Quality Assurance Unit



الجمهورية اليمنية وزارة التعليم العالي والبحث العلمي جامعة صنعاء كلية الصيدلة قسم الكيمياء الدوانية والتحليلية والعضوية الصيدلانية وحدة ضمان الجودة

Program Specification of Master of Pharmaceutical Quality Control

1. Program Introduction/Description

This program combines the study of theories and doing research on a range of pharmaceutical field. The program is designed to prepare students to be leaders in the pharmacy and to provide them with the tools to effectively practice in senior research and teaching position in the field of innovative pharmaceutical research, pharmaceutical quality control research, pharmaceutical assessment, design, analysis of new drug in research institutions, universities and enterprises. Students in this program studying pharmacy-related courses intensively and required to take specialized courses in quality control, pharmaceutical analysis and choose their research's fields and publish it in international journals.

2. Program Identification and General I	nformation			
Program Title	Master of Pharmaceutical Quality Control			
Total credit hours required to award the	39 credit hours			
degree				
Awarding Institution	Faculty of Pharmacy, Sana'a University			
Department	Medicinal, Pharmaceutical Organic and Analytical			
Department	Chemistry			
Other Departments with major Teaching				
Contributions	-			
Language of study	English			
Date of Specification Preparation/Revision				
Mode of Study	Courses and thesis			
Study System	full time			
Main Location of Study	Faculty of Pharmacy			
Mode of Delivery	Full time			
Study Duration	Full-time (minimum 4 semesters)			
Award(s) or Final Award	Master of science (M.S.c) in Pharmaceutical Quality			
Awara(s) or Final Awara	Control			
	- a bachelor's degree in Pharmacy from the Faculty of			
Qualification required to join the program:	Pharmacy, Sana'a University or from any of the			
	faculties of Pharmacy in Yemeni universities recognized			
Minimum grade requirements to enroll in	by Ministry of Higher Education.			
the program	-			
me program	- The student must pass English as a Foreign Language			
	(TOEFL) with a condition of no less than 450 or its			
Other admission requirements	equivalent as a requirement for admission to the			
	program.			
Program coordinator:	Dr. Yahya A.S Al Dokhin.			



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Approval date:

Program Curriculum Committee:

- 1 .Dr Yahya A.S Al Dokhin.
- 2. Prof. Dr. Tawfeek A. Yahya
- 3. Dr. Mohamed Abbas.

4. Vision, Mission & Aims of the University

Vision of the University

Sana'a University aspires to achieve a national leading role in teaching, learning, scientific research and community service; and to be among the best regional universities and the foremost house of expertise and think tank in Yemen.

Mission of the University

To contribute to the sustainable development efforts by providing an accredited higher education environment and excellent research services within a fruitful national partnership based on transparency, professionalism and creativity.

Aims of the University

The University seeks to achieve the following objectives:

- 1. To provide specialized and in-depth academic opportunities for students in different fields of knowledge to meet the country's needs of specialties, technicians and experts, with special focus on the following:
- 2. To boost the level and quality of preparation and qualification tasks.
- 3. To create a general culture aiming at developing the elements of sound Islamic personality and the proper cognitive and scientific training.
- 4. To stabilize the true Islamic vision emanating from the broad horizons of Islamic knowledge and its perception of the universe, man and life.
- 5. To develop innovative and critical scientific thinking skills.
- 6. To provide students with the required knowledge and scientific and applied skills for solving problems effectively and efficiently.

7. Vision, Mission & Aims of the Faculty

Vision of the Faculty

Excellence and leadership locally, regionally and globally, in providing knowledge and continuous education in the academic and research field in pharmaceutical sciences According to the markets needs and community services

Mission of the Faculty

The College of Pharmacy seeks to prepare scientifically and practically qualified pharmaceutical graduates with high professional ethics and able to compete locally, regionally and globally in providing healthcare services through educational programs in accordance with quality standards that can support national pharmaceutical industries, market needs and serve community.

Aims of the Faculty



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- 1. Providing students with comprehensive knowledge about physiochemical properties and biological activities of medicinal substances required for formulating and preparing pharmaceutical products from their different sources, natural or synthetic.
- 2. Providing students with opportunities, practical skills, and training in different pharmaceutical sciences to ensure effective contribution in enhancing the requirements of pharmaceutical industries and labor market needs to serve the community.
- 3. Performing students the pharmaceuticals qualitative and quantitative analytical techniques according to GLP and GPMP guidelines to assess the quality and quantity of raw materials from natural or synthetic sources and different pharmaceutical products.
- 4. Possessing students the core knowledge concerning the principles of pathophysiology of diseases, pharmacotherapy, pharmacovigilence and pharmacoeconomics to be able to participate with other health care professionals in improving health care services using evidence-based
- 5. Planning, designing and conducting undergraduate and postgraduate research using appropriate methodologies.
- 6. Developing student's presentation, promotion, pharmaceutical marketing, administration, numeric and computation skills.
- 7. Demonstrating student's capability of communication skills, time management, critical thinking, problem-solving, decision-making and team-working.
- 8. Manage the safe and efficient distribution of medications and participate in quality assurance and improvement programs to maintain the sustainability of good practice.
- 9. Demonstrate a professional attitude through practicing in an ethical, legal manner and according to the GMP and GPP guidelines and continuously maintaining his/her competence through lifelong learning.

