Skyepharma

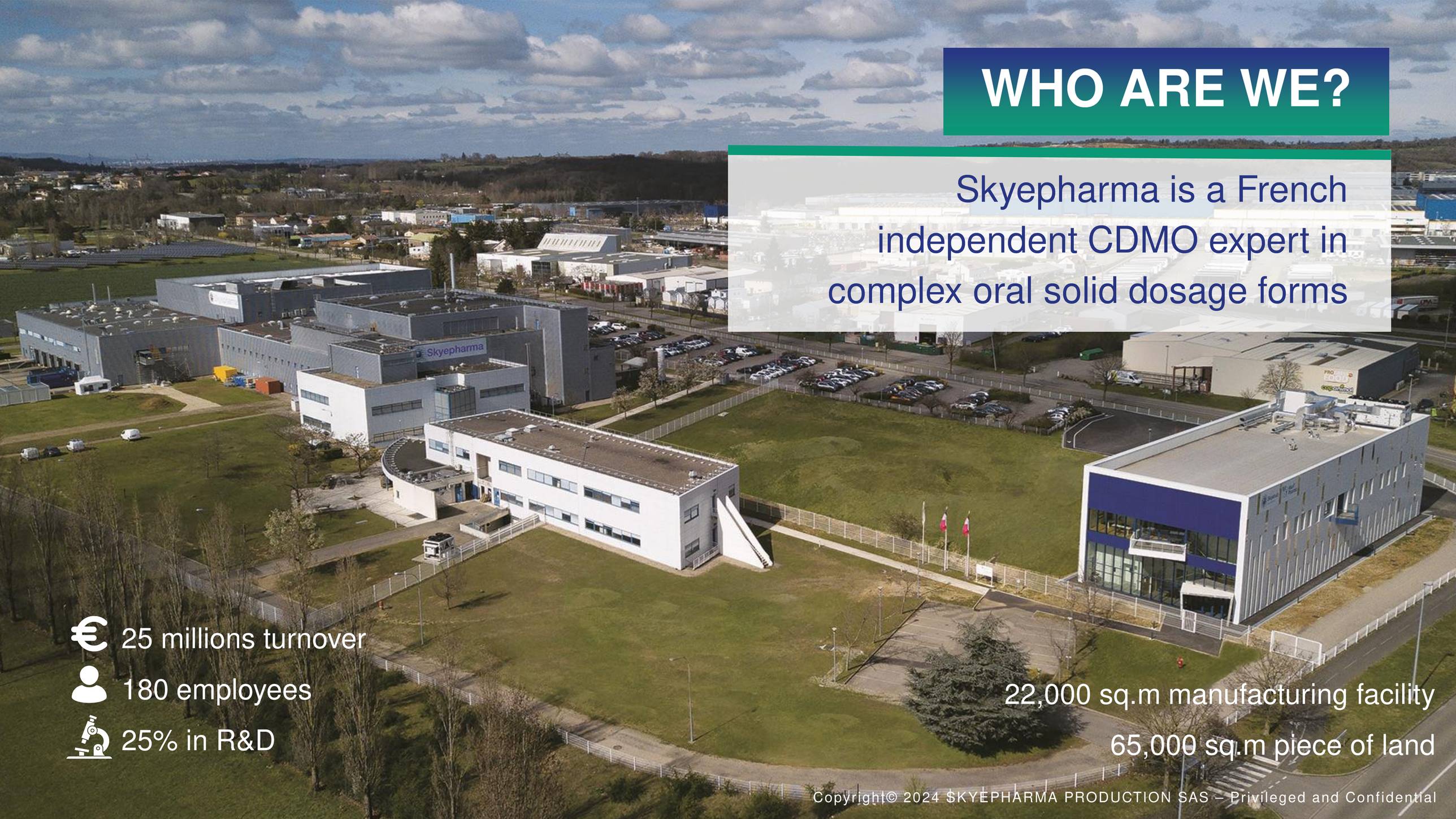
Presentation 2024

# EXPERT AND INNOVATIVE CDMO

www.skyepharma.com

# WHO ARE WE?

Skyepharma is a French independent CDMO expert in complex oral solid dosage forms




