No. | Lecture contents | Practical session |
|---|---|---|
| 1 | Introduction of pharmaceutical industry and GMP | -- |

## D- Contents

| | | |
|---|---|---|
| 2 | History of GMP development within years | Introduction of various definitions and abbreviations concerning GMP |
| 3 | Therapeutic good regulators | Demonstration of receiving raw, printed and packaging materials |
| 4 | Safety and quality regulations of therapeutic good regulators | Description of batch documents and batch documentation checklist |
| 5 | Guidelines of GMP towards premises and production areas | Control of air flow in production areas with diagrams |
| 6 | Airlocks and air cleanliness levels | Identification of contents of batch manufacturing records |
| 7 | Steps of production process | Representations and evaluation of batch manufacturing records |
| 8 | Types, causes and prevention of products contamination | Videos about different cleaning of equipment and accessories sheets |
| 9 | Documentation | Display sheets of standard operating procedure on personal hygiene |
| 10 | Processing operations during production process | Discussion about contents of sheets of standard operating procedure on cleaning of equipment and accessories and personal hygiene |
| 11 | Proper control of packaging | Final revision about practical course contents |
| 12 | Qualification and validation of production process | Practical exam |
| 13 | Personal training and hygiene | -- |
| 14 | Complaints, Recalls and Product quality review | -- |
| 15 | Final written exam | -- |

## E-Teaching and learning methods:

- Lectures
- Practical
- Demonstrative videos

## F- Assessment schedule:

| Assessment task | Week due |
|---|---|
| **Assessment (1):** Written exam | Week 15 |
| **Assessment (2):** Practical exam | Week 12 |

## Weighting of assessment:

| Assessment task | Marks | Proportion of total assessment |
|---|---|---|
| **Assessment (1):** Written exam | 40 | 80% |
| **Assessment (2):** Practical exam | 10 | 20% |
| **Total** | 50 | 100% |

## G-Students assessment:

1- Written exams to assess: a1, a2, a3, a4, b1, b2, c1, and d1

2- Practical exams to assess: a1, a2, a3, a4, b1, b2, c1, and d1

## H- Facilities required for teaching and learning:

1- For lectures: boards, and data show

2- For labs: data show

## H- List of References:

1. The Inspection and Standards Division of the Medicines and Healthcare products Regulatory Agency, Rules and Guidance forPharmaceutical Manufacturers and Distributors (the "OrangeGuide"), Pharmaceutical Press, 2007.
2. Gero Beckmann; WilfriedBellack; Helmut Bender; and others, GMPMANUAL; Good Manufacturing Practice & Implementation, Maas &Peither AG – GMP Publishing, 2007.
3. World Health Organization, Quality Assurance of Pharmaceuticals; A compendium of guidelines and related materials; Volume 2, 2nd updated edition; Good manufacturing practices and inspection, WHO Press, 2006.
4. WHO Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series 937, WHO Press, 2006.

5. Gillian Chaloner-Larsson; Roger Anderson; Anik Egan; Manoel Antonio da Fonseca Costa Filho; Jorge F. Gomez Herrera, A WHO guide to good manufacturing practice (GMP) requirements; Part 1: Standard operating procedures and master formulae, World Health Organization; Global Programme for Vaccines and Immunization, 1997.
6. Gillian Chaloner-Larsson; Roger Anderson; Anik Egan; Manoel Antonio da Fonseca Costa Filho; Jorge F. Gomez Herrera, A WHO guide to good manufacturing practice (GMP) requirements; Part
2: Validation, World Health Organization; Global Programme for Vaccines and Immunization, 1997.
7. Office of Women's Health, FDA Milestones in Women's Health: Looking Back as We Move into the New Millennium (FDA, Rockville, MD, 2000), www.fda.gov/womens/milesbro.html.
8. FDA History: FDA Commissioners and Their Predecessors, U.S. Food and Drug Administration, Rockville, MD, rev. 6 April 2000, www.fda.gov/opacom/morechoices/comm1.html.
9. "Jonas Salk, MD — Biography" (American Academy of Achievement, 2000), www.achievement.org/autodoc/halls/sci.
10. Code of Federal Regulations, Food and Drugs, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs," revised April 2000, Title 21 Part 210–211 (U.S. Printing Office, Washington, DC).