8. Mission & Aims of the Department

Mission of the Department

To prepare high professional, ethical, qualified pharmaceutical postgraduates who able to compete locally, regionally and globally in providing healthcare services through excellence education and research study in the field of analysis, and synthesis of raw materials and synthesis, analysis and designing of pharmaceutial compounds.

Aims of the Department

- 1. Possessing advanced knowledge and practical experience in simple and new methods for synthesis and analysis of raw materials used as starting material for designing and synthesis of pharmaceutical compounds.
- 2. Providing students with advanced principles and practical experience in modern methods and techniques of pharmaceutical analysis.
- 3. Enriching advanced knowledge and skills in medicinal chemistry focusing on design, synthesis and biological evaluation of pharmaceuticals.
- 4. Planning, designing and conducting pharmaceutical research using appropriate methodologies.
- 5. Perform research studies on specific pharmaceutical active compounds based on applying the scientific basis of research methodologies, ethics and professional practice.

عميد الكلية عميدة مركز التطوير وضمان الجودة رئيس الجامعة رئيس القسم نائب العميد لشؤون الجودة نائب العميد للشؤون الأكاديمية



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- **Quality Assurance Unit**
 - 6. Encouraging students for discovering and development of pharmaceutical active substances.
 - 7. Demonstrating communication skills, problem solving, critical thinking and decision making abilities in research field.
 - 8. Comprehending reliably literature in the field research and developments of professionalism and long life learning.
 - 9. Interpreting the work results and information to solve problems.
 - 10. Providing the student with knowledge and skills for writing reports and thesis and publishing papers.

9. Mission & Aims of the Program

Mission of the Program

Preparing qualified students with high professional ethics by providing applied interdisciplinary research in analysis and quality control of the raw materials and pharmaceutical products to meet the needs of the governmental and private health sector, pharmaceutical factories and research centers.

Aims of the Program

- 1. Enriching students with advanced knowledge regarding drug quality supervision.
- 2. Designing plans for pharmaceutical research using appropriate methodologies...
- 3. Conducting pharmaceutical research using appropriate scientific methodologies, ethics and professional practice
- 4. Demonstrating skills for writing reports and thesis and publishing papers.
- 5. Developing problem-solving skills and critical thinking ability and apply these in developing the experimental design to obtain the aims of research.
- 6. Providing the ability to critically review the scientific literature,
- 7. Developing professionalism and long life learning in pharmaceutical area of interest.

10. Program Standards & Benchmarks [Annex (2)]

Program Standards

• Rules and Regulations of the Ministry of Higher Education and Scientific Research, Yemen.

Program Benchmarks

- 1- Master in Pharmaceutical Analysis-Quality Control- Faculty of Pharmacy- Athens university-
- 2- Master in Medical Product Quality USC School of Pharmacy Southern California University- USA
- 3- Master in Pharmaceutical Analysis and Quality Control- King's Collage London university-UK.
- 4- **Master in** Quality Control of Pharmaceutical Products College of Pharmacy King Saud University KSA.
- 5- Master in Pharmaceutical Quality Control Faculty of Graduate studies- Jordan University of Science and Technology Jordan.
- 6- Master in Pharmaceutical analysis and Quality assurance- Faculty of Pharmacy- university Kart- India .

