Course Outline for Self-Direct Study in the Discipline of Clinical Pharmacology for the Students Enrolled in 2022 Program: 33.05.01 Pharmacy (Specialist Degree, Full-Time Study) Academic Year: 2025–2026

№	The topic of independent work	Hours
		(academic)
7th semester		
1.	Fundamentals of evidence-based medicine. Clinical drug research: phases of clinical research, the concept of GCP, ethical and legal standards of clinical research, participants in clinical research. Evidence-based medicine: principles, the level of reliability of the evidence, the level of credibility of recommendations. Sources of information about the drug: meta-analysis, randomized clinical trials, reference books, electronic databases, online resources.	32
2.	Independent work control	2
8th semester		
3.	Development of an analog replacement form for an INN-defined precursor drug. Description of the clinical pharmacology of the original drug. Determination of the list of reproduced drugs. Determination of the main characteristics by which drugs are ranked. Justification of the ranking of drugs for analog replacement.	37
	Independent work control	2

Reviewed at the meeting of the Department of Clinical Pharmacology and Intensive Care, Protocol No. 11 dated May 26, 2025.

Head of the Department

May V.I.Petrov