€ 25 millions turnover

180 employees

25% in R&D

22,000 sq.m manufacturing facility

65,000 sq.m piece of land

**FDA**
Approved

# OUR EXPERT OFFER IN COMPLEX OSD

## COMPLEX FORMULATION

Multi-layer, mini-tabs, modified release, combo-API

## COMPLEX MOLECULE

HPAPI, oncology, controlled substances

## COMPLEX SUPPLY CHAIN

Orphan drugs, rare diseases, clinical trial material

**GMP**
Certified

# OUR SERVICES

SUPPLY CHAIN

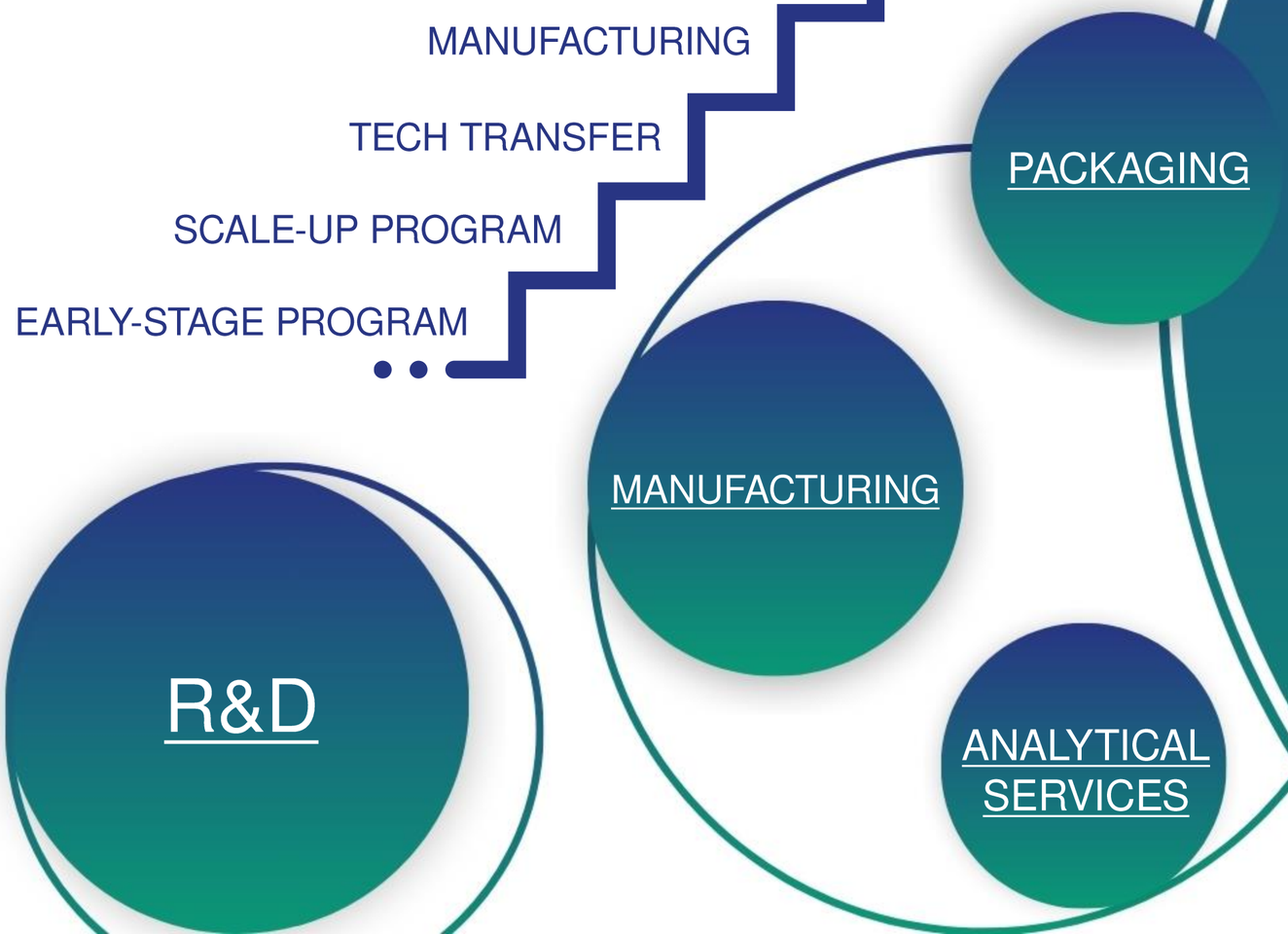
PACKAGING

MANUFACTURING

TECH TRANSFER

SCALE-UP PROGRAM

EARLY-STAGE PROGRAM




# OUR CAPABILITIES

- HPAPI
- MODIFIED RELEASE
- INNOVATION
- CONTROLLED SUBSTANCES
- WIDE RANGE OF BATCH SIZE
  Adapted for rare and orphan diseases

# OUR DEDICATED AND CONTAINED AREAS FOR HIGHLY-POTENT DRUGS (HPAPI)

ONCOLOGY PRODUCTS