11. Program Intended Learning Outcomes (PILOs)

Quality Assurance Unit



A. Kr	nowledge and Understanding
Upon suc	ccessful completion of the Master of pharmaceutical quality control Program, graduates should be able
to:	nesserier comprehensit or master or pharmacochical quantity common regram, graducates should be able
A 7	Demonstrate basic knowledge specialized in the field of pharmaceutical quality control
A1.	quality assurance, good manufacturing practices and others.
A2.	Illustrate the different methods of stability studies of pharmaceutical products.
A3.	Recognize ethical research methodologies, regulations, and guidelines required for practicing the research of Quality control of drugs.
A4.	Recognize the essential knowledge in analysis of pharmaceutical dosage forms in the biological samples and bioavailability and bioequivalence studies.
B. Int	ellectual Skills
Upon suc	cessful completion of the Master of pharmaceutical quality control Program, graduates should be able
to:	
B1.	Design scientific research proposals and studies according to scientific foundations and methodology.
B2.	Evaluate the data and results obtained from the laboratory practical investigations
вз.	Distinguish different procedures of quality assurance and good manufacturing practices and
ъъ.	pharmaceutical stability studies
B4.	Develop different methods for isolation, separation and purification of drugs in the biological samples.
C. Pro	actical and Professional Skills
Hoon suc	cessful completion of the Master of pharmaceutical quality control Program, graduates should be able
to:	cession completion of the Musier of pharmaceolical quality control frogram, graduates should be uble
	Utilize different methods and apparatus for performing research in quality control and
C1.	stability of drugs.
C2.	Use different methods for separation and purification of samples as dosage forms or in the biological samples.
C3.	Practice bioavailability and bioequivalence studies.
C4.	Apply different biostatistics calculations related to quality control tests of the pharmaceutical dosage forms.
C5.	Utilize skills for writing reports and thesis and publishing papers.
D. Ke	y Transferrable Skills
Upon suc	ccessful completion of the Master of pharmaceutical quality control Program, graduates should be able
to:	
D1.	Communicate effectively and ethically with public, and health care professionals.
D2.	Apply management, decision-making, time management, organization and teamwork skills.
D3.	Take responsibility for adaptation to change needs in pharmacy practice.
D4.	Use internet to communicate and publishing researches.
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12. Teaching Strategy to Achieve Program Learning Outcomes						
PILOs	Teaching Strategy	Assessment Methods				
Knowledge and	Lectures.	Written Exam				
Understanding	Independent study	Oral Discussion				
A1, A2, A3,A4	Self-Learning.	Presentations				
	Active learning	Quizzes				
	Computer hands-on sessions.	Survey				
	Presentations	Assignments				
	Seminar	Seminar				
Intellectual Skills	Interactive Lectures	Written Exam				
B1, B2, B3, B4	Seminars	Oral Discussion				
	Discussions & Small group discussions	Presentations				
	Presentation	Quizzes				
	Problems solving	Assignments				
	Brain storming	Seminar				
	Self-learning	Written report				
Professional &	Independent study	Oral Discussion				
practical skills	Self-Learning.	Presentations				
C1, C2, C3, C4, C5	Analysis and Problem Solving.	Laboratory Reports				
	Laboratory works.	Experimental and field work				
	Presentation	Survey				
	Seminar	Assignments				
	Project supervision	Seminar				
	Brain storming	Written report				
	Publish research	Written research proposal				
	Research activities	Thesis and publications				
General &	Self-Learning.	Oral Discussion				
Transferable Skills	Active learning	Presentations				
D1, D2, D3, D4	Presentations	Assignments				
	Seminar	Seminar				
		Written report				

Teaching Strategy	Description of the Main Strategy Used			
Self -study	Self-study is an individualized learning experience that allows students to select a topic focus, define problems or questions, gather and analyze information, apply skills, and create a product to show what has been learned. A variety of web-based searches students will be assigned to learn how they can search for solutions using the Web.			
Computer hands-on sessions.	Practical applications using a variety of software before the real design and implementation.			



Problem Solving.	It allows students to become more active in their learning as they work out what information, they need to find out how to solve a particular problem. They can work out a problem collaboratively, practice research as well as testing different components to come up with a valid solution.
Laboratory works.	During laboratory sessions, students will be given experiments to work in groups where they can apply the theories and principles gained. This gives them the opportunity to have hands-on experience to design and conduct experiments in addition to analyzing, interpreting data obtained from experiments, and maximize their learning through actual simulation
Presentations	students present their work to the whole group, for discussion, criticism, and suggestions for improvement. Presentation sessions provide an opportunity to address questions, queries, and problems.
Project supervision	The teacher needs to set advance work for students, and then have the students present their work to the whole group, for discussion, criticism, and suggestions for improvement. Project sessions provide an opportunity to address questions, and problems.
Brain storming	Brainstorming is an effective technique for generating lists of ideas and creating interest and enthusiasm for new concepts or topics. Brainstorming provides teachers and students with an overview of what students know and/or think about a specific topic. Students can use brainstorming to organize their knowledge and ideas.
Seminar	The teacher needs to set advance work for a selected number of students, and then have the selected students present their work to the whole group, for discussion, criticism, and suggestions for improvement. Seminar sessions provide an opportunity to address questions, queries, and problems.
Research activities	Research-led activities envisage activities in which students learn about current research in the discipline and are frequently an audience. The emphasis is put on the research content.

Assessment Strategy	Description of the main strategy used.					
Oral Discussion	To know the knowledge of the students.					
Presentations	For Final Results displaying, to enhance the level of students in different subjects.					
Laboratory Reports	To demonstrate the personal skills, practical expertise, communication skills, report writing skills, and team work expertise they are expected to be learned and gained through their education.					



