



**UPM**<sup>®</sup>  
CRDMO

**CREAMS, CAPSULES,  
GELS, OINTMENTS,  
POWDERS & TABLETS**  
***CLINICAL DEVELOPMENT TO  
COMMERCIALIZATION***

UPM'S mission is to advance Client formulation development efforts to the fullest extent possible with the ultimate goal of commercialization, all while adhering to strict standards of quality, timeliness, scientific fundamentals, and affordability.

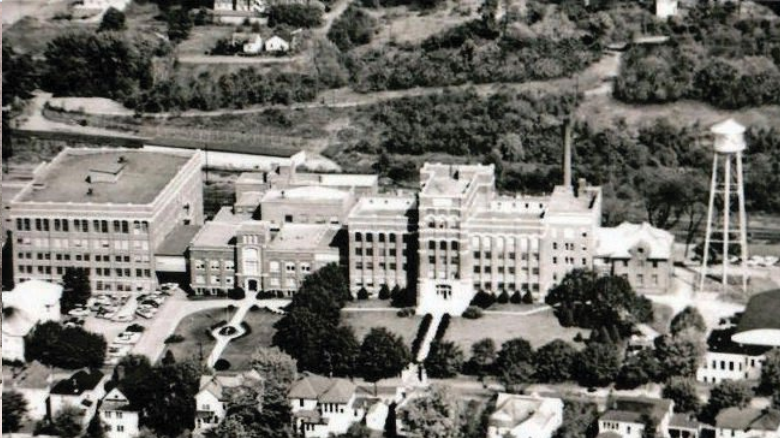




# UPM CRDMO

LARGE & SMALL SCALE PHARMA SOLUTIONS

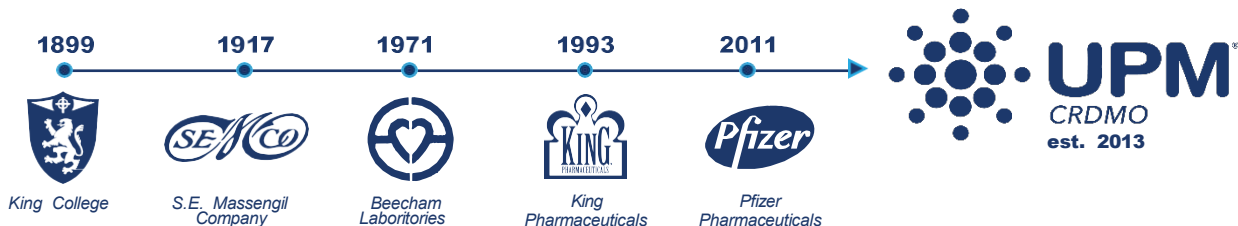
**Bespoke Servicing At Every Stage.** UPM is an independent, USA based, award-winning CRDMO based in Bristol, Tennessee. Offering complete end-to-end pharmaceutical solutions for the development and manufacturing of solid dosage and semi solids. We are an experienced commercial partner, UPM has time-tested procedures in place to optimize production processes wherever you are in your journey. Our history includes successful collaborative interaction with small virtual companies to multi-billion dollar organizations.



## Local Heritage

OVER A CENTURY OF MANUFACTURING HISTORY

The **Bristol, TN Facilities** that UPM currently occupies has over a century of continuous pharmaceutical operation. We continue this legacy of intellectual distinction and uncompromising performance with every new project. The talent and experience of our team, our dedication to science-based formulation design and our commitment to communication and timeliness have enabled us to offer the highest level of customized drug development services to our clients, from concept through commercialization.





# Financial & Organizational Overview

**BIG PHARMA SUPPLIER. AGILE AWARD-WINNING CRDMO PARTNER.**

As a privately owned company, UPM is an independent, highly experienced contract development and manufacturing organization. Autonomously able to make investment and risk sharing decisions focused entirely on the best course of action for our relationship with clients and their projects success.

**UPM has supported more than 85+ compounds with 16+ compounds taken** from concept to market. It's crossing the commercial finish line with our customers where we really excel—and where our greatest passion lies. Whether you're looking to formulate a complex compound or simply in need of a solid commercial manufacturing partner, UPM has the same unwavering objective: to get you to market.

