

National Academic Reference Standards (NARS)

Pharmacy

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1st Edition

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Preface

Based on the Presidential Decree number (82) for the year 2006, the National Authority for Quality Assurance and Accreditation of Education (NAQAAE) was founded to enhance the quality of education in Egypt.

In the light of NAQAAE's mandates, developing National Academic Reference Standards (NARS) for higher education comes on the top of its priorities. NARS are intended to set out clearly the graduate attributes and academic characteristics expected to be achieved in the academic programs of different disciplines.

The natural resources are no longer the backbone for development and prosperity; instead knowledge economy has become the main base for inducing tremendous and progressive breakthroughs in the resources of nations. In this regard, knowledge economy requires high quality education based on well defined reference standards.

The international changes and the concomitant alterations in the socio-economic conceptions obliged quality education as the main gate for human resources development. The latter, in turn, is counted as one of the most important determinants of national sustainable development.

Good practice in education should encourage students to improve their innovative and creative capabilities, employ appropriate technologies and pursue independent and life-long learning. This would necessitate setting out plans to develop the institutional capabilities and educational efficiency. Accordingly, educational institutions have to reform their programs and courses to meet the demands of the labor market. In addition, graduates should acquire the flexibility that enables them to adapt to the future needs of the labor market.

In alignment with its functions, NAQAAE, in collaboration with the stakeholders, has developed an integrated system to assure education quality. One of the system's outcomes is a series of guides for NARS in different academic disciplines to help higher education institutions in designing their programs to meet the accreditation requirements.

***National Authority for
Quality Assurance and
Accreditation of Education (NAQAAE)***

Acknowledgements

The National Authority for Quality Assurance in Education, (NAQAAE) would like to thank all the stakeholders involved in this work. The stakeholders included are representatives from the Ministry of Higher Education, National Syndicates, the Academic university staff members and the Private Sector. All of them were committed to make this work possible through their knowledge and experience.

The President of the National Authority for Quality Assurance in Education, Professor Magdy Kassem and Board members would like to acknowledge the efforts done by the task force group assigned to prepare this guideline for their hard work to ensure high quality graduates and to be comparable to the international standards.

Professor Magdy Kassem
NAQAAE, President

Methodology

NAQAAE has invited a group of education experts, in different academic disciplines, from state, private and Al-Azhar Universities to develop a general framework of the guide for the national academic reference standards (NARS) in the different sectors of higher education. The steps proceeded as follows:

1. Brain Storming

The authority held several workshops for expert groups to discuss the general framework and elements/contents of the NARS guide and Standardization of concepts and terms used in the NARS within a definite time table.

2. Reviewing of the International Academic Standard

Experts groups have reviewed the academic standards of some World accreditation institutions and standard applied in the corresponding faculties at universities from different countries in the world to have access to the global level, taking into account the need to preserve the Egyptian identity.

3. Reviewing the Available Academic Standards in Egypt

The working groups have reviewed the academic standards which have been developed by the sectors of the Supreme Council of Universities - Ministry of Higher

Education and Scientific Research. In accordance with the required amendments to NAQAAE, groups developed the guidelines to meet the needs of higher education institutions.

4. Reviewing by Technical Committee

Standard first drafts were reviewed by technical committees formed by NAQAAE board, to insure that standards meet the agreed essential elements as well as the technical editing of the draft.

5. Stakeholders Approval

After the completion of the draft of national academic reference standards, it was presented to representatives from stakeholders, faculty members from different universities and Al-Azhar institutions and representatives from the Ministry of Higher Education and the State for Scientific Research, to take appropriate action.

6. Dissemination

The Authority posted academic standards on its website (naqaae.org.eg), to receive feedback from students, faculty members and stakeholders.

7. Endorsement of Standards

The draft was revised according to the feedback received and introduced to NAQAAE's Board for approval.

Introduction to Pharmacy Education

Pharmacists participate in the public health programme within the national framework of pharmaceutical care in Egypt. Pharmacists are the main contributors to the development of local drug industry. Data from the national health account in Egypt indicate that about 35% of health expenditures are spent on drugs.[7] This fact, in addition to the significant role of pharmaceutical industry in Egypt in covering more than 90% of local drug consumption, demonstrates the importance of pharmacy profession in promoting health of the Egyptians and overall national economic development. Pharmacy profession is responsible for the achievement of the national drug policy objective of ensuring the safety, efficacy and quality of all medicines available in the Egyptian market.

Pharmacy profession is also responsible for ensuring equity, accessibility and affordability of essential drugs and vaccines to all Egyptian population. In addition, pharmacist's role in development of pharmacy education, science and technology, research and continued professional development is essential to meet the global challenges and the new technological development in pharmaceutical sciences.

Pharmacy Education

A five-year pharmacy education programme, offering a bachelor's degree of pharmaceutical sciences (B. Pharm. Sci.), should:

- Provide the appropriate mix of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice to support the role of pharmacists in multidisciplinary health team;
- Enhance pharmaceutical care and problem solving approaches;
- Promote knowledge of pharmacoeconomics as well as communication, presentation and management skills;
- Encourage lifelong-learning and evidence-based practices; and
- Develop and implement an efficient system for quality assurance and accreditation.

Pharmacy programmes must be regularly evaluated and the content of the curriculum must be revised and assessed to conform to the NARS and ensure relevance to recent advances in pharmacy practice.

The majority of pharmacists in Egypt work in community pharmacies followed by hospitals as well as industrial, academic and research institutions. Pharmacists are also

involved in other professional practices including forensic services, biomedical laboratories, cosmetic industry, veterinary medicines and military pharmacy services. Furthermore, a large number of Egyptian pharmacists work abroad, mainly in Arab countries.

I.National Academic Reference Standards (NARS)

1. Attributes of the Graduates

Pharmacy graduates work in a multi-disciplinary profession and must acquire the necessary attributes in various pharmacy aspects for pursuing their career. They should demonstrate comprehensive knowledge, clear understanding and outstanding skills as follows:

- 1.1. Handle chemicals and pharmaceutical products effectively and safely with respect to relevant laws and legislations.
- 1.2. Capable of formulating, preparing pharmaceutical products from different sources and participating in systems for dispensing, storage and distribution of medications.
- 1.3. Perform various qualitative and quantitative analytical techniques and fulfill criteria of GLP and GPMP to assure the quality of raw materials, procedures and pharmaceutical products.
- 1.4. Provide information and education services to community and patients about rational use of medications and medical devices.
- 1.5. Comprehend principles of pathophysiology of diseases and participate with other health care

professionals in improving health care services using evidence-based data.

- 1.6. Plan, design and conduct research using appropriate methodologies.
- 1.7. Develop presentation, promotion, marketing, business administration, numeric and computation skills.
- 1.8. Demonstrate capability of communication skills, time management, critical thinking, problem-solving, decision-making and team-working.
- 1.9. Perform responsibilities in compliance with legal, ethical and professional rules.
- 1.10. Able to be a life-long learner for continuous improvement of professional knowledge and skills.

2. Knowledge and Understanding

The pharmacy graduate must demonstrate comprehensive knowledge and clear understanding of the core information associated with the profession as follows:

- 2.1. Principles of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice.
- 2.2. Physico-chemical properties of various substances used in preparation of medicines including inactive

- and active ingredients as well as biotechnology and radio-labeled products.
- 2.3. Principles of different analytical techniques using GLP guidelines and validation procedures.
 - 2.4. Principles of isolation, synthesis, purification, identification, and standardization methods of pharmaceutical compounds.
 - 2.5. Principles of drug design, development and synthesis.
 - 2.6. Properties of different pharmaceutical dosage forms including novel drug delivery systems.
 - 2.7. Principles of various instruments and techniques including sampling, manufacturing, packaging, labeling, storing and distribution processes in pharmaceutical industry.
 - 2.8. Principles of pharmacokinetics and biopharmaceutics with applications in therapeutic drug monitoring, dose modification and bioequivalence studies.
 - 2.9. Principles of hospital pharmacy including I.V. admixtures, TPN and drug distribution system.
 - 2.10. Principles of public health issues including sources and control of microbial contamination as well as sanitation, disinfection, sterilization methods and microbiological QC of pharmaceutical products.

- 2.11. Principles of body function in health and disease states as well as basis of genomic and different biochemical pathways regarding their correlation with different diseases.
- 2.12. Etiology, epidemiology, laboratory diagnosis and clinical features of different diseases and their pharmacotherapeutic approaches.
- 2.13. Pharmacological properties of drugs including mechanisms of action, therapeutic uses, dosage, contra-indications, ADRs and drug interactions.
- 2.14. Principles of clinical pharmacology, pharmacovigilance and the rational use of drugs.
- 2.15. Basis of complementary and alternative medicine.
- 2.16. Toxic profile of drugs and other xenobiotics including sources, identification, symptoms, management control and first aid measures.
- 2.17. Methods of biostatistical analysis and pharmaceutical calculations.
- 2.18. Principles of management including financial and human resources.
- 2.19. Principles of drug promotion, sales and marketing, business administration, accounting and pharmacoeconomics.

- 2.20. Principles of proper documentation and drug filing systems.
- 2.21. Regulatory affairs, pharmacy laws and ethics of health care and pharmacy profession.

3. Professional and Practical Skills

- 3.1. Use the proper pharmaceutical and medical terms, abbreviations and symbols in pharmacy practice.
- 3.2. Handle and dispose chemicals and pharmaceutical preparations safely.
- 3.3. Compound, dispense, label, store and distribute medicines effectively and safely.
- 3.4. Extract, isolate, synthesize, purify, identify, and/or standardize active substances from different origins.
- 3.5. Select medicines based on understanding of etiology and pathophysiology of diseases.
- 3.6. Monitor and control microbial growth and carry out laboratory tests for identification of infectious and non-infectious diseases.
- 3.7. Assess toxicity profiles of different xenobiotics and detect poisons in biological specimens.
- 3.8. Apply techniques used in operating pharmaceutical equipment and instruments.

- 3.9. Maintain public awareness on rational use of drugs and social health hazards of drug abuse and misuse.
- 3.10. Advise patients and other health care professionals about safe and proper use of medicines.
- 3.11. Conduct research studies and analyze the results.
- 3.12. Employ proper documentation and drug filing systems.

4. Intellectual Skills

- 4.1. Apply pharmaceutical knowledge in the formulation of safe and effective medicines as well as in dealing with new drug delivery systems.
- 4.2. Comprehend and apply GLP, GPMP, GSP and GCP guidelines in pharmacy practice.
- 4.3. Apply qualitative and quantitative analytical and biological methods for QC and assay of raw materials as well as pharmaceutical preparations.
- 4.4. Recognize and control possible physical and/or chemical incompatibilities that may occur during drug dispensing.
- 4.5. Select the appropriate methods of isolation, synthesis, purification, identification, and

- standardization of active substances from different origins.
- 4.6. Apply the principles of bio-informatics and computer-aided tools in drug design.
 - 4.7. Apply various principles to determine the characteristics of biopharmaceutical products.
 - 4.8. Select and assess appropriate methods of infection control to prevent infections and promote public health.
 - 4.9. Utilize the pharmacological basis of therapeutics in the proper selection and use of drugs in various disease conditions.
 - 4.10. Calculate and adjust dosage and dose regimen of medications.
 - 4.11. Assess drug interactions, ADRs and pharmacovigilance.
 - 4.12. Apply the principles of pharmacoeconomics in promoting cost/effective pharmacotherapy.
 - 4.13. Analyze and interpret experimental results as well as published literature.
 - 4.14. Analyze and evaluate evidence-based information needed in pharmacy practice.

5. General and Transferable Skills

- 5.1. Communicate clearly by verbal and written means.
- 5.2. Retrieve and evaluate information from different sources to improve professional competencies.
- 5.3. Work effectively in a team.
- 5.4. Use numeracy, calculation and statistical methods as well as information technology tools.
- 5.5. Practice independent learning needed for continuous professional development.
- 5.6. Adopt ethical, legal and safety guidelines.
- 5.7. Develop financial, sales and market management skills.
- 5.8. Demonstrate creativity and time management abilities.
- 5.9. Implement writing and presentation skills.
- 5.10. Demonstrate critical thinking, problem-solving and decision-making abilities.

II. Curriculum Structure

Sciences	Subjects
Basic 10-15%	Physical, organic and analytical chemistry; biology; biophysics; computer sciences; mathematics.
Pharmaceutical 35-40%	Pharmacy orientation; medical terminology; physical pharmacy; pharmaceutics; industrial pharmacy; pharmaceutical technology; biopharmaceutics; pharmacokinetics; pharmaceutical chemistry; pharmacognosy; pharmaceutical microbiology; molecular biology and pharmaceutical biotechnology; quality assurance and quality control; instrumental analysis; biological drug assays.
Medical 20-25%	Anatomy; histology; physiology and pathology; biochemistry; parasitology; pharmacology; clinical pharmacology; therapeutics; medical microbiology; immunology and virology.
pharmacy practice	Pharmaceutical care and professional pharmacy (clinical,

10-15 %	hospital, community... etc); complementary and alternative medicines; drug and poison information; pharmacy laws and regulations.
Health and environmental 5-10 %	Public health; Egyptian health system and its policies; biostatistics; healthy lifestyle; toxicology and forensic medicine; first aid and emergency medicine.
behavioral and social 2-4%	Psychology; communication; social and administrative pharmacy; pharmacy ethics.
pharmacy management 2-4%	Sales, marketing and drug promotion; pharmaceutical business administration; pharmacoeconomics.
Discretionary up to 8%	Professional and non-professional sciences.

Summer training (not less than 300 hours in a pharmaceutical location) should be included in B. Pharm. Sci. programme.

III. Glossary

1. Institution

A University, faculty or higher institute providing education programs leading to a first university degree or a higher degree (Master's or Doctorate).

2. Graduate Attributes

Competencies expected from the graduate based on the acquired knowledge and skills gained upon completion of a particular program.

3. National Academic Reference Standards (NARS)

Reference points designed by NAQAAE to outline / describe the expected minimum knowledge and skills necessary to fulfill the requirements of a program of study.

4. Academic Standards

Reference points prescribed (defined) by an institution comprising the collective knowledge and skills to be gained by the graduates of a particular program. The academic standards should surpass the NARS, and be approved by NAQAAE.

5. Subject Benchmark Statements

Guideline statements that detail what can be expected of a graduate in terms of the learning outcomes to satisfy the standards set for the program. They enable the outcomes to be compared, reviewed and evaluated against agreed upon standards.

6. The Program

A set of educational courses and activities designed by the institution to determine the systematic learning progress. The program also imparts the intended competencies required for the award of an academic degree.

7. Intended Learning Outcomes (ILOs)

Subject-specific knowledge, understanding and skills intended by the institution to be gained by the learners completing a particular educational activity. The ILOs emphasize what is expected that learners will be able to do as a result of a learning activity.

8. Knowledge and Understanding

Knowledge is the intended information to be gained from an educational activity including facts, terms, theories and basic concepts. Understanding involves comprehending and grasping the meaning or the underlying explanation of scientific objects.

9. Intellectual Skills

Learning and cognitive capabilities that involve critical thinking and creativity. These include application, analysis, synthesis and evaluation of information.

10. Professional and Practical Skills

Application of specialized knowledge, training and proficiency in a subject or field to attain successful career development and personal advancement.

11. General and Transferable Skills

Skills that are not subject-specific and commonly needed in education, employment, life-long learning and self development. These skills include communication, team work, numeracy, independent learning, interpersonal relationship, and problem solving... etc.

IV. Abbreviations:

ADR	Adverse Drug Reaction
DTC	Drug Therapeutic Committee
FDA	U.S. Food and Drug Administration
FIP	International Pharmacy Federation
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GPMP	Good Pharmaceutical Manufacturing Practice
GSP	Good Storage Practice
I.V.	Intravenous
OTC	Over The Counter
QA	Quality Assurance
QC	Quality Control
R & D	Research and Development
TPN	Total Parental Nutrition
WHO	World Health Organization

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