

GENERAL BOARD EXAMINATION – GBE (Complex Final Examination)

Topics of the final exam 2024

Subject of the final examination: **General pharmaceutical knowledge**

The aim of the final examination is to state whether the candidate is in possession of all knowledge and skills necessary to perform a job with a pharmacy diploma in public and institutional pharmacies, pharmaceutical companies, Galenic and other laboratories, or at the health authorities.

Given that, under the relevant legislation, the graduate pharmacist must be able to make autonomous decisions in the field of pharmacy without supervision, therefore he or she must be able to prove this in the final examination. This requires the presentation of the knowledge and the indispensable approach of exploration as well as independent and professional decision-making in the final examination system. Therefore, the final examination should pay particular attention to the expected work and professional activities of the graduated pharmacists and to the assessment of *integrated knowledge* of practical pharmacist decision-making situations.

Applying all of these considerations will also help future pharmacists to keep up with the profession and to be an active participant in their professional careers over the coming decades.

The final exam consists of the knowledge that enables the pharmacist to carry out independent work in the above positions at the level expected of a graduate practitioner under their own responsibility.

The three parts of the final examination are:

- I.) nationally unified written examination
- II.) practical examination
- III.) oral examination

I. Nationally unified written examination

As the nationally unified test based on integrated knowledge is partially different from the exams of previous years, for the successful preparation it is recommended to use the practising opportunities of the integrated test based on the recently published online test book (www.zarovizsga.hu).

The majority of the questions are problem-analysing and synthesising groups of questions, which cover pharmaceutical technology, pharmacology, pharmaceutical administration, pharmaceutical chemistry, pharmacognosy, public health and epidemiology, microbiology, biopharmacy, clinical pharmacy, pharmacotherapy and pharmaceutical historical knowledge.

II. Practical exam

The practical final examination consists of preparation of medicines (compounding) in the pharmacy.

Within the framework of this, the tasks of the candidate are

- formal and content-based supervision of prescriptions, the adequate reading of the prescriptions in Latin and the correct preparation of such prescriptions,
- dose calculation of potent-effect preparations, the precise and professional correction of the excess of the dose limits,
- description of the pharmaceutical technological, physico-chemical drug testing, biopharmaceutical, pharmacological and legislative dispensing aspects of the magistral preparations,
- solving conflicts of interest in magistral formulations (incompatibilities), with particular regard to stability and accurate dosing,
- knowledge of the materials used in the preparation of the medicinal product and of the properties of the active substances and excipients,
- a detailed description of the use of a medical device.

Process of the practical final examination:

1. In the examination, the candidate draws an assortment of topics including three prescriptions and a medical device. These topics cover various dosage forms, and comprise formulation, technological and dosage issues. Two preparations have to be made *lege artis*, in accordance with the technological rules and related regulations, and information on the third prescription must be given.
2. As incorrect recipes may also occur in terms of form and content, the candidate must consider:
 - a.) the prescription's regularity in terms of form and content, with particular reference to potent effect active ingredients;
 - b.) whether the preparation can be prepared, or the correct preparation thereof, in terms of the incidental incompatibility as well as the related legal regulations.
If the candidate deems the prescription to be suitable for preparation, they have to prepare it without any comments. If the prescription cannot be prepared for any reason, this fact must be reported to the examination committee, which after listening to the professional justification of the candidate, shall consider them and provide the necessary information.
3. After proper reading of prescriptions, an oral report shall be given on prescriptions and preparation regarding the steps followed and the knowledge about the prescriptions and the preparation of the formulae.
4. The candidate shall describe the medical device.

III. Oral final examination

In the oral part of the final exam, students will be required to take an integrated assessment of the following topics:

- A. Pharmacological basics of drug therapy
- B. Primary-care, hospital and clinical pharmacy decision making situations
- C. Interpretation of summary of product characteristics (SmPc), importance of the dosage form
- D. Pharmacy administration
- E. Manufacturing and control of medicinal preparations

Oral Final Exam Topics for Pharmacy Students 2022

In the oral part of the final exam, students will be required to take an integrated assessment of the following topics:

	<i>Recommended duration (min)</i>
A. Pharmacological basics of drug therapy	5-7
B. Primary-care, hospital and clinical pharmacy decision making situations	3-5
C. Interpretation of summary of product characteristics, importance of the dosage form	1-2
D. Pharmacy administration	3-5
E. Manufacturing and control of medicinal preparations	3-5
<i>Sum:</i>	15-24

*You can also get additional questions for the topics, which should be answered shortly, 1-2 minutes!
The exam preparation time is 20-30 minutes, during which the Ph.Eur. VIII. can be used!*

List of topics A-E

A. Pharmacology, structure-activity relationships (5-7 min)

Mechanism of action, indications, side effects, interactions and clinical uses of the specific drugs should be mentioned. Use the drug lists. In addition to Pharmacology and toxicology, the exam also covers the subjects of Basic medical pathophysiology and Drug therapy.

- A.1. Characterization of drug – receptor binding. Dose – response curves.
- A.2. Targets for drug action and the role of signal transduction pathways, agonist and antagonist effects.
- A.3. Absorption, distribution, accumulation, elimination, metabolism, and excretion of drugs. Typical blood level curves, pharmacokinetic parameters. LADME-model, Bioavailability, Biopharmaceutical Classification System (BCS). Physicochemical characteristics, lipophilicity. Prodrugs.
- A.4. Factors influencing the drug effect. Adverse effects and drug interactions. Dosage regimen.
- A.5. Parasympathomimetics and parasympatholytics. Drug therapy of urinary incontinence.
- A.6. Sympathomimetic and sympatholytic drugs.
- A.7. Local anesthetics.
- A.8. Skeletal muscle relaxants and spasmolytic drugs.
- A.9. General anesthetics and perioperative medication.
- A.10. Sedative and hypnotic drugs, anxiolytics. Drug therapy of anxiety and sleeping disorders.
- A.11. Opioid analgesics. Practical aspects of analgesia.
- A.12. Antipsychotic drugs. Drug therapy of schizophrenia.
- A.13. Antidepressants and mood-stabilizing drugs.
- A.14. Drugs of abuse and drug dependence.
- A.15. Antiepileptics.
- A.16. Drugs applied in neurodegenerative disorders. Drug therapy of Parkinson's disease.
- A.17. Drug therapy of headaches.
- A.18. Non-steroidal antiinflammatory drugs and drugs used in gout.
- A.19. Drugs used in rheumatoid arthritis.
- A.20. Antihistamines and the pharmacotherapy of allergic rhinitis.
- A.21. Drugs applied in chronic heart failure, therapeutic principles.
- A.22. Antidysrhythmic drugs.

- A.23. Antihypertensive drugs, therapeutic principles.
- A.24. Drugs used in ischemic heart disease, therapeutic principles.
- A.25. Antidyslipidemic drugs.
- A.26. Diuretics and their clinical uses.
- A.27. Drugs used in the treatment of bronchial asthma and COPD, therapeutic principles.
- A.28. Anticoagulants. Drug therapy of deep vein thrombosis.
- A.29. Antithrombotic and fibrinolytic drugs.
- A.30. Retinoids. Drug therapy of acne.
- A.31. Water soluble vitamins. Drugs affecting the hemopoetic system.
- A.32. Drugs used in peptic ulcer and GERD, therapeutic principles.
- A.33. Laxatives and antidiarrheal drugs. Therapy of constipation and diarrhea.
- A.34. Antiemetic and prokinetic drugs and the principles of their therapeutic uses.
- A.35. Pharmacology of female sex hormones. Contraceptives.
- A.36. Pharmacology of male sex hormones. Drug therapy of benign prostate hyperplasia and erectile dysfunction.
- A.37. Drugs that affect calcium and bone metabolism. Drug therapy of osteoporosis.
- A.38. Drugs affecting carbohydrate metabolism, therapy of diabetes mellitus.
- A.39. Corticosteroids and their systemic and topical administrations.
- A.40. Drugs affecting the pituitary and thyroid.
- A.41. Protein synthesis inhibitor antibacterial drugs. Antimycobacterial drugs.
- A.42. Cell wall synthesis inhibitor antibacterial drugs. Therapeutic principles of community acquired respiratory tract infections.
- A.43. Nucleic acid synthesis inhibitor antibacterial drugs. Therapeutic principles of community acquired urinary tract infections.
- A.44. Drugs used in herpes and influenza virus infections.
- A.45. Antiretroviral drugs.
- A.46. Antifungal drugs. Therapy of fungal skin infections.
- A.47. Immunosuppressants, drugs used in organ transplantation.
- A.48. Antiprotozoal and anthelmintic drugs.
- A.49. Cytotoxic anticancer drugs.
- A.50. Cytostatic anticancer drugs.

B. Primary-care, hospital and clinical pharmacy decision making situations(3-5 minutes)

Situations should pay attention to the following aspects (general questions):

1. *How would you deal with the dispensing of individual prescriptions? How would you solve the problems you encountered considering the aspects below:*

- *importance of medication therapy,*
- *effectiveness of the medication therapy,*
- *safety of the medication therapy,*
- *appropriate patient' adherence.*

2. *What questions would you ask the patient for safe therapy? What advice would you give to the patient in order to achieve the most effective and efficient therapy?*

3. *Describe the forwarding situation in accordance with the "Professional Guideline on checking of the safe drug application in the frame of basic pharmacy care" as appropriate. What professional guidance and resources would you use during the dispensing process? (Aspects of safe dispensing of prescription and over-the-counter drugs and dietary supplements)*

- B.1. A polypharmacy patient arrives at the pharmacy with a prescription containing Syncumar Mite® (acenocoumarol 1mg) and a new prescription containing Nootropil® (1200 mg piracetam) but instead wants to buy Ginkgo Biloba drops recommended by her friend for her worsening tinnitus and loss of memory.

- B.2. Regular expedition of highly controlled analgesic transdermal patch; pharmaceutical care activity related to the use of TTS patches.
- B.3. A diabetic patient wants to buy a metformin-containing medicine together with an antihypertensive drug with paper-based prescriptions at the pharmacy and ask for a "sticky patch" for his unhealed wound on his leg because his patch at home was running out very quickly.
- B.4. A diabetic patient complains about the inefficiency of the drugs he is taking because his blood glucose levels are wrong and, by his own admission, would almost give up the fight against high blood sugar, and he can hardly see the display of the device.
- B.5. A COPD patient complains of coughing, and he wants to take medicine while holding a prescription for a new type of inhaler, which he does not want to buy because of it is too expensive and does not understand why the doctor prescribed such a medicine.
- B.6. Patient with high blood pressure, heart failure, and diabetes has low GFR according to a recent lab test (<28), regularly taking metformin and digoxin, coming to the pharmacy with paper prescriptions, but intend to go to the General Practitioner the next day. Still, it was a long time ago when he visited the specialist.
- B.7. A patient taking PPI arrives at the pharmacy with the appropriate prescription and asks the pharmacist if there is a herbal remedy for it, as she would rather take it instead of PPI.
- B.8. A self-conscious, male patient would buy Neo-Citran® (phenylephrine, pheniramine, ascorbic acid, paracetamol) for his cough.
- B.9. A patient with chronic renal failure (low GFR) and heart failure has recently returned from the hospital, and his GP prescribes a diclofenac-containing painkiller to his used medicines for his worsening waist and knee pain.
- B.10. After one month, an asthma patient arriving at the pharmacy would like to buy only the reliever inhaler because of her difficulty in breathing.

C. Interpretation of summary of product characteristics, importance of the dosage form (1-2 min)

Based on the available Summary of Product Characteristics (or Patient Information Leaflet), it is necessary to interpret the formulation and the administration characteristics (e.g. timing of administration, half-life, etc.) and the pharmacokinetic aspects. The key features and explanations of the function of the excipients are provided by the supplementary lecture materials of Pharmaceutical Technology and Clinical Pharmacokinetics and Biopharmacy.

Examples of dosage forms, medicinal preparations (See the list in a Neptun list):

- coated tablet/capsule, dragee
- concentrate for solution for injection
- dermal preparation
- dispersible tablet
- eye drop, artificial tear
- hard capsule
- inhalation powder, hard capsule
- injection, infusion
- liposomal concentrate for solution for infusion
- modified-release capsule
- modified-release tablet
- nasal spray
- orodispersible tablet
- paediatric suspension
- powder, granules
- powder and solvent for prolonged-release suspension for injection (microspheres)
- pressurized metered-dose inhaler (MDI)
- prolonged-release tablet
- rectal dosage forms (suppository, klyisma)

soft capsule
solution for infusion
solution for injection
solution for injection in pre-filled syringe
tablet
suspension for injection
transdermal patch
vaginal dosage forms

D. Pharmacy administration (3-5 min)

- D.1. The aim and application areas of drug utilization studies, importance, advantages of DDD-ATC classification
- D.2. The European Pharmacopoeia – concept, structure and content
- D.3. European Marketing authorization, the four main authorisation procedures
- D.4. The focus of Pharmaceutical research, characteristics of the Pharmaceutical Industry
- D.5. Marketing of Pharmaceuticals, 4P-model
- D.6. Good Clinical Practice
- D.7. Good Manufacturing Practice
- D.8. Aspects of the Good Pharmacy Practice Guideline
- D.9. Good documentation systems
- D.10. How can we manage quality in health care, information needs and medical errors
- D.11. Explain the today's financial pressures (reasons and consequences) in health care
- D.12. What are the main types of pharmacoeconomic analysis (CMA, CBA, CEA, CUA) and their use in decision making? What does "cost-effectiveness" mean?
- D.13. The importance of quality of life measurement, in clinical practice and in economic evaluations.
- D.14. What is Evidence Based Pharmacy (Medicine), what is its importance?
- D.15. What are the most important International Health Care Organizations and what are their activities?

E. Manufacturing and control of pharmaceuticals (3-5 min)

- Summarize the main aspects related to the question!
- Where possible, address the different types of drug dosage forms, biopharmaceutical aspects, and manufacturing techniques associated with the topic.
- Review the key critical quality characteristics of the pharmaceutical formulation and the tests required (e.g. identification, active substance content, impurities, microbiological purity, tablet disintegration time, dissolution profile, etc.).
- The Ph. Eur. can be used during the exam to review the aspects!

- E.1. Quality requirements for medicinal preparations, principles and control methods (Ph. Eur. General chapters 1 General notices and 2. Methods of analysis, their significance)
- E.2. Preformulation and formulation, Developmental aspects of dosage forms. Salt selection, Significance of polymorphic and amorphous materials, solid-state structural analysis, biopharmaceutical aspects.
- E.3. Significance and study of compatibility. Physical and chemical incompatibilities in pharmaceutical technology.
- E.4. Preparation of stable medicinal products, stability studies. Unwanted physical, chemical, and microbiological changes during storage. Stabilization.
- E.5. Significance of unit operations in the preparation of medicinal products. Packaging and containers, packaging materials.
- E.6. Engineering principles of pharmaceutical manufacturing, scale-up, in-process control, critical quality attributes and process parameters. Conditions of pharmaceutical manufacturing, plants, GMP, Qualified person.

- E.7. Preparation and control of solutions.
- E.8. Preparation and quality control of emulsions (HLB, surface active agents).
- E.9. Preparation and quality control of suspensions.
- E.10. Preparation and control of pharmaceuticals containing plant extracts.
- E.11. Preparation and control of parenterals (aseptic preparation, clean-room and isolation techniques, sterilization, pyrogen-free requirements and parametric release.
- E.12. Preparation and quality control of rectal and vaginal dosage forms. Pharmaceutical sticks.
- E.13. Preparation and quality control of dermal and transdermal preparations.
- E.14. Preparation and quality control of ocular, ear and nasal preparations.
- E.15. Preparation and quality control of inhaled and aerosol preparations, foams.
- E.16. Preparation and quality control of peroral powders, granules.
- E.17. Preparation and quality control of pharmaceutical pellets.
- E.18. Preparation and quality control of capsules.
- E.19. Preparation and quality control of tablets.
- E.20. Preparation and quality control of coated dosage forms.
- E.21. Modified release dosage forms. Pharmaceutical technological possibilities for control of drug release, testing, aspects of administration methods. Patient-centric drug delivery systems.
- E.22. Technological aspects of veterinary and other preparations.
- E.23. Preparation and quality control of medicinal products with improved bioavailability (improvement of dissolution and absorption, solubilization, complexation).
- E.24. Preparation and quality control of colloidal systems and drug nanocarriers. Reduction and analysis of particle size.
- E.25. Formulation aspects and quality control of biological pharmaceuticals.

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