Experimental and field work	For evaluation, to demonstrate the personal skills, practical expertise, communication skills, report writing skills, and team work expertise they are expected to be learned and gained through their education.				
Seminar	As mentioned in the course specification and used to measure the higher thinking skills of students.				
Assignments	The entire assignments including problem-solving exercises of coursework activities and homework during the teaching period of each course. (which includes group and individual work, tests and presentations, etc.)				
Written research proposal	research According to university guidelines				
Thesis and publications					

13.	Intended Learning Outcomes Mapping:
See Annex	

1	4. Program Structu	re:			
No	Requirements		No. of Courses	Credit Hours	Rational Weight %
1	Hairanita Daniiran arta	Compulsory			
•	University Requirements	Elective			
2	D'. D	Compulsory			
2	Basic Requirements	Elective			
3	Faculty Requirements	Compulsory	3	6	15.4
3	racony kequirements	Elective			13.4
4	Danastmant Paguiraments	Compulsory			
4	Department Requirements	Elective			
5	Dura aurana Da aurina mananta	Compulsory	9	27	69.2
3	Program Requirements	Elective			07.2
6	Ciald Training	Compulsory			
0	Field Training	Elective			
_	Desired Comme	Compulsory		6	15.4
7	Project Courses	Elective			13.4
	Total:			39	100%

3

1

PHR3



Legislation and Regulatory affairs

Total

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Electiv	Elective Courses: None								
1.	1.1. Faculty Requirements								
Comp	ulsory C	ourses (3	courses/ 6 Hrs)						
No.	Level- Sem.	Course Code	Course Name	اسم المقرر	Cr. Hrs.	L	т	P	Prerequisit es, Co-requisites
1	1	PHR1	Pharmaceutical biostatistics		2				
2	1	PHR2	Research methodology		2				

6

Electiv	Elective Courses: None								
1.	1.2. Program Major								
Comp	ulsory C	ourses (9	courses/ 27 Hrs)						
No.	Level- Sem.	Course Code	Course Name	اسم المقرر	Cr. Hrs.	L	Т		Prerequisit P es, Co- requisites
1	1	PHQ1	Advanced Pharm. Instrumental analysis I		3	3			
2	1	PHQ2	Pharmaceutical Quality Control I		3	3			
3	2	PHQ3	Advanced Pharm. Instrumental analysis II		3	3			
4	2	PHQ4	Pharmaceutical Quality Control II		3	3			
5	2	PHQ5	Stability of Pharmaceutical Products		3	3			
6		PHQ6	Separation and purification methods		3	3			
7	2	PHQ7	Bioassay of Pharmaceutical Products		3	3			
8	3	PHQ8	Quality Assurance		3	3			
9	3	PHQ9	Good Manufacturing Practices		3	3			
			Total		27	27			
	Project Work Courses (courses/ 3 Hrs)								
No	Level- Sem.	Course Code	Course Name	اسم المقرر	Cr. Hrs.	L	Т	P	Prerequisites, Co-requisites
1									
	Total								



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Level 1

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No.	Level- Sem.	Course Code	Course Name	اسم المقرر	Cr. Hrs.	L	Т	P	Prerequisite s, Co- requisites
1		PHQ1	Advanced pharm. Instrumental analysis I		3	3			
2		PHR1	Pharmaceutical biostatistics		2	2			
3		PHQ2	Pharmaceutical Quality control I		3	3			
4		PHR2	Legislation and Regulatory affairs		2	2			
5		PHR3	Research methodology		2	2			
6		PHQ9	Good Manufacturing Practices		3	3			
					1.5	15			

Semester2

No.	Level- Sem.	Course Code	Course Name	اسىم المقرر	Cr. Hrs.	L	т	Р	Prerequisite s, Co-requisites
1		PHQ3	Advanced Pharm. Instrumental analysis II		3	3			
2		PHQ4	Pharmaceutical Quality control II		3	3			
3		PHQ5	Stability of Pharmaceutical Products		3	3			
4		PHQ6	Separation and purification methods		3	3			
5		PHQ7	Bioassay of Pharmaceutical products		3	3			
6		PHQ8	Quality Assurance		3	3			
			Total		18	18			



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Distril	hution	of Tota	l Credit	Hours

Level	Term		versity irements	Facı Require			gram ements	Trair			Total Cr. Hrs.		Total Cr. Hrs./ Level	
		No. of Courses	Credit Hours	No. of Courses	Credit Hours	No. of Courses	Credit Hours	No. of Courses	Credit Hours	No. of Courses	Credit Hours	No. of Courses	Credit Hours	,
First	First			3	6	3	9					6	15	
FILST	Second					6	18					6	18	
											6		6	
Total:				3	6	9	27				6		39	
Percentage:														

15. Admission Requirements:

- 1. Admissions to the program shall be made as per the admission rules set by the Ministry of Higher Education and Scientific Research as well as University of admission guidelines.
- 2. Bachelor in Pharmacy with at least performance of Good.

Attendance and Graduation Requirements:

- 1. Passing all the courses exams.
- 1. Student will graduate after successfully passing all program requirements.
- 2. Publishing at least one research in one of the international journals.

