



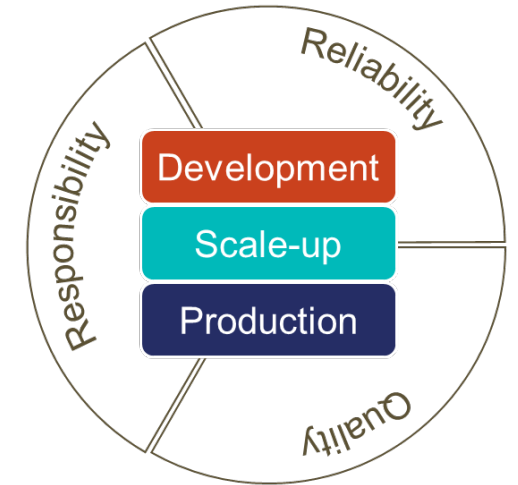
Lundbeck CDM

Padova, Data XXX

Lundbeck Custom Development & Manufacturing

Our Offering

We help our customers be successful by providing diligent development, scale-up and production of small-molecule active pharmaceutical ingredients. We support you throughout development and into commercial phase ensuring efficient processes, high-quality products and a resilient supply-chain design. Benefit from our skilled workforce, advanced technologies and modern facilities.



Our Heritage



Lundbeck was founded in 1915 and for more than 70 years millions of people have benefited from our pioneering therapies. Lundbeck is a global pharmaceutical company recognised for being a specialist in bringing innovative treatments for brain diseases to the market.

As a global research based vertically integrated pharmaceutical company Lundbeck masters the pharmaceutical value-chain. We operate development and production facilities and understand the full implications hereof; such as safety, GMPs, environmental protection and regulatory and legislative adherence.

Lundbeck Custom Development & Manufacturing



- ✓ >20 years experience in Contract Manufacturing of small molecules
- ✓ 6-10 projects handled every year
- ✓ Major Pharma companies but also biotech supported from early stage to commercial launch
- ✓ Approved by all the major authorities

R&D team

27 Employees in total
Director & Deputy / Sn. Specialist

PROCESS R&D

(11 persons)

- ✓ Senior Manager
- ✓ Process R&D Specialist
- ✓ Senior R&D & Process Safety Chemist
- ✓ 8 lab. Technicians

ANALYTICAL R&D

(8 persons)

- ✓ Manager
- ✓ Analytical R&D Specialist
- ✓ 6 analysts

PILOT PLANT /KILOLAB

(6 persons)

- ✓ Manager
- ✓ Senior technician
- ✓ 4 plant technicians (2 shifts)

Active Pharmaceutical Ingredient Facilities

Site Lumsås in Denmark



H. Lundbeck A/S

Oddenvej 182, DK-4500, Nykøbing Sj., Denmark

Site Padova in Italy



Lundbeck Pharmaceuticals Italy S.p.A.

Quarta Strada 2, I-35129, Padova, Italy

Lundbeck API Facilities Information

	Padova	Lumsås
Employees	140	215
Reactors, Stainless Steel	19 (150-6000 litres)	49 (300-6000 litres)
Reactors, Glass-Lined	15 (800-9000 litres)	25 (500-5000 litres)
Reactors, Hastelloy	4 (250-3000 litres)	-
Total Reactor Capacity	140 m ³	200 m ³
Temperature Range	-50 to +300°C	-25 to +150°C
Pressure Range	0 to 12 bar	0 to 10 bar
Dryers	7	12
Milling/Delumping	2	3
Special strength	Micronisation Bromination Thin-film Distillation Hydrogenation	Simulated Moving Bed Chromatography Continuous Production Flow-Chemistry Controlled Substances
Safety, Health & Environmental	ISO14001/45001	ISO14001/45001
GMP Accreditation	EMA, FDA, PMDA, MFDS	EMA, FDA, PMDA, MFDS

New Production Building under Construction

New state-of-the-art production facility to be commissioned by end of 2023.

- Segregated production lines
- Separate personnel and material flows
- Containment level: $1\mu\text{g}/\text{m}^3 < x < 10\mu\text{g}/\text{m}^3$
- Gravity flow vs. horizontal flow
- Separated product handling and maintenance areas
- Future expansion will not affect existing lines

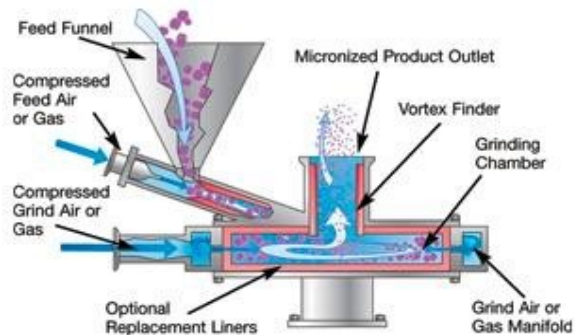
FLEXIBILITY

CONTAINMENT

CLEANABILITY



Jet-Mill Micronisation



Micronisation unit mounted with isolators

All product contact parts manufactured in AISI316 stainless steel

Top plate with possibility to install classifiers of different depth

Bottom plate, with 10 nozzle fittings

Micronisation chamber 10" diameter

Feed type inlet by means of dedicated injector nozzle (with adjustable position)

Milling chamber inlet from top tangential position.

Static classificatory

Interchangeable nozzle set

Continuous Manufacturing

Continuous reaction at Commercial Scale using Flow Reactors:

- Continuous Grignard reagent formation
- Continuous Grignard reaction
- Continuous Diazotization/Sandmeyer reaction



Simulating Moving Bed (SMB)

Continuous Chromatography:

- Continuous closed fully automated production scale unit.
- Suitable for e.g. separation of racemates into enantiomeric pure components.

