



GSK provides contract manufacturing facilities for the production of respiratory products including Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI). The MDI is composed of several components, resulting in a product with a high degree of sophistication and technical complexity. Our DPI, known as a Rotadisk®, is produced in blister doses.

Our micronisation process, which reduces the particle size of the active ingredient to facilitate delivery to the lungs of the patient, requires specific technical expertise and complex technology. Our sites are approved to supply US, EU, and International markets including Japan. GSK is at the forefront of process optimization with the application of methodologies that include Process Analytical Technology (PAT) and Quality by Design (QbD). Our manufacturing has support from comprehensive corporate resources, including Chemistry and Pharmaceutical Development.

Our state-of-the-art equipment for the development of inhaled medicines provides an environment that supports your product at every stage, small scale or exploratory, formulation and process development, commercial process development, clinical Phase I to IIA, and clinical Phase IIB & III.

For over 40 years our quality control analysts have developed a recognized expertise in respiratory physical and chemical analysis. Their expertise covers analytical method development, stability studies, and specific respiratory equipment development.

Molecule to Market — Extending Your Capabilities

Manufacturing Capabilities

- Metered Dose Inhalers (MDI)
- Dry Powder Inhalers (DPI)

Processes

- Dedicated cGMP manufacturing facilities
- Dedicated dispensing room per line
- ATEX (flame proof)
- Environmental control filtration system
- Electronic batch documentation
- Compliant with US, EU, Japan, and International standards
- Respiratory analytical expertise
- X-Ray technology (tomography)

Facilities and Equipment

Micronisation Equipment and Technology:

- 5 APTM micronisers of 4 or 8 inches
- Nitrogen or air grind technology
- Compressed air with dew point - 70°C
- Environmental humidity and temperature controlled
- Capacity: from 3 to 10 kg/hour
- Batch size: from 300g to 7 kg

Metered Dose Inhaler Equipment:

- Dedicated cGMP pharmaceutical manufacturing facility
- 5 production HFA manufacturing lines
- Dedicated dispensing room per line
- ATEX (flame proof)
- Waste treatment
- Environmental control system
- 1 pilot line with the same above characteristics
- 6 automatic packaging lines

Powder Filling:

- 6 blending areas
- 6 filling areas diskus and 6 filling lines rotadisk
- 6 assembly lines diskus
- 5 packaging lines diskus and 4 automatic packaging lines rotadisk

