GlaxoSmithKline

GSK Contract Manufacturing
Solid Dose

GSK provides contract manufacturing facilities capable of producing a wide range of solid dose products from traditional capsules and tablets in any shape and color, and engraving/printing to immediate, controlled and extended release, including bi-layer, tri-layer tablets, and DiffCORE® technology, in high containment facilities when necessary.

We also offer specialized Liquid Dispensing Technology (LDT), a novel manufacturing platform technology developed by GSK to aid in the rapid development and manufacture of low-dose and/or highly potent products. This allows highly potent agents to be manufactured in a respirator-free environment within a conventional manufacturing space, protecting workers and reducing costs.

Our oral high-containment facility is suitable for the manufacturing and packaging of cytotoxic products filled in hard gel capsules. We also have facilities that can produce tablets and products up to OHC5 exposure limits as well as highly-explosive compounds with dispensing, granulation, compression, coating, primary packaging in blister packs and bottles. These multi-product facilities are designed to provide flexible support for all phases from late development to cGMP final commercial production for granulation batches from 10 to 150kg.

Production is performed in highly automated facilities including state-of-the-art technologies such as Manufacturing Execution Systems, SCADAs, Optimized Material Flow and Environmental Monitoring Systems. There is also an outstanding level of automation in the lab and packaging equipment. All these features give us a high degree of flexibility and fast delivery, particularly advantageous for your new product launch.

Our global manufacturing network is engaged in cost effective scale-up activities, launch of new products, and long-term commercial supply. 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.

Molecule to Market — Extending Your Capabilities

Manufacturing