NON-SEXUAL HORMONES

# HIGHLY-POTENT PRODUCTS

- R&D, clinical supply and small/mid-size commercial production (up to 70kg batch size)
- OEB 4/5+ molecules, NCE, immuno/oncology drugs
- Segregated area and contained equipment suite

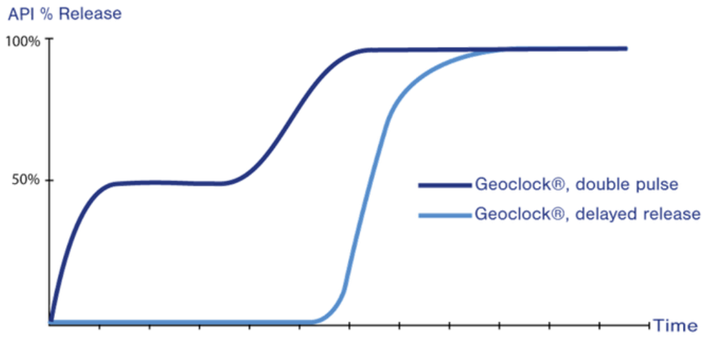
**OPENING IN JUNE 2024**

# NON-SEXUAL HORMONES

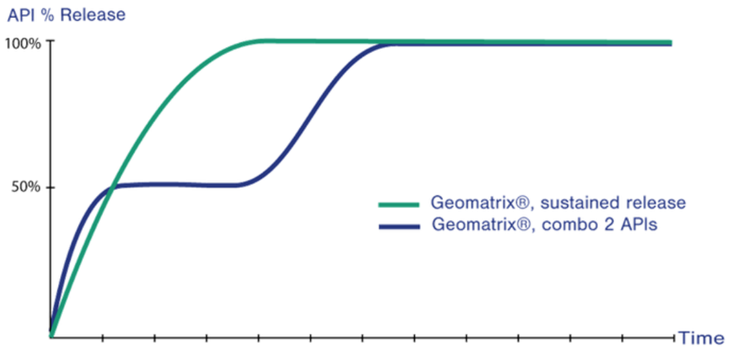
- Commercial production
- Segregated area
- From 20 to 400+ kg batch size

# OUR PROPRIETARY CONTROLLED RELEASE TECHNOLOGIES

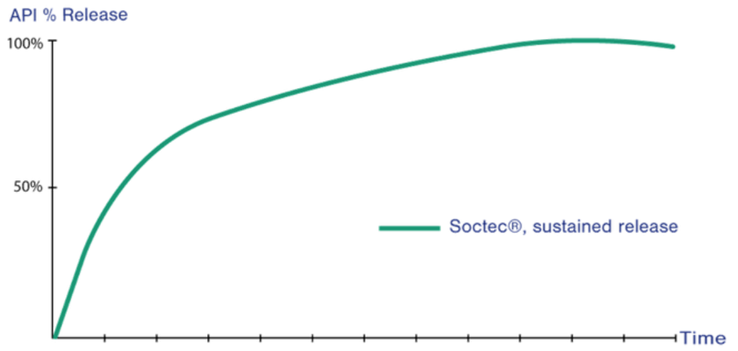
## GEOCLOCK ®
Press-coated tablets




## GEOMATRIX®
Multi-layer tablets




## SOCTEC®
Gastro-retentive capsule



INNOVATION PROGRAMS

# LOOKING FOR...

...biologics in oral dosage ?