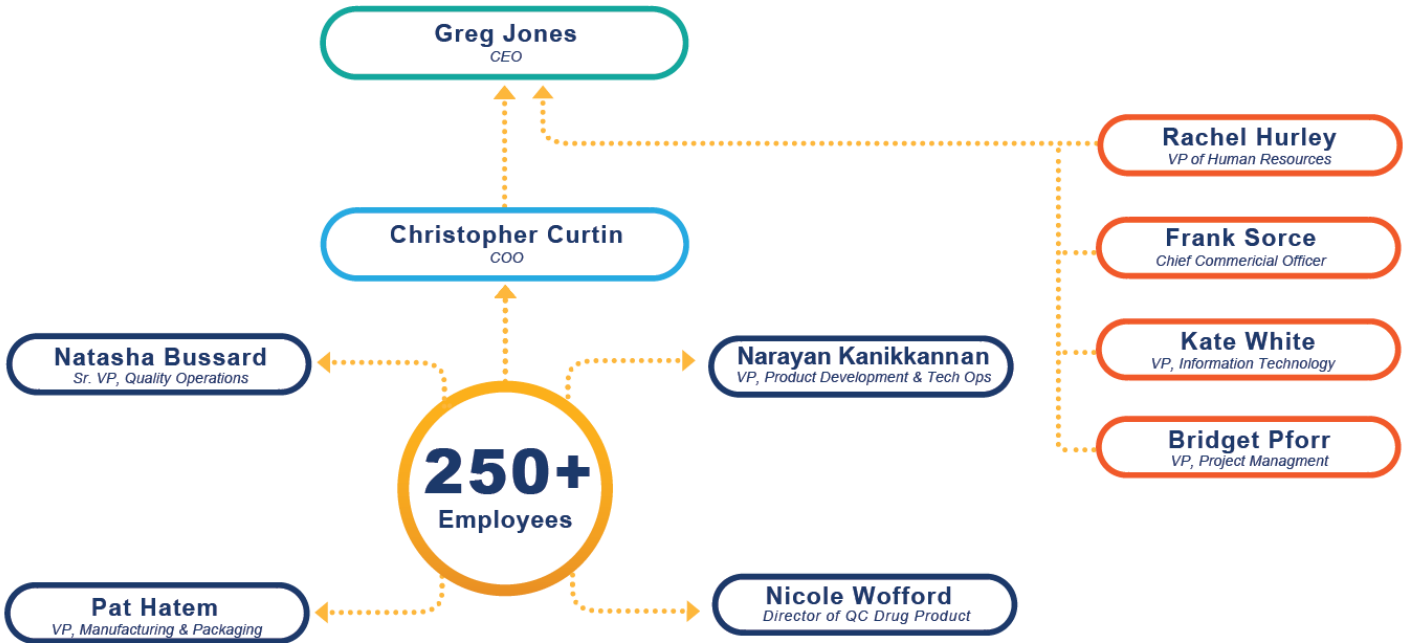
## **No Competitive Landscape**

- UPM does not own any proprietary technology
- Family owned and completely financially independent & stable
- Quicker decisions, better use of resources & timeline adherence
- We are Fee-For-Service, No Partnerships or conflicts with owned products.
- Capital Investment Opportunities: We are always open to discussions on equipment purchases & facility modifications if the project is substantial and both parties agree to investment.



# Corporate Flow Chart

EXPERIENCED PHARMA SOLUTIONS





# Manufacturing & Packaging Facility

## COMMERCIAL MANUFACTURING SITE

UPM conducts large-scale commercial manufacturing and packaging of semi-solid creams and ointments as well as oral solid dose drug product. Offering flexibility and designed to provide full tech transfer and scale-up support, the facility has an extensive track record of optimizing processes to achieve commercial success.

In addition to our production capacity, the site is also equipped to handle analytical, microbial and stability testing, with a full-service, analytical laboratory to support every facet through every phase of development.

