GMP Pilot Plant - MUNI PHARM (BioPharmaHub)

Intro

The **GMP Pilot Plant** is a part of the research and development of innovative and generic drugs fulfilling the crucial role in the final **processing/formulations/manufacturing** of active substances into suitable application forms. It represents a small-batch drug/application form manufacturing facility operated under **Good Manufacturing Practice** (GMP), serving to develop drug formulations and **produce small-volume (clinical) batches of drugs**.

Intention

The intention of MUNI realized through the Faculty of Pharmacy activities is to build a **GMP facility to develop and manufacture drug forms and evaluate their quality**. The innovative technical concept of the new facility is **high flexibility in responding to the requirements of a specific project**. The GMP pilot plant will serve the development, evaluation, and production of **liquid, semi-solid**, and **solid drug forms**. The uniqueness of this facility also lies in the possibility of preparing liquid and lyophilized **sterile drug** forms.

The GMP Pilot Plant will be part of the **BioPharmaHub**, where the development and production part itself occupies an area of approximately 350 m^2 and consists of separate production areas of solid, semi-solid, and liquid drug forms (cleanliness class D) and a cleanliness class C area with isolators for sterile preparation of liquid and lyophilized drug forms. The sizes of the **produced batches** will range from **1-10 kg**. An integral part

of this facility will be dedicated **Quality Control (QC) laboratories** with the possibility of pharmacopoeial and in-house developed testing of prepared drugs and stability testing (see below).

Motivation

The entire concept will help **researchers** and **companies** with limited possibilities in **manufacturing** small batches of drugs under **GMP conditions**.

Cooperation

FaF MUNI, through its employees, is a bearer of expertise in the **R&D of application/dosage forms** and already **offers services** and **cooperation** in non-GMP mode:

- research, development, and evaluation of modern solid, semi-solid, and liquid dosage forms
- possibility of cooperation in the areas of pharmacy, cosmetics, medical devices, veterinary medicine, food industry
- consulting activities, formulation proposals
- evaluation of dosage forms, stability testing, analytics

Current partners and projects

- Addicoo – modern veterinary application forms
- Oritest – toxic substance detection tubes
- Oncomed – parenteral lyophilized drugs
- Promed – formulation of innovative solid preparation

Modern GMP facility will have a significant scientific-research contribution. Opportunities will open up for the inclusion of the GMP facility into biomedical research infrastructures. Concentration on applied research/industrial development will contribute to solving the pressing problem of **transferring excellent research results into practice**. In the production/industrial area, the facility will suitably supplement large-capacity manufacturers and has an undeniable commercial potential (reduction of drug evaluation costs). The commissioning of this facility will logically **connect the area of R&D with the industrial sphere**.

Contact

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Production Operations and Equipment - Solid, Semi-Solid, and Liquid Forms

Operations

- Sieving
- Dry & wet milling/milling
- Granulation, compaction
- Spraying
- Drying
- Extrusion/spheronization
- Encapsulation
- Tableting
- Coating of solid drug forms
- Packaging

Equipment

- Vacuum dryer
- Ball mill
- High-shear mixer
- Duplex boiler with heating
- Roller compactor
- Moisture analyzer
- Multi-purpose ERWEKA device
- Rotary/excentric tablet press
- Fluid bed equipment - granulation, drying, and coating (Wurster)
- Tablet/capsule coating device
- Automatic capsule filler
- Extruder and spheronizer
- Tablet evaluation device (height, width, strength)
- Tabletop container filler/tablet counter

Production Operations and Equipment - Liquid and Lyophilized Sterile Forms

Operations

- Wet mixing
- Lyophilization
- Filling
- Hot air sterilization
- Steam sterilization

Equipment

- Hazard box
- Hot air pass-through sterilizer
- Isolator
- Lyophilization device
- Steam sterilizer
- Filling device
- Tabletop bottle capper by crimping
- Sterile packaging welder
- Shaker
- Analytical balance

QC Laboratory (Unit Capable of Independent Operation)

Operations

- Pharmacopoeial methods (F-CH)
- “In-house” methods (F-CH)

Equipment

- BET
- Dissolution device with flow-through cell, USP IV, on/off configuration with UV/VIS (DAD)
- Dissolution device with paddles/baskets, USP I / USP II, on/off configuration with UV/VIS (DAD)
- Helium pycnometer
- HPLC with UV/VIS (DAD) and MS with nitrogen supply from nitrogen generator
- IR spectrometer
- Conductometer
- Laser diffraction (wet and dry measurement)
- Refrigerator, freezing box (-70 °C)
- X-ray powder diffraction
- Stability boxes for 25 °C/60 %RH; 30 °C/65 %RH; 40 °C/75 %RH
- Thermal analysis (differential scanning calorimetry, thermogravimetry)
- UV/VIS spectrophotometer (DAD)
- Analytical balance
- Device for measuring bulk and tapped volume
- Device for determining tablet abrasion
- Device for determining tablet disintegration
- Device for determining flowability
- Vibration sieving and device with the possibility of sieve analysis