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وزارة التعليم العالي والبحث العلمي
Ministère de l'Enseignement Supérieur et de la Recherche Scientifique

Université Djilali Bounaama, Khemis Miliana
Faculté des Sciences de la Matière et d'informatique
Conseil Scientifique de la Faculté

جامعة جيلالي بونعامة خميس مليانة
كلية علوم المادة والإعلام الآلي
المجلس العلمي للكلية

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EXTRAIT DU PV
DE LA REUNION ORDINAIRE DU CONSEIL SCIENTIFIQUE
Du 02/02/2026

Objet : : Expertise de polycopié pédagogique

En l'an deux mille vingt-six (2026), le lundi 02 février à 13 h 30, une réunion ordinaire du Conseil Scientifique de la Faculté des Sciences de la Matière et de l'Informatique s'est tenue dans la salle de réunion de la faculté (Bloc B).

Suite aux rapports favorables reçus de la part des experts cités ci-après concernant l'expertise du polycopié pédagogique, le CSF a prononcé favorablement pour la conformité du polycopié pédagogique en vue de préparer son professorat.

- **Auteur du polycopié** : Dr. FIZIR Meriem (MCA)
- **Intitulé du polycopié** : Drug Analysis and Control « Course Material and Evaluation Exercises »
- **Destiné aux étudiants de** : 2ème année Master Chimie Pharmaceutique.
- **Experts du polycopié** :

• REZALA Houria	MCA	UDB-Khemis Miliana
• DJAFER Abderrahmane	Pr	UHB- Chlef.

Président du
Conseil Scientifique de la Faculté SMI
Dr. BOUDERBALA Mihoub

رئيس المجلس العلمي
إمضاء: بودربالة ميهوب

المجلس العلمي
كلية علوم المادة و الإعلام الآلي

People's Democratic Republic of Algeria
Ministry of Higher Education and Scientific Research

Djilali Bounaama University Khemis Miliana
Faculty of Matter Sciences and Computer Science
Department of Chemistry

Handout

Drug Analysis and Control

"Course Material and Evaluation Exercises"

Prepared by:
Dr. Meriem FIZIR

Academic Year: 2025-2026

People's Democratic Republic of Algeria

Ministry of Higher Education and Scientific Research

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Faculty of Matter Sciences and Computer Science

Department of Chemistry

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Preface

This course handout for ***Drug Analysis and Control*** is designed for second-year Master's students in Pharmaceutical Chemistry, and is also suitable for those in Pharmaceutical Engineering and Pharmacy programs.

The content integrates fundamental chemical principles with their specialized applications to ensure the safety, efficacy, and quality of medicinal products. The knowledge presented in these chapters forms the essential foundation supporting the pharmaceutical industry's commitment to public health. Drawing on several years of teaching experience in this field, this handout aims to provide students with comprehensive support to master the essential concepts of pharmaceutical quality control.

This handout has been developed in accordance with the official program curriculum. It guides students from broad regulatory frameworks to the detailed application of analytical techniques for specific drug classes.

The essential context is first established in Chapters I and II, which examine the State System Structure in Quality Control and the rigorous preparation of technical documentation for standards. The core principles of pharmaceutical analysis are systematically presented in Chapter III, detailing specific characteristics, essential criteria, method validation parameters, and the general principles for establishing the authenticity of medicinal substances. Chapter IV discusses the types of technical analysis within a pharmaceutical complex. This theoretical foundation is complemented by the practical aspects covered in Chapter V: Sample Selection, emphasizing that the validity of any sophisticated analysis depends entirely on obtaining representative samples.

A comprehensive examination of modern pharmaceutical quality control methods is provided in Chapters VI through X. Chapter VI discusses sterilization methods for microbiological safety; Chapter VII presents ash analysis for purity assessment; Chapter VIII details physical characterization methods, including melting point and optical rotation determination; Chapter IX covers chemical analysis techniques through titrimetric methods and functional group identification; and Chapter X explores advanced physicochemical instrumentation, including

spectral, chromatographic, and electrochemical techniques that form the core of modern quality control laboratories. Subsequent chapters (XI-XIV) apply these methods to specific drug classes, including aliphatic, aromatic, heterocyclic, and alkaloid compounds.

Upon completion of this course, students will be equipped not only to perform these analyses but also to critically evaluate analytical data, develop robust quality control protocols, and contribute to advancements in pharmaceutical sciences.

The final assessment consists of two components, each worth 50% of the final grade: a practical work assessment (comprising mini-projects, attendance, and participation) and a final written exam covering all course material from the semester. A minimum overall grade of 10 out of 20 is required to pass the module.

This manuscript is written in a clear style, rich with examples, to ensure its accessibility. I warmly invite all readers, students, and fellow educators to share their feedback, comments, and suggestions concerning the content and format of this work at my email address: meriem.fizir@univ-dbkm.dz. Your input would be highly valued.

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CHAPTER I: CONCEPT OF STATE SYSTEM STRUCTURE IN DRUG QUALITY CONTROL

1. Objectives

By the end of this chapter, the student will be able to:

- Explore the state system structure in drug quality control
- Examine quality management systems in the pharmaceutical industry
- Understand the role of pharmacopoeias
- Develop knowledge of quality documentation and standards

2. Introduction

Every medicine is characterized by special requirements of efficiency and safety, which determine its quality. High-grade medicines and their active substances always comply with all regulatory requirements. Medicine quality control is carried out during the whole manufacturing process (at every stage), also when releasing the drug on the market and during its circulation there.

3. Concept of state system structure in drug quality control

The concept of state system structure in drug quality control refers to the organization and management of quality control processes for drugs. This includes the establishment of protocols and procedures for testing, analysis, and evaluation of drug products to ensure that they meet the required standards for safety, efficacy, and quality. The state system structure may involve the use of various analytical techniques and technologies, such as chromatography, spectroscopy, and microbiological methods, as well as the implementation of quality management systems and regulatory frameworks to monitor and control drug quality throughout the entire supply chain. The ultimate goal of the state system structure in drug quality control is to safeguard public health by ensuring that drugs are safe, effective, and of high quality.

4. Quality management systems

The process of standardization and quality control is implemented in three main areas: identification of medicines, purity assessment (absence of impurities) and assay. Drugs quality indicators together with the methods of their analysis are stated in special regulatory documents (RD). The main one is Pharmacopoeia. There are other several quality management systems used in drug quality control. Here are a few examples:

4.1. Good Manufacturing Practice (GMP)

GMP is a set of guidelines that ensure that pharmaceutical products are consistently manufactured and controlled according to quality standards. GMP covers all aspects of the manufacturing process, including the facilities, equipment, personnel, documentation, and procedures.

4.2. International Organization for Standardization ISO 9001

ISO 9001 is a quality management system standard that can be applied to any industry, including the pharmaceutical industry. ISO 9001 provides a framework for implementing a quality management system that focuses on customer satisfaction, continuous improvement, and the prevention of defects.

4.3. Pharmacopeial standards

Pharmacopeial standards are a set of standards for the identity, strength, quality, and purity of drugs and drug ingredients. These standards are developed by organizations such as the United States Pharmacopeia (USP) and the European Pharmacopoeia (Ph. Eur.) and are used by regulatory authorities and pharmaceutical companies to ensure the quality of drugs.

4.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines

The ICH is a global organization that brings together regulatory authorities and the pharmaceutical industry to develop and harmonize guidelines for the development, registration, and post-approval of pharmaceutical products. The ICH guidelines provide a framework for ensuring the quality, safety, and efficacy of drugs by establishing standards for the design, conduct, and reporting of clinical trials, as well as for the manufacturing and quality control of drug products. The guidelines cover various aspects of drug development and quality control, including stability testing, impurity testing, analytical methods validation, and risk management. By implementing the ICH guidelines, pharmaceutical companies can