**GEOBIOLOGICS™**

...specific colon targeting ?

**GEOCOLON™**

...enhancement of API bioavailability ?

**NANOMICS™**

...API release for more than 24H ?

**MUCOTABS™**

# RESEARCH AND DEVELOPMENT

- R&D LABORATORIES
- CLINICAL TRIAL MATERIAL
- FORMULATION DESIGN
- QUALITY BY DESIGN
- PROTOTYPING
- REFORMULATION & TROUBLESHOOTING

# MANUFACTURING

- AQUEOUS & ORGANIC COATING
- TOP SPRAY
- DRY/WET GRANULATION
- HOT MELTING EXTRUSION
- MICROFLUIDIZATION
- DIRECT COMPRESSION

## TABLETS

Mono-bi-three-layer, tab-in-tabs, press-coated and oral disintegrating tablets, mini-tablets

## CAPSULES

Filled with powder, granules, pellets, capsules, tablets and mini-tablets

# PACKAGING CAPABILITIES

Including serialization and aggregation

## BOTTLE

Plastic and glass bottle
Cylindrical or square
Desiccant - Additional cotton
All types of caps
Bottle width 18 to 90 mm
Caps's width 7 to 50 mm
Bottle height 35 to 180 mm
100% visual counting & inspection

## BLISTER

PVC, PVDC, Triplex / Alu
Alu/Alu
Blister length 70 to 140 mm
Blister width 30 to 86 mm
Depth Up to 12 mm
100% visual counting & inspection


## STICK-PACK

Filled with powder, granules and pellets
Adjustable blister length
Blister width 32 mm