### 450,000+ Sq ft Facility

- 240,000 Sq ft for Manufacturing
- 160,000 Sq ft for Administrative Offices
- 35,000 Sq ft for Raw Material and API
- 3,200 Sq ft of DEA Approved Vault Space
- 37,000 Sq ft for Packaging
- 2,000 Sq ft for Label Storage
- Handling Capabilities of OEB 1-5 Potent Compounds



# RESEARCH & DEVELOPMENT

ORAL-SOLID, SEMI-SOLID , POTENT & HORMONE PRODUCT

## Development Scale Equipment

- GEA PMA-1, SeJong SM-50L High Shear Granulator
- Mini-Glatt, Glatt GPCG-2 Fluid Bed Processor, GPCG-30/60
- Alexanderwerk WP 120 Roller Compactor, RFG 150 Granulator
- Vector TFC-LAB Micro Roller Compactor
- Schaefer Lab-Cap Encapsulator
- Sty'l One Multi-Layer Tablet Press
- Korsch XL-100 Tablet Press
- O-Hara Pan Coater (15" to 30") & Vector Freund LDCS Pan Coater
- V-Blenders, 0.5-16 qt., 1-10 cu.ft.
- Fitzmill & Comil - Multiple Sizes
- Ekato LM6, Ekato SRT-80 - Semisolid Processors



# Pharmaceutical Technology

WE CAN TAKE IT FROM HERE

**UPM has a strong legacy of successfully scaling up to commercialization**, maintaining product quality and homogeneity from lab-scale to commercial quantities. We understand you are the greatest source of knowledge when it comes to your project's history as well as your long-term goals. Our multidisciplinary tech transfer team—comprising experts in R&D, manufacturing, engineering, quality and regulatory affairs—will work with you and your teams to understand your project from every aspect, with full transparency into all future activities and open access to all project stakeholders.

## **Pharmaceutical Technology Mission**

*Provide timely, integrated product development and manufacturing support leading to reliable & cost efficient, high quality commercial supply.*



# PharmTech Management

UPM's integrated PharmTech services ensures that resources are closely involved and immediately available throughout the formulation, process development, and tech transfer processes. Whether for trouble-shooting, scale-up, or validation, this integration provides time and cost efficiency for you.

- **Formulation:** *Process Development for Tablets, Capsules, Semisolids & Ointments*
- **Manufacture of Clinical Supplies:** *Registration Batches for NDA's & ANDA's*
- **Technology Transfer:** *Scale-up to Commercial Scale Manufacturing*
- **Process Validation**
- **Trouble-Shooting, Investigations, Manufacturing & QA Support**
- **Technical Writing:** *Batch Records, Protocols & Reports*

## PharmTech Capabilities

UPM has a strong legacy of successfully scaling up to commercialization, maintaining product quality and homogeneity from lab-scale to commercial quantities. Scale-up and tech transfer in the pharmaceutical industry are intricate processes that require cross-functional collaboration and transparent communication to mitigate risks and avoid interruption to a project's progress. In a CRDMO partnership, the expertise of the CRDMO should mirror that of the client's organization to ensure a clear, mutual understanding of all development, manufacturing, quality and regulatory considerations.

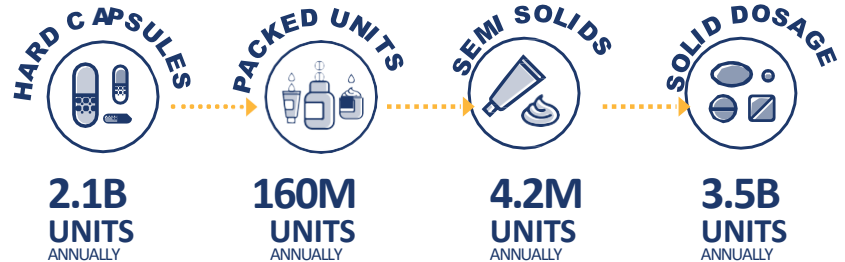
- **Tech Transfer From Bench Scale To Pilot Scale To Commercial Scale Manufacturing**
- **Site Transfer Of Existing Development Or Commercial Products And Processes**
- **Development & Implementation of Analytical & Manufacturing Processes**
- **Process Development, For All Tablet And Capsule Unit Operations**
- **Project Management & Scale-Up Support & Risk Gap Analysis**



# Commercial Production Capabilities

## 3-SHIFT ANNUAL CAPACITIES

Producing over several billion doses annually of semi-solid creams and ointments, as well as oral solid tablets and capsules. UPM serves as a Second-Source Supplier for several name brand, generic, nutraceutical and cosmetic products on the shelf and in the current market today.





