**SYLLABUS**

**for the State Exam in**

**PHARMACEUTICAL CHEMISTRY AND PHARMACEUTICAL ANALYSIS**

1. General anesthetics. Inhalational and non-inhalational anesthetics. Local anesthetics.
2. Sedative-hypnotic agents. Anxiolytics (tranquillizers).
3. Antipsychotics (neuroleptics). Atypical antipsychotics.
4. Antidepressants. Selective inhibitors of serotonin and norepinephrine reuptake (SSRI and SNRI). MAO inhibitors. Atypical antidepressants.
5. CNS stimulants. Psychostimulants. Nootropic agents and central vasodilators. Drugs acting on CNS metabolism.
6. Antiepileptic drugs (anticonvulsants).
7. Antiparkinsonian drugs.
8. Opioid analgesics. Natural, semisynthetic and synthetic opioid agonists. Mixed agonist-antagonists. Opioid antagonists.
9. Non-opioid analgesics. Non-steroidal anti-inflammatory drugs (NSAID), antipyretics and antimigraine agents.
10. Parasympaticomimetics. Parasympaticolytics (anticholinergic drugs). Neuromuscular blockers.
11. Sympathomimetics and sympatholytics. Catecholamines. α- and β-adrenomimetics. α- and β-adrenoblockers.
12. Antihypertensive drugs. Calcium antagonists and vasodilators. Angiotensin-converting enzyme inhibitors (ACEI).
13. Diuretics. Cardiotonic (positive ionotropic) agents. Antianginal drugs.
14. Lipid-lowering agents.
15. Antihemorrhaging (haemostatic) drugs. Antifibrinolytics. Anticoagulants. Antiplatelet drugs. Thrombolytic (fibrinolytic) drugs.
16. Antiasthmatic drugs. Bronchodilators. Anti-inflammatory agents. Mast cell stabilizers.
17. Antitussive drugs. Expectorants and mucolytics.
18. Antihistamine and antiallergic drugs. H1 antagonosts.
19. Antiulcer drugs. H2 antagonists. Selective muscarinic antagonists. Proton pump inhibitors (PPI). Antiemetic drugs.
20. Endocrine drugs. Antidiabetic drugs. Corticosteroids. Sex hormones.
21. Antibacterial drugs. Sulfonamides, pyrimidines, quinolones, and nitrofurane derivatives.
22. Antibiotics. β-lactam antibiotics. Aminoglycosides. Tetracyclines. Macrolides. Ansamycins. Chloramphenicols.
23. Antimycobacterial and antileprosy drugs. Antiprotozoal and antimalarial drugs. Drugs for the treatment of amebiasis, leishmaniasis, and trypanosomiasis.
24. Antifungal drugs.
25. Antineoplastic (anti-cancer) agents.
26. Antiviral drugs.

While discussing the above classes of drugs, the candidates must demonstrate knowledge of the following:

1. General characteristics and chemical classification of the given class of drugs;

2. Relationship between chemical structure and pharmacologic action;

3. Chemical structure and INN (international nonproprietary name) of representative drugs in the group

4. Chemical synthesis of a representative drug from the group.

5. Pharmaceutical analysis according to the EU (BP) pharmacopoeia of more significant representatives using the following methods, techniques, and approaches:

* + Spectral methods of analysis: Spectrophotometry in the visible and ultraviolet regions. Infrared spectroscopy. Raman spectroscopy. Nuclear magnetic resonance and mass spectrometry. Applications for the analysis of drug substances and products.
  + Chromatographic methods for analysis. Principles of chromatographic separation. Chromatographic parameters. Types of chromatographic methods. Thin layer chromatography. Gas chromatography. HPLC. Applications of chromatographic methods for the analysis of drug substances.
  + Thermal analysis. Classification of the methods thereof. Differential scanning calorimetry (DSC). Applications of DSC.
  + Quality control of drugs: pharmacopeial methods for testing purity, impurities, and limits for the content of impurities.
  + Basic pharmacopeial identity tests. Ion and Functional Group Identity Tests.
  + Analytical method validation.

***Bibliography***

***Main:***

* D. G. Watson, *Pharmaceutical Chemistry*, Elsevier, 2011.
* D. G. Watson, *Pharmaceutical Analysis, A textbook for pharmacy students and pharmaceutical chemists,* Churchill Livingstone, 2012.

***Additional:***

* ICH Q2 (R1) Validation of Analytical Procedures: Text and Methodology. Harmonized Tripartite Guideline.
* GUIDELINE ON SUMMARY OF REQUIREMENTS FOR ACTIVE SUBSTANCES IN THE QUALITY, PART OF THE DOSSIER (February 2005).
* GUIDELINE ON EXCIPIENTS IN THE DOSSIER FOR APPLICATION FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS, January 2008.