APPROVED BY
Head of Department of
Pharmaceutical technology with a course in
biotechnology – "Ozon Pharmaceuticals"
Partnership Department, PhD, professor
_____ A.V. Kurkina
August 29, 2026

TOPIC PLAN OF LECTURES
ON FUNDAMENTALS OF PHARMACEUTICAL DEVELOPMENT
FOR 5TH-YEAR STUDENTS, 9TH SEMESTER, 2026 - 2027 ACADEMIC YEAR

No.	Hours	LECTURE TOPIC
1.	2	Introduction to pharmaceutical development. Aim and objectives of the discipline. Basic terms and definitions. Regulatory framework. Stages of the medicinal product life cycle.
2.	2	Biopharmaceutics as the scientific basis for drug development. Pharmaceutical factors. Pharmaceutical and therapeutic equivalence of medicinal products.
3.	2	Physicochemical characteristics of APIs. Biopharmaceutics Classification System.
4.	2	Development of the dosage form and composition of a medicinal product. Formulation design considering biopharmaceutical requirements. The role of excipients in ensuring quality and bioavailability. Selection of the optimal dosage form.
5.	2	Development of semi-solid dosage forms using ointments as an example. Specifics of compositions and technologies. Quality control and stability of semi-solid dosage forms.
6.	2	Pharmaceutical development of sterile liquid dosage forms and lyophilizates.
7.	2	Development of modified-release drug products. Principles of delivery system design. Types of modified release (prolonged, targeted, etc.). Methods for controlling release kinetics.
8.	2	The "Quality by Design" approach in pharmaceutical development. Principles of quality-by-design. Quality Risk Management (ICH Q9). Critical quality attributes and critical process parameters.
9.	2	Stability studies of medicinal products. Storage conditions and shelf life of medicinal products. Influence of packaging on product stability.

Head teacher of department, Associate Professor
29.08.2026
L.D. Klimova