## Manufacturing

**BIG PHARMA SUPPLIER. AGILE CDMO PARTNER.**

**Whether your product is oral-solid or semi-solid dose**, establishing the appropriate analytical framework and formulation design is vital to ensuring optimal production at clinical and commercial scale. UPM's manufacturing experts have advanced several complex compounds from concept to commercialization, applying multidisciplinary expertise to develop the best processing conditions and formulation solutions for each unique product.

### **Manufacturing Mission**

*Proactively guide our commercial and clinical partners as their product(s) progress through its lifecycle by working together with forecasting, planning, preparing launch, launch & support of line extensions or new markets gained.*



# Manufacturing Processes

As an experienced commercial partner, UPM has time-tested procedures in place to optimize production processes wherever you are in your journey. With this strong infrastructure, we can quickly devise the most efficient method to commercialize your product, quickly adjusting as necessary and making collaborative decisions that are truly in the best interest of your product and overall commercial strategy.

## Mill/Sift

- Fitzmill (3)
- Trost Mill
- Quadro Comil (5)
- Sweco Sifter (4)

## Granulate

- High Shear Wet Granulator 10, 120, 150 & 800L
- Littleford Day Mixer- 600L
- Glatt GPCG 30/60/GPCG2
- ACG FBE 300/500
- Fitzpatrick IR520 Dry Granulator, PMA-25

## Dry

- Lydon Tray Dryer (2)
- ACG 350/500
- Cascade Tek TFO-3

## Blend

- Bin Blenders 128, 320, 800 & 2100L
- V-Blenders 0.5qt - 40 cubic ft

## Compression

- Fette Press (5) (4 single, 1 Dual)
- Manesty Press (2)
- Korsch 100

## Coating

- O'Hara 15", 19", 24" & 30"
- Accela Cota Coater 48"

## Encapsulate

- MG2/140
- MG Suprema (2)
- MG Planeta
- Capsule Polisher (2)
- Weight Sorter (2)
- Metal Check (2)

## Package

- Solid Dose Bottle Lines (3)
- Lakso 990 Slat Filler
- Bellatrix Vibratory

## SEMI-SOLID

- 450 gallon oil phase
- 500 gallon with in line emulsification
- 2,000 gallon with in line emulsification

## Mixers

- Ekato LM6 Mixer
- Ekato SRT-80 Mixer

## Mixing Tanks

- Portable Tank: 150 & 175 gal.
- Stationary Tank: 300, 500, 600, 2000 gal.

## Package

- Tubes - Kalix Filler
- Jars - Accuro Filler



# Packaging Line Equipment

50-100 BOTTLES PER MIN ON AVERAGE

## Solid Dosage Packaging Lines (3)

**Line 1** - Lakso 990 Slat Filler Capable Of Packaging Solid Dose Capsules And Tablets, w/ Isolated Fill Room For Oxygen Sensitive Product And Nitrogen Flushing Abilities. Capable Of Serialized Aggregation.

**Line 2** - Lakso 990 Slat Filler Capable Of Packaging Solid Dose Capsules And Tablets. Capable Of Serialized Aggregation.

**Line 3** - Clinical Trial/Small Scale Line - Bellatrix Vibratory Filler.

- **Print & Apply Labeler**
- **BANNER Vision System**
- **UV Vision System**
- **ACCRAPLY Labeler**
- **OMEGA Desiccant Feeder**
- **JEKSON Vision System**
- **MSG Outsarter**
- **OMEGA Shrink Bundler**
- **OMEGA Unscrambler**
- **LAKSO Slat Filler**
- **KAPS - All Capper**
- **KAPS - All Tightener**
- **DOMINO Printer**
- **Induction Sealer**
- **NITA Labeler**
- **EDL Bundler**
- **Cottoner**



## Quality Control

SUPPORTING YOU AT EVERY STAGE

**Across all development stages**, we approach every project with a commercial mindset. Analytical development is no exception. Working with you to gain a deep understanding of your project goals and challenges, we design detailed protocols for method development, validation and technology transfer based on your product profile and development phase.

