Statistical Analysis and Pharmaceutical Operations

1. **Course number and name:** 020ASCCS5 Statistical Analysis and Pharmaceutical Operations

2. **Credits and contact hours:** 4 ECTS credits, 2x1:15 contact hours

3. **Name of instructor:** -

4. **Instructional materials:**
   - PowerPoint slides

5. **Specific course information**

   a. **Catalog description:**
   The course introduces statistical analysis and experimental design methods and their applications in the design and optimization of pharmaceutical processes. Classical statistical concepts and methods will be examined using pharmaceutical examples, including product/process development scenarios, routine testing during manufacturing, finished products, and failure investigations. Regulatory requirements for sample testing, sampling plans, tablet and capsule dosage, content uniformity, hardness, friability, dissolution, and bioavailability testing will be discussed in detail.

   b. **Prerequisites:** 020STACS2 Statistics

   c. **Required/ Selected Elective/Open Elective:** Selected Elective

6. **Educational objectives for the course**
   a. **Specific outcomes of instruction:**

By the end of this course, students will be able to:
- Apply classical statistical methods to analyze data from pharmaceutical development and manufacturing.
- Design and interpret experiments using appropriate statistical tools to optimize pharmaceutical processes.
- Evaluate pharmaceutical product quality through statistical analysis of dosage, content uniformity, and process performance.
- Develop and assess sampling plans based on regulatory guidelines and risk-based approaches.
- Use statistical tools in failure investigations and process troubleshooting.
- Understand and apply regulatory requirements related to pharmaceutical testing (e.g., USP, FDA, EMA).
- Analyze and interpret data from tablet and capsule testing (e.g., dissolution, friability, hardness, bioavailability).

   b. **PIs addressed by the course:**

PI	7.1	7.2
Covered	x	x
Assessed	x	x

7. Brief list of topics to be covered

- Introduction to statistical analysis in pharmaceutical sciences
- Descriptive statistics: mean, median, SD, variance, confidence intervals
- Inferential statistics: hypothesis testing, t-tests, ANOVA
- Design of experiments (DOE): factorial design, response surface methods
- Sampling plans: random, stratified, acceptance sampling in pharma
- Content uniformity and assay testing
- Tablet hardness and friability testing
- Dissolution testing and release profiles
- Bioavailability and bioequivalence assessment
- Regulatory standards: ICH Q6A, USP <905>, FDA/EMA guidance
- Case studies on process validation and failure investigation
- Statistical software tools (e.g., JMP, Minitab) in pharmaceutical applications