2. Grading System:

From 90% to 100% of total marks	Excellent
From 80% to less than 90%	Very Good
From 75% to less than 80%	Good
From 65% to less than 75%	Pass
Less than 50%	Poor/Fail

Facilities Required for Running the Program:

- 1. Sufficient hall furnished with all necessary pieces and equipment.
- 2. A Lab. as per the courses specifications.
- 3. Academic and administrative staff offices
- 4. Library.
- 5. Researching center.

Thesis

The student must prepare and discuss a Thesis.

Thesis and Its Requirements (if any)



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1. Registration of the thesis:

(Requirements/conditions and procedures for registration of the thesis as well as controls, responsibilities and procedures of scientific guidance)

- Completion of all university requirements.
- Field of Research and precise research topic with short Description and suggested time plan.
- First Department Seminar.
- Decision letter (Supervisors) of acceptance of the research topic.
- Any further requirements and controls based on post-graduate deanship regulations.

2. Scientific Supervision:

(The regulations of the selection of the scientific supervisor and his/her responsibilities, as well as the procedures/mechanisms of the scientific supervision and follow-up)

- At most 2-3 supervisors are selected for the supervision of a thesis.
- At least 1-Associate (or Full) Professor is appointed as supervisor either from the department or from another department outside the faculty.
- Any Assistant Professor appointed as supervisor should have at least 4-year experience in the field of research and have published at least one paper.

Candidates may apply for one-year extension (full-time) for completion of the thesis to the Postgraduate Program Administration at the Faculty of Pharmacy, which will be granted if the candidate provides a valid reason for extension.

The supervisor responsibilities are -:

- Help and assist the candidate/researcher in preparing the research plan.
- -Guide the candidate to adhere to certain standards of academic integrity and research ethics, including combating plagiarism.
- Monthly, follow up and meeting with the researcher (at least one meeting per month) :
- Guide the researcher at every step to be done during thesis work.
- Write follow-up (progress report) after each meeting
- Write a follow-up (evaluation report) every semesters.
- -The supervisor shall submit copies of these reports to the Postgraduate-Program coordinator, the Head of the Department and the Head of the Faculty Post-graduate.
- Write the final thesis acceptance report in order to prepare the final department seminar and then initiating the preparation for thesis presentation, defense and approve.

The candidate/student responsibilities are -:

- Student present his/her accomplishment at the end of every semesters
- plan and actively pursue the research:
- identify and deal with any research-related problems:
- comply with administrative requirements
- meet ethical guidelines:
- take responsibility for the final form of the thesis
- A thesis or research portfolio is the outcome of independent research, or creative activity

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conducted under supervision.

- The length of a (6) credit hours thesis or research portfolio will be appropriate to the discipline and must not exceed ... words, including bibliography, footnotes or endnotes and essential appendices, unless specific permission has been granted by the Department .

3. Thesis Defense/Examination:

(The regulations for selection of the defense/examination committee and the requirements to proceed for thesis defense, the procedures for defense and approval of the thesis, and criteria for evaluation of the thesis)

- A thesis proceeds for defense following completion of:
- At least two research paper is accepted in a journal in the field of research.
- Final acceptance letters provided by the supervisor(s) and the department final seminar committee (at least 3-department members):
- The examination committee should consist of -:
- One -Associate (or Full) Professor specialized in the field of research from an external university (
- One -Associate (or Full) Professor from the department of Medicinal chemistry, Pharmacy in addition to the supervisor of the thesis.
- A session for presentation, defense and approval of the thesis should be done based on the following:
- At least two members of the examination committee accept their assignment and reply by acceptance letter and approve the thesis for defense within one month.
- The session of defense should be declared within two weeks after receiving of examination committee members' approval letters.



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16.	Teaching staff			
	Professor	Associate Professor	Assistant Professor	Technicians Assistants
Required Number	1-2	1	1	2
Available Number		1	1	2
Note:			•	

17. Program Management and Regulations

1. Program Management

1.1 Program Structure

(including boards, councils, units, committees, etc.)

1.2 Stakeholders' Involvement

Describe the representation and involvement of stakeholders in the program planning and development. (students, professional bodies, scientific societies, alumni, employers, etc.)

2. Program Regulations

Provide a list of related program regulations, including their link to online version: admission, study and exams, recruitment, appeals and complaint regulations, etc.)

Decision of the Presidency of the Council of Ministers No. 40 of 2008

Decision of the Presidency of the Council of Ministers No. 141 of 2008

Graduate Studies Guide to Sana'a University

18. Evalu	18. Evaluation of Program Quality Matrix:										
Evaluation Areas/Aspects	Evaluation Sources/References	Evaluation Methods	Evaluation Time								

Note:

Evaluation Areas/Aspects (e.g., leadership, effectiveness of teaching & assessment, learning resources, partnerships, etc.)