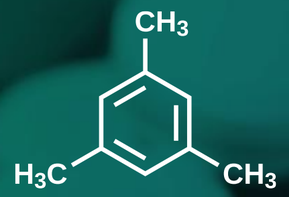
REGULATORY SUPPORT

ANALYTICAL DEVELOPMENT

QUALITY CONTROL

# STRONG REGULATORY TRACK RECORD

# OUR EQUIPEMENT




## FORMULATION SCALE

*50 g-15 kg*

Learn more

## PILOT SCALE

*5-80 kg*

Learn more

## INDUSTRIAL SCALE

*80 kg-3 000 kg*

Learn more


# OUR PRODUCTS ARE COMMERCIALIZED IN US, EUROPE, BRAZIL, ASIA

Skyepharma


## FOR ANY FURTHER INFORMATION

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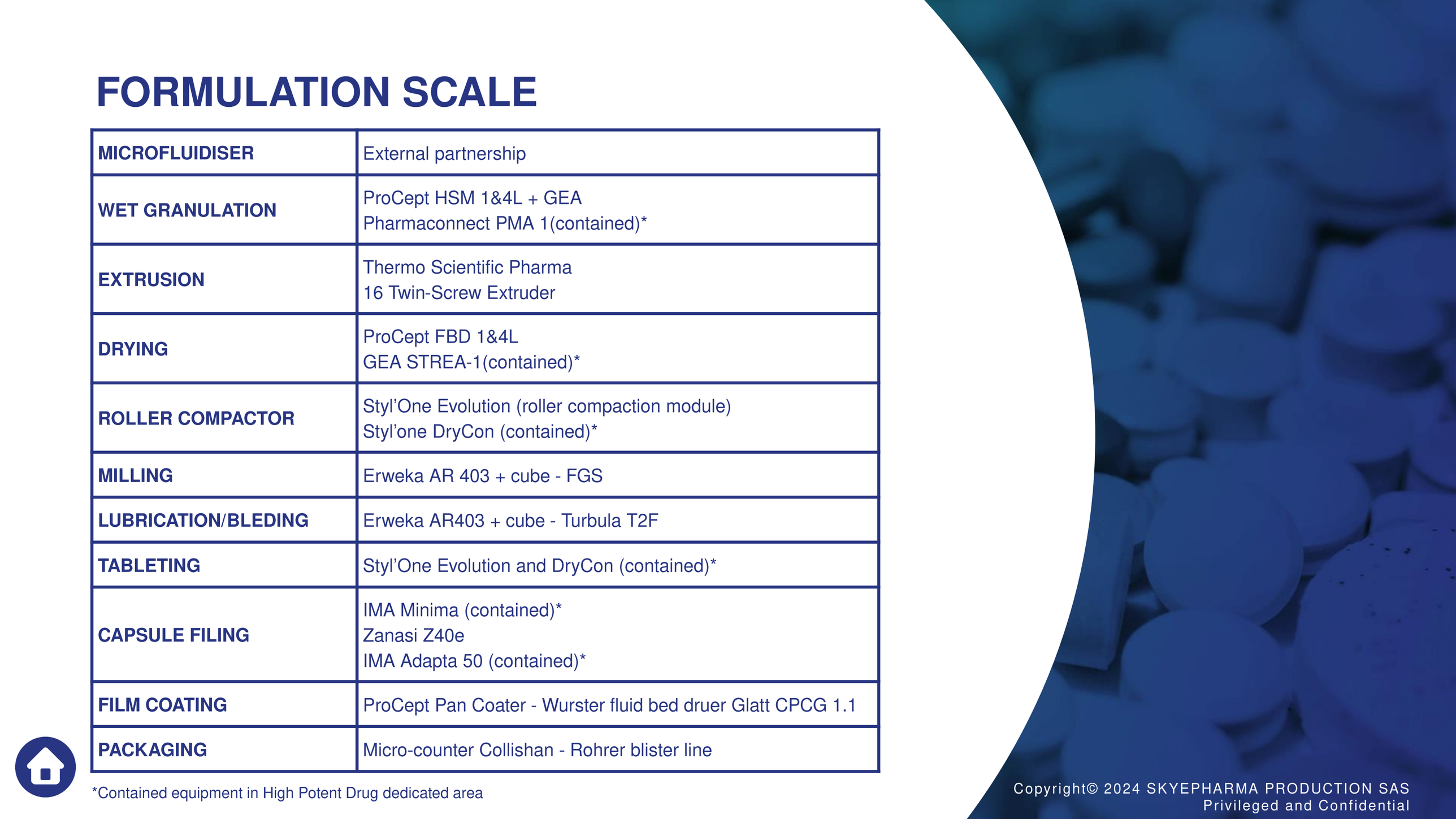
www.skyepharma.com

Follow us on LinkedIn

# FORMULATION SCALE

| | |
|---|---|
| **MICROFLUIDISER** | External partnership |
| **WET GRANULATION** | ProCept HSM 1&4L + GEA<br>Pharmaconnect PMA 1(contained)* |
| **EXTRUSION** | Thermo Scientific Pharma<br>16 Twin-Screw Extruder |
| **DRYING** | ProCept FBD 1&4L<br>GEA STREA-1(contained)* |
| **ROLLER COMPACTOR** | Styl'One Evolution (roller compaction module)<br>Styl'one DryCon (contained)* |
| **MILLING** | Erweka AR 403 + cube - FGS |
| **LUBRICATION/BLEDING** | Erweka AR403 + cube - Turbula T2F |
| **TABLETING** | Styl'One Evolution and DryCon (contained)* |
| **CAPSULE FILING** | IMA Minima (contained)*<br>Zanasi Z40e<br>IMA Adapta 50 (contained)* |
| **FILM COATING** | ProCept Pan Coater - Wurster fluid bed druer Glatt CPCG 1.1 |
| **PACKAGING** | Micro-counter Collishan - Rohrer blister line |

*Contained equipment in High Potent Drug dedicated area




# PILOT & CLINICAL SCALE

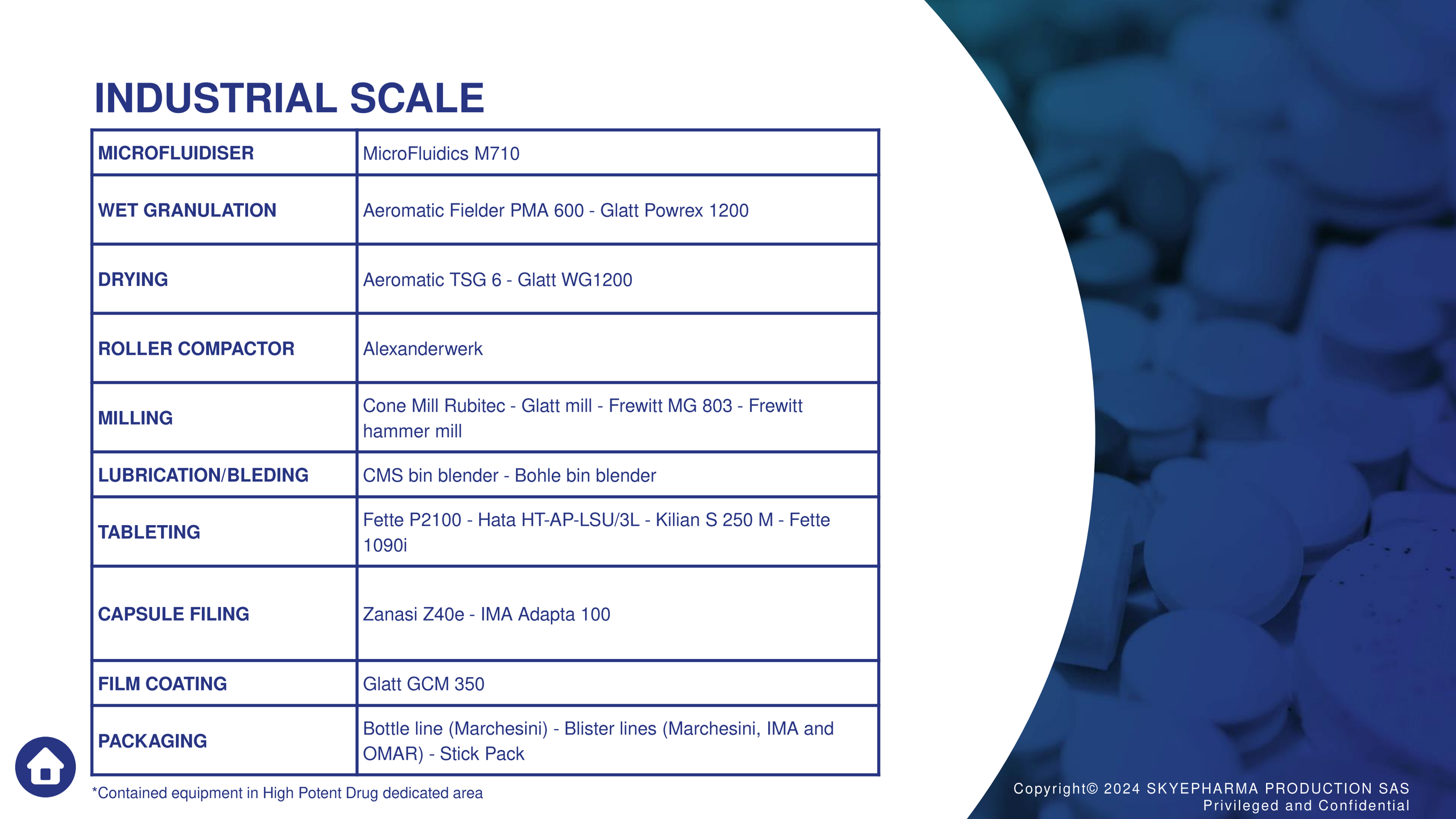
| | |
|---|---|
| **MICROFLUIDISER** | External partnership |
| **WET GRANULATION** | Aeromatic Fielder PMA 25/65<br>GEA Pharmaconnect plus PMA 30 (contained)* |
| **EXTRUSION** | Thermo Scientific Pharma<br>16 Twin-Screw Extruder |
| **DRYING** | Aeromatic T/SG2 B5-F4<br>GEA AirConnect (contained)* |
| **ROLLER COMPACTOR** | Styl'One Evolution (roller compaction module)<br>Styl'one DryCon (contained)* |
| **MILLING** | Quadro Comil 197S - Frewitt MG205 |
| **LUBRICATION/BLEDING** | Bohle bin blender |
| **TABLETING** | Eliza Pilot press (mono and bi-layer)<br>BD Italia contained Pilot press (mono, bi, tri-layer and tab in tab)* |
| **CAPSULE FILING** | IMA Minima (contained)*<br>Zanasi Z40e<br>IMA Adapta 50 (contained)* |
| **FILM COATING** | O'Hara Lab Coat M50 + IMA Perfima Lab coated (contained)* |
| **PACKAGING** | Micro-counter Collishan - OMAR and Rohrer blister lines |

*Contained equipment in High Potent Drug dedicated area

# INDUSTRIAL SCALE

| | |
|---|---|
| **MICROFLUIDISER** | MicroFluidics M710 |
| **WET GRANULATION** | Aeromatic Fielder PMA 600 - Glatt Powrex 1200 |
| **DRYING** | Aeromatic TSG 6 - Glatt WG1200 |
| **ROLLER COMPACTOR** | Alexanderwerk |
| **MILLING** | Cone Mill Rubitec - Glatt mill - Frewitt MG 803 - Frewitt hammer mill |
| **LUBRICATION/BLEDING** | CMS bin blender - Bohle bin blender |
| **TABLETING** | Fette P2100 - Hata HT-AP-LSU/3L - Kilian S 250 M - Fette 1090i |
| **CAPSULE FILING** | Zanasi Z40e - IMA Adapta 100 |
| **FILM COATING** | Glatt GCM 350 |
| **PACKAGING** | Bottle line (Marchesini) - Blister lines (Marchesini, IMA and OMAR) - Stick Pack |

*Contained equipment in High Potent Drug dedicated area



# REGULATORY SUPPORT

We assist our clients in preparing their submissions, support them during product maintenance processes and advise on regulatory strategies, such as for:

- NDA / ANDA / EU-Marketing Authorization Application writing,
- Supplement / variation writing and other lifecycle management activities,
- Answers to health authorities' inquiries and periodic registrations,
- Proactive regulatory intelligence monitoring.

Skyepharma regulatory affairs department is experienced in assisting on projects of all kind of products (health/dietary), markets and specificities.


# ANALYTICAL DEVELOPMENT

•Analysis of all R&D samples and technical batches

•Follow-up of the analysis of the prototyping formulation during the early-stage development

•Evaluation of the deterrent properties of formulations, recommended by recent regulatory guidelines.

•Special support services such as high storage capacities for stability studies :

19 rooms (conditions ICH 25/60 30/65 40/75 30/75, and refrigerated conditions)

•Method development and method optimization (such as liquid chromatography)

•Identification by Mass Spectrometry (Q-TOF)

•Characterization of powders with BET / Particle size analyzer

•Infrastructure suitable for the handling of narcotic drugs or controlled substances.

•Laboratory rooms equipped with yellow light for handling photosensitive compounds

# QUALITY CONTROL

Entire analyses are made according to applicable pharmacopoeias or internal monographs.

•Microbiological controls and chemical testing of API, raw material, IPC and finished product

•Control of production equipment cleaning between each campaign

•Handling and analysis of scheduled substances

•Handling and analysis of light-sensitive products

•Regulatory and documentation upgrade