### Quality Control Mission

*Provide a full range of analytical testing services for raw materials and drug products. Design detailed protocols for method development, validation and technology transfer based on the products phase in the drug development process.*

### cGMP Labs

- ▶ 34,500 sq ft of cGMP Laboratory Space
- ▶ 5 Subgroups
  - Analytical Development
  - Raw Materials
  - Microbiology
  - Drug Product
  - QC Metrology



# Quality Control

## QC Laboratory

UPM's Analytical Services Group has deep expertise in analytical method development and a complete understanding of all facets for the analytical testing of pharmaceutical drug products.

### Focus

- Analytical Method Development
- Method Verifications & Validations
- API & Excipient Release
- Full Micro Testing
- Drug Product Release

### Analytical Methods

- Raw Materials & Excipients
- Drug Substances
- Drug Products
- Forced Degradation Including Photo Stability
- Full Stability Indicating

### Full Characterization & Identification

- Raw Materials & APIs
- Drug Substances
- Intermediates
- In-Process Lots
- Finished DP Stability
- Finished DP Release

### Dissolution Testing

*(Apparatus I, II & III)*

- Specialize in Immediate, Delayed & ER Testing
- Fully Compliant with ICH & USP Guidance
- Auto-Sampler Capability For Full Profile Studies
- In-Process & Release Testing



# Quality Control Overview

STATE-OF-THE-ART INSTRUMENTATION

## CHROMATOGRAPHY

### EMPOWER 3 DATA ACQUISITION & INSTRUMENT CONTROL SOFTWARE

- HPLC with Dual Wavelength & PDA Detectors (44)
- UPLC with Dual Wavelength & PDA Detectors (4)
- GC (4 Capable of Headspace Analysis) (5)

### DISSOLUTION BATHS (23)

- Apparatus I & II (21), Apparatus III (2)

### UV SPECTROPHOTOMETERS (4)

### TOC ANALYZERS (3)

### PARTICLE SIZE ANALYZERS (3) FT-IR (2)

*RELIABLE, BRAND NAME EQUIPMENT IN HOUSE:*

 micromeritics

 Malvern  
Panalytical

 Agilent

Waters

DiSTEK



SHIMADZU

varian

PerkinElmer



## Quality Assurance

EVERY RECORD, 24/7 DIGITAL ACCESS

**UPM's Quality Assurance team is fully dedicated** to ensuring that only the highest quality products are manufactured. To accomplish this, quality assurance personnel are fully engaged in the process from start to finish.

### **Quality Re-Assured**

*QA personnel inspect and release raw materials, rooms and equipment prior to production as well as monitor the manufacturing process, perform in process inspections and review all documentation prior to completing material and batch dispositions.*



# Quality Assurance Services

The Quality Assurance team provides product support such as performing annual product reviews and post marketing surveillance. As part of becoming a UPM customer, UPM's document control group ensures that all documents related to your product are readily available 24 hours a day. Each customer is provided access to a customized internal website that houses all master and executed batch records, analytical data, stability reports, technical reports and so on.

## QA Compliance & Systems

- Master Control Administration
- SOP Control
- Data Archive
- BR Issuance
- E-Room Control
- Label Issuance
- Change Control
- Audits, Metrics, APR's
- Stability Chamber Control
- Trackwise Administration
- Complaints
- Vendor Qualifications
- QC Investigation Approvals

### 29 Stability Chambers

- 2,245 sq ft in Total
- 600 sq ft Controlled
- 1,645 sq ft Non-Con

## Manufacturing Support

- MQA Product Support
- Real-time Floor Presence
- Room Release
- Equipment Release
- In Process Inspections
- Acceptable Quality Level Inspections
- Raw Material Release / Sampling
- Component Release / Sampling
- Investigation Approvals
- Batch Record Approvals
- Protocol Review / Approval
- Product Development Support / Approval
- Serialization / Aggregation
- Development
- Stability Work
- Raw Material Handling
- Finished Product

## QA Technical Operations

- Site Investigations
- Compendial Review
- CAPA's
- COS Investigations

## Validations

- Equipment Validation
- Utilities Validation
- Cleaning Validation



# Certified Excellence

As your **Partner in Quality & Compliance**, the QA Department hosts 20+ Client Audits annually & performs internal audits in each of the six pharmaceutical systems.

## Drug Enforcement Agency

Cyclical Inspections: 2013-2024

- *No Notice Of Violations*
- *No For Cause Investigations*
- *Obtained Quota Routinely For Controlled Drug Substances*



## Food and Drug Administration

Cyclical Inspections: 2015, 2016, 2019 & 2024 Last Inspection : SEPT 2024

- *cGMP Inspection*
- *VAI Inspection Classification*



## National Health Surveillance Agency (Brazil)

Inspection: JAN 2025

- *Compliant*



## Turkish Medicines & Medical Agency

Inspection: FEB 2024

- *Compliant*



## Pharmaceuticals & Medical Device Agency (JAPAN)

Inspection: MAY 2024

- *Compliant*



## Ministry of Industry and Trade of the Russian Federation

Inspection: MARCH 2025

- *Compliant*



# Premier Development and Manufacturing Partner for Leading Pharmaceutical and Healthcare Brands



UPM Pharma is an innovative and proven CRDMO with an exceptional growth story



*Delivering  
comprehensive  
and flexible  
development  
and  
manufacturing  
solutions*

**1**

CRDMO with proven commercial track record and specialized capabilities in high-quality drug development and manufacturing services

**2**

Strong focus on high-demand dosage forms including oral solids (tables and capsules) and semi-solids (creams and ointments)

**3**

Large, high-quality U.S. manufacturing footprint with underutilized capacity and significant scalability

**4**

Vertically integrated services to allow your project to stay under one roof

**5**

Integrated PharmTech expertise for seamless scale-up and commercialization

**6**

Strong compliance and quality reputation with an experienced management team and big pharma legacy





# Capital Machinery

## ANALYTICAL

- UPLC & HPLC w/ UV-VIS & Diode Array Detectors
- GC w/ Direct Inject & Headspace Autosamplers
- Dissolution Apparatus 1/ 2 / 3
- Dissolution Autosamplers
- Karl Fischer Moisture Analyzers
- Particle Size Analyzers
- Raw Material Characterization
- Excipient Compatibility Testing
- Solubility Screening
- Impurity Identification
- Hygroscopicity Studies
- Methods Development & Validation
- Class I-V Testing Capabilities
- Full Drug Product Testing
- Stability Testing
- Microbiological Testing

## RESEARCH & DEVELOPMENT

- Styl One Multilayer Press: 1,200 Tablets/hr.
- Vector Freund TFC Compactor: 5g-1kg/hr.
- Mini Glatt: 25-375g Batch Size
- Fitzmill L1A(SS): 360-9000RPM
- Freund Vector LDCS Coater
- Diosna P1-6 High Shear: 50- 1500 g
- V-Blender-PK Blend Master
- Schaefer Lab-Cap 3000: 3,000/hr. shift
- Silverson L5M-A Homogenizer
- Quadro Comil U5
- Fitz Mill L1A

## FORMULATION

- Molecule Size: Small to Medium
- IND, ANDA, NDA
- Phase I,II,III
- Immediate & Modified Release
- Delayed & Sustained Release
- Oral Disintegrating Tablets
- Chewable & Matrix Tablets (Sublingual Tabs)
- Coating: Particle, Powder, Pellets
- Combined Tech
- Registration Batch Manufacturing
- Topical Formulation Development

## COATING

- O'Hara 15", 19", 24", 30"
- Accela Cota Coater 48" (2): 125kg

## BLENDEERS

- V-Blenders: 0.5qt, 1, 2, 4, 8, 16qt
- V-Blender: 1, 2, 3, 5, 10, 20, 40 cubic ft
- Bin Blenders: 128, 320, 800, 2100L
- Pedestal Tote 2992: 128L, 320L,(3) 800L
- Custom Powder Systems Bin (4): 2100L

## MILL/SCREEN/SIEVE

- Fitzpatrick DAS06:(2) All Continuous
- Fitzmill: Continuous
- Quadro Co-mill 194S:(2) All Continuous
- Quadro Co-mill 196S, 197S (2), U5: Cont.
- SWECO Sieve: 18", 24", & 30" sizes
- Russel Finex Sieves:(3) Various Sizes

## DRY GRANULATORS

- Alexanderwerk WP 120x40: 1-5 kg/hr
- Alexanderwerk RFG 150: 1kg Min Batch size (Continuous Feed)
- Fitzpatrick Chilsonator IR 520: 30-50kg/hr
- Fitzpatrick Chilsonator Unit #1 4LX10D (4x10 Rolls):(2) 80-100kg/hr

## WET GRANULATORS

- Mini-Glatt w/ Microkit Insert: 5-350g
- Glatt GPCG-2: 0.75-2kg
- Glatt GPCG-30/60 w/ Wurster: 15-60kg
- ACG FBE 300/500 Combo: 150 kg, 250k
- Diosna P1-6 High Shear: 50-1500g
- PMA-1: 1-3kg
- PMA 150L High Shear: 40-60kg
- PMA 800L High Shear: 150-300kg
- AMF mixer 160qt Low Shear: >60kg
- AMF Mixer 340qt Shear: 100-140kg

## OVENS, FREEZE DRYER, SPRAY-DRYER

- Cascade Tek TFO-3 Ovens:(1) 1-8kg
- Lydon Drying Ovens:(2) 150kg

## FLUID BEDS

- GPCG-2: 3L & 6L Wurster, 6L Drying Bowl Attachment
- Glatt 30/60: 18" Wurster, 68L & 125L Bowl Attachments
- ACG 300/500: 202L & 367L Bottom Spraying, 397L Top Spray/ Drying Bowl, 517L Top Spray/ Drying Bowl

## HOMOGENIZER

- Silverson L5M-A: 1ml-12mL
- BEE International Micro DeBee: 25L/kh
- Silverson LX60C: Continuous Feed
- Silverson 600UHL: Continuous Feed
- Silverson 600UHLs: Continuous Feed

## TABLET PRESSES

- Korsch 100XL Press: 10,000/hr
- Fette 1200i Press: 172,000/hr
- Fette 1010 Press: 100,000/hr
- Fette 2020 Press: 259,000/hr
- Fette 2090 Press: 248,000/hr
- Fette 3030 Press: 1,080,000/hr
- Manesty Diamond:(2) 480,000/hr

## ENCAPSULATORS

- Schaefer Lab-Cap 3000: 3,000/hr shift
- MG Planeta 50: 100,000/hr shift
- MG2 140: 140,000/hr shift
- MG Suprema Powder: 100,000/hr shift
- Felton ProFill: Manual Encapsulation
- Felton Capsule Fillers: 2,000/ hr shift

## TANKS AND VESSELS

- Ekato LM6: 6L & SRT-80: 80L
- Scott Turbon: 200L
- MT-1 Jacketed Processing Tank
- Lee Kettles:(3) 200 Gallons
- Lee Kettles: 300 & 500 Gallons
- Mixer Direct Jacketed:(2) 450 Gallons
- Mixer Direct Jacketed: 2000 Gallons
- Transfer Tanks:(9) 150 Gallons

## PACKAGING

- Auto-Pack For Bottles Line #1: Lakso 990 Slat Filler: <100 Bottles/min
- Auto-Pack For Bottles Line #2: Lakso 990 Slat Filler: <100 Bottles/min
- Auto-Pack For Bottles Line #3
- Bellatrix Vibratory: <30 Bottles/min
- Kalix Filler: 40 Tubes/min
- Accuro Filler: 40 Jars/min

## ANCILLARY EQUIPMENT

- Safelene Metal Detector:(12)
- CPT-200 Dedust/Polish
- Key TD101-WD:(2) Deduster
- Kramer Tower: Deduster
- Pharmatron: Dedust/Metal Detector
- Gratec: Deduster
- Key: Disintegration Tester
- Distek GD-2: Disintegration Tester
- Floflex: Flowability Tester
- Logan TP2: Tap Density Tester
- Erweka AR200: Friability
- Soltax: Tap Density Tester

## OTHER

- Coy Laboratory Products Isolation Glove Box:<5kg Batch Size
- Master Control EDMS System
- Form Weigh: Materials Management System
- E-Room: 24/7 Document Access
- Blue Mountain: Calibration Software
- Scientek Stability Software
- Mini Tab Software: DoE & QbD
- Flow Sciences FS 2024 BKDVA:(2) Ventilated [Work Stations](#)





**UPM**<sup>®</sup>  
CRDMO

**SCAN THE SMART CODE!**  
And Take A Look At Our Facility  
Then, Lets Talk About Your  
Pharma Project Today!



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