Evaluation Sources (students, graduates, alumni, faculty, program leaders, administrative staff, employers, independent reviewers, and others (specify)

Evaluation Methods (e.g., Surveys, interviews, visits, etc.)

Evaluation Time (e.g., beginning of semesters, end of academic year, etc.)

رنيس القسم نانب العميد لشؤون الجودة نانب العميد للشؤون الأكاديمية عميد الكلية عميدة مركز التطوير وضمان الجودة رئيس الجامعة اد. توفيق احمد د. عبدالواسع القدسى د. مجد عباس حميد الدين اد. احمد السباتى اد. هدى العماد اد. القاسم مجد عباس

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19. List of Annexes

Annex (1)	Academic Standards Curriculum Criteria of Accreditation Board for program.
Annex (2)	Survey of names of Similar Accredited Programs at International Universities (Benchmarks)
	for Programs.
Annex (3)	Survey of Intended Learning Outcomes for similar Accredited electrical Programs
	at International Universities.
Annex (4)	Summary of similar Programs (Benchmarks) for Program.
Annex (5)	Survey of course names of Similar Programs.
Annex (6)	Survey/Mapping of Vision, Mission and Objectives of similar Accredited Programs at
	International Universities (Benchmarks) for master programs.
Annex (7)	Mapping of the mission and objectives of the program with the vision, mission and
	objectives of faculty, and the university.
Annex (8)	Main Themes/Sub-Themes with Relative weight for Program (if need)
Annex (9)	PILOs Distribution to General Themes for Program (if need)
Annex (10)	Matrix of mapping program P- ILO's with courses
Annex (11)	Mapping the benchmarks with PILO's (if need)
Annex (12)	Mapping Program's Goals with Intended Learning Outcomes
	The Admission Requirements for the Program.



الجمهورية اليمنية وزارة التعليم العالي والبحث العلمي قسم الكيمياء الدوائية والتحليلية والعظ وحدة ضمان الجودة

Appendix



الجمهورية اليمنية وزارة التعليم العالي والبحث العلمي كلية الصيدلة قسم الكيمياء الدوائية والتحليلية والعضوية الصيدلانية وحدة ضمان الجودة

Annex (4); Summary of similar Programs (Benchmarks) for Master of pharmaceutical quality control Program.

-		-	he Similar Prog		rks)		Current
	1st Program	2 nd Program	3 rd Program	4th Program	5 th Program	6th Program	Program
Progra m Title	Pharmaceuti cal Analysis- Quality Control	Medical Product Quality	Pharmaceuti cal Analysis and Quality Control	Quality Control of Pharmaceuti cal Products	Pharmaceuti cal Quality Control	Pharmaceuti cal analysis and Quality assurance	Pharmaceuti cal Quality Control
Faculty	Faculty of Pharmacy	USC School of Pharmacy	King's Collage	College of Pharmacy	Faculty of Graduate studies	Faculty of Pharmacy	Faculty of Pharmacy
Universi ty	Athens	Southern California	London	King Saud	Jordan University of Science and Technology	Kart	Sana'a
Country	Greece	USA	UK	KSA	Jordan	India	Yemen
Type of Progra m	Master	Master	Master	Master	Master	Master	Master
Study method s in the progra m:	Courses + Thesis	Courses +graduati on project	Courses +graduatio n project	Courses + research project	Courses + Thesis	Courses + research work	Courses + Thesis
Number of semeste rs	4 Semisters	10 Semisters	2 Semisters	4 Semisters	4 Semisters	4 Semisters	4-8 Semisters
Total Credit Hours	120 ECTS (60 Credit Hours)	32 unit	105 credit hours	46 Unit	47 credit hours	-	39 credit hours
No. of Courses	11	7	5	18	16	12	12

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الجمهورية اليمنية وزارة التعليم العالي والبحث العلمي كلية الصيدلة قسم الكيمياء الدوائية والتحليلية والعضوية الصيدلانية وحدة ضمان الجودة

Annex- 5 :Survey of course names of Similar Programs.

Unive	rsity	Sana'a	Athens	Southern California	London	King Saud University	at Jordan University of Science and Technology	Kart
Facu	lty	Faculty of Pharmacy	Pharmacy	USC School of Pharmacy	King's Collage	College of Pharmacy		Faculty of Pharmacy
Progi	ram	Pharmaceutic al Quality Control	Pharmaceutical Analysis-Quality Control	Medical Product Quality	Pharmaceutic al Analysis and Quality Control	Quality Control of Pharmaceutical Products		Pharmaceutic al analysis and Quality assurance
Coun	itry	Yemen	Greece	USA	UK	K SA	Jordan	India
No. Cour	ses	12+thesis	11+Thesis	7+graduatio n project	5+ graduation project	18+research project	16+Thesis	12+ research work
Total Hr:	s.	39 credits	120 ECTS	32 unit	105 credits	46 Unit	47	
Tote Yed	-		4 Semisters	five years	1 year	2 years	2 years	2yesrs
Ter m	Z 0							
		Advanced pharm. Instrumental analysis I	Advanced Pharmaceutical Analysis I		Advanced Spectroscopic Instrumental, Chemical and Bio-analytical Techniques	Quality Control of Pharmaceutical Raw Material	Instrumental Analysis	Modern pharmaceutic al analytical techniques
		Pharmaceutic al biostatistics	Statistics & Chemometrics	RSCI 507: Quality Systems & Statistical Process Control	Numerical Methods and Regulatory Affairs	Pharmaceutical Statistics	Advanced Biostatistics	Research methodology and statistics
		Pharmaceutic al Quality control I	Quality control of medicines		Quality Control and Regulatory Matters	Comprehensive Pharmaceutical Quality Control	Pharmaceutic al Quality Control: Methods and Tests	Quality Control And Quality Assurance
		Legislation and Regulatory affairs	Legislation and Regulator y affairs		Regulatory Affairs			Audit and regulatory compliance
		Research methodology	Bibliographic search methods		Literature Review Project	Research Project (1) and (2)	Research Methodology	Research methodology and statistics
		Good Manufacturin g Practices		MPTX 526: Chemistry Manufacturin g and Control		Good Manufacturing Practices (GMP)		
		Advanced Pharm. Instrumental analysis II	Advanced Pharmaceutical Analysis II		Advanced Analytical Techniques		Instrumental Analysis	Advanced Pharm. analysis
		Pharmaceutic		MPTX 515:		Quality Control	Seminar in	Pharmaceutic



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	al Quality control II		Quality Systems & Standards		by Advanced Analytical Methods	Quality Control	al validation
	Stability of Pharmaceutic al Products	Stability of Pharmaceutical Products	RSCI 527: Medical Product Safety		Quality Control Testing of Stability & Packaging Stability- Indicating Methods for Pharmaceutical Products	Drug Stability	
	Separation and purification methods			Advanced Separation Science			
	Bioassay of Pharmaceutic al products		RSCI 508: Quality Assurance for Drugs and Biologics		Biological Techniques for Quality Control of Biopharmaceutica		Modern Bioanalytical Techniques
ı	Quality Assurance		RSCI 509: Quality Assurance for Medical Devices & Combination Products		Quality Control & Assurance in Hospital Pharmacy	Pharmaceutic al Quality Assurance and Validation Quality Management and Assurance	Quality Control And Quality Assurance

Annex (7) Mapping of the mission and objectives of the program with the vision, mission and objectives of faculty, and the university.

Relationship between Program Mission and the Mission of the Faculty.

There is a relationship between Program Mission and the Mission of the Faculty as both of them encourage development in discovery of potential drug by research

Mission of the Faculty	Program Mission
Excellence and leadership locally, regionally and	Preparing qualified students with high
globally, in providing knowledge and continuous	professional ethics by providing applied
education in the academic and research field in	interdisciplinary research in analysis and quality
pharmaceutical sciences According to the markets	control of the raw materials and pharmaceutical
needs and community services	products to meet the needs of the governmental
	and private health sector, pharmaceutical
	factories and research centers.

Relationship between Program Goals and the Goals of the Faculty.

no	Goals of the Faculty	no.	Program Goals
7	Demonstrating student's capability of	5	5.Developing problem-solving skills and critical
	communication skills, time management, critical		thinking ability and apply these in developing



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	thinking, problem-solving, decision-making and team-working.		the experimental design to obtain the aims of research.
5	Planning, designing and conducting undergraduate and postgraduate research using appropriate methodologies.	2,3,	2.Designing plans for pharmaceutical research using appropriate methodologies. 3.Conducting pharmaceutical research using appropriate scientific methodologies, ethics and professional practice 6.Providing the ability to critically review the scientific literature,
6	Developing student's presentation, promotion, pharmaceutical marketing, administration, numeric and computation skills.	4,7	4.Demonstrating skills for writing reports and thesis and publishing papers. 7.Developing professionalism and long life learning in pharmaceutical area of interest.
1	Providing students with comprehensive knowledge about physiochemical properties and biological activities of medicinal substances required for formulating and preparing pharmaceutical products from their different sources, natural or synthetic.	1	Enriching students with advanced knowledge regarding drug quality supervision.

The mission program with mission of the university.

Mission of the University	Mission of the Program
Sana'a University aspires to achieve a national	Preparing qualified students with high professional
leading role in teaching, learning, scientific research	ethics by providing applied interdisciplinary research
and community service; and to be among the best	in analysis and quality control of the raw materials
regional universities and the foremost house of	and pharmaceutical products to meet the needs of
expertise and think tank in Yemen.	the governmental and private health sector,
	pharmaceutical factories and research centers.

Relationship between Program Goals and the Goals of the University

Aims of the University	Aims of the Program
 To provide specialized and in-depth academic opportunities for students in different fields of knowledge to meet the country's needs of specialties, technicians and experts, with special focus on the following: 	1,
To boost the level and quality of preparation and qualification tasks.	2, 3
 To create a general culture aiming at developing the elements of sound Islamic personality and the proper cognitive and scientific training. 	3, 4, 7
 To stabilize the true Islamic vision emanating from the broad horizons of Islamic knowledge and its perception of the universe, man and life. 	3,
5. To develop innovative and critical scientific	2, 6, 5, 7

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Quality Assurance Unit



thinking skills.	
 To provide students with the required knowledge and scientific and applied skills for solving problems effectively and efficiently. 	5

Advanced pharm. Instrumental analysis I Pharmaceutical biostatistics Pharmaceutical	Annex (10) Matrix of mapping program P- ILO's with courses																	
Advanced pharm. Instrumental analysis I Pharmaceutical biostatistics Pharmaceutical Quality control I Legislation and Regulatory affairs Research methodology Good Manufacturing Practices Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Pharmaceutical Signature A * * * * * * * * * * * * * * * * * *																		
Instrumental analysis I Pharmaceutical biostatistics Pharmaceutical		A1	A2	A3	A4	B1	B2	В3	B4	C1	C2	C3	C4	C 5	D1	D2	D3	D4
analysis I Pharmaceutical biostatistics Pharmaceutical Quality control I Legislation and Regulatory affairs Research methodology Good ** ** ** ** ** ** ** ** ** ** ** ** **		*	*							*								
Pharmaceutical biostatistics Pharmaceutical Ruality control I Legislation and Regulatory affairs Research Research Research Randard Ra																		
biostatistics Pharmaceutical Quality control I Legislation and Regulatory affairs Research methodology Good Manufacturing Practices Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Regulatory affairs * * * * * * * * * * * * *		¥								*			¥	*				*
Quality control I Legislation and Regulatory affairs Research * * * * * * * * * * * * * * * * * * *		*								*			*	*				*
Legislation and Regulatory affairs Research	Pharmaceutical	*	*		*					*								
Research																		
Research		*		*						*					*			
methodology Good																		
Good Manufacturing Practices Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Bioassay of Pharmaceutical		*		*		*	*			*				*		*		*
Manufacturing Practices Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Bioassay of Pharmaceutical																		
Practices Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Pharmaceutical * * * * * * * * * * * * * * * * * * *		*					*	*		*								
Advanced Pharm. Instrumental analysis II Pharmaceutical Quality control II Stability of Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical	_																	
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analysis II Pharmaceutical Quality control II Stability of * * * * * * * * * * * * * * * * * *		*	*							*		*						
Pharmaceutical * * * * * * * * * * * * * * * * * * *																		
Quality control II Stability of * * * * * * * * * * * * * * * * * *																		
Stability of * * * * * * * * * * * * * * * * * *		*	*		*				*	*								
Pharmaceutical Products Separation and purification methods Bioassay of Pharmaceutical Pharmaceutical * * * * * * * * * * * * * * * * * * *								_	_									
Products Separation and purification methods Bioassay of Pharmaceutical * * * * * * * * * * * * * * * * * * *		*	*					*	*	*	*							
Separation and * * * * * * * * * * * * * * * * * * *																		
purification methods Bioassay of * * * * * * * Pharmaceutical		- 14			310				34	310	- 14	334						
methods Bioassay of * * * * * * Pharmaceutical		*			*				*	*	*	*						
Bioassay of * * * * * * * Pharmaceutical	•																	
Pharmaceutical Pharmaceutical		*			*				*	*	*	*						
NTOCHICTS	products																	
Quality * * * * * *		*			*			*		*		*	*					
Assurance	-																	



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(Annex 12) Mapping Program's Goals with Intended Learning Outcomes

1.	Enriching students with advanced knowledge regarding drug quality supervision.	A1, A2, A3, A4
2.	Designing plans for pharmaceutical research using appropriate methodologies	B1, B2, B3, B4
3.	Conducting pharmaceutical research using appropriate scientific methodologies, ethics and professional practice	A3, C1, C2, C3, C4
4.	Demonstrating skills for writing reports and thesis and publishing papers.	C5, D4
5.	Developing problem-solving skills and critical thinking ability and apply these in developing the experimental design to obtain the aims of research.	D2, D3
6.	Providing the ability to critically review the scientific literature,	D3
7.	Developing professionalism and long life learning in pharmaceutical area of interest.	D1, D3

(Annex -13) The Admission Requirements for the Program.

- a bachelor's degree in Pharmacy from the Faculty of Pharmacy, Sana'a University or from any of the faculties of Pharmacy in Yemeni universities recognized by Ministry of Higher Education.

Good in bachelor's degree

- The student must pass English as a Foreign Language (TOEFL) with a condition of no less than 450 or its equivalent as a requirement for admission to the program.