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**Course Coordinators: Prof. Dr. Mahmoud Abdel GhanyMahdy**

**Head of Department: Prof. Dr. Nagia Ahmed El-Amin El-Megrab**

**Date: 2018-11-26** **تم مناقشة و اعتماد توصيف المقرر من مجلس القسم بتاريخ**

## Matrix I of GMP course

| Course Contents | | ILOs of GMP course | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Knowledge and understanding | | | | Professional and practical skills | | Intellectual skills | Transferable and general skills |
| | | a1 | a2 | a3 | a4 | b1 | b2 | c1 | d1 |
| **Lectures** | | | | | | | | | |
| 1 | Introduction of pharmaceutical industry and GMP | x | | x | | | | | |
| 2 | History of GMP development within years | x | | | | | | | |
| 3 | Therapeutic good regulators | x | x | x | | | | | x |
| 4 | Safety and quality regulations of therapeutic good regulators | x | x | | | | | | |
| 5 | Guidelines of GMP towards premises and production areas | x | | | | | | | |
| 6 | Airlocks and air cleanliness levels | x | | | | | x | x | |
| 7 | Types, causes and prevention of products contamination | | x | | x | x | | | |
| 8 | Documentation | x | | | | | | | |
| 9 | Steps of production process and following processing operations | x | x | x | | | | x | |
| 10 | Proper control of packaging | x | x | x | | | x | x | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 11 | Qualification and validation of production process | | | x | | | | | |
| 12 | Personal training and hygiene | x | x | | | | | | |
| 13 | Complaints, Recalls and Product quality review | | | x | x | | | | |
| | **Practical sessions** | | | | | | | | |
| 1 | Introduction of various definitions and abbreviations concerning GMP | x | | | | | | | |
| 2 | Demonstration of receiving raw, printed and packaging materials | | | x | | | | | |
| 3 | Description of batch documents and batch documentation checklist | | x | | | x | | | |
| 4 | Control of air flow in production areas with diagrams | | x | | | | | x | |
| 5 | Identification of contents of batch manufacturing records | | x | | | | | x | |
| 6 | Representations and evaluation of batch manufacturing records | | | | | | | | x |
| 7 | Videos about different cleaning of equipment and accessories sheets | | x | x | | | | | |
| 8 | Display sheets of standard operating procedure on personal hygiene | | | | | | x | x | |
| 9 | Discussion about contents of sheets of standard operating procedure on cleaning of equipment and accessories and personal hygiene | | x | | | | | x | x |

# Matrix II for GMP

| NARS | | Program ILOS | Course ILOS | Course content | Sources | Teaching and learning methods | | | Method of assessment | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Lecture | Practical session | Self learning | Written exam | Practical exam |
| 2.1 | Principles of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice. | A2 | a1. | Pharmaceutical History History of GMP Good Manufacturing Practice Production Documentation Personnel hygiene Personnel Training qualification and validation Complaints, Recalls and Product quality review Therapeutic Goods Regulators | notebook | x | | x | x | |
| | | | a2 | Production Quality assurance Documentation Personnel | notebook | x | x | | x | x |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | hygiene , qualification and validation Therapeutic Goods Regulators | | | | | | |
| **2.3** | Principles of different analytical techniques using GLP guidelines and validation procedures | A11 | a3 . | Pharmaceutical History Production Documentation Personnel hygiene Personnel Training Complaints, Recalls and Product quality review | notebook | x | | | x | x |
| **2.7** | Principles of various instruments and techniques including sampling, manufacturing, packaging, labeling, storing and distribution processes in pharmaceutical industry. | A18 | a4. | Complaints, Recalls and Product quality review | notebook | x | | | x | |
| **3.8** | 3.8 Apply techniques used in operating pharmaceutical equipment and instruments | B15. | b1 | required documentation during manufacturing process | practical notebook | | x | | | x |
| | | | b2 | personal training and hygeine | practical | | x | x | | x |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | notebook | | | | | |
| **4.2** | 4.2Comprehend and apply GLP,GPMP, GSP and GCP guidelines in pharmacy practice | C3, C4 | c2 | Personal hygiene and required documentation during manufacturing process | practical notebook& notebook | | | x | x | x |
| **5.10** | 5.10 Demonstrate critical thinking, problem-solving and decision-making abilities | D11 | d1 | Personal hygiene and required documentation during manufacturing process | practical notebook& notebook | x | | | x | x |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | d2. | Good Manufacturing Practice | | | | | | | |

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# COURSE SPECIFICATIONS

## Forensic chemistry

### Fifth Year- Elective Courses
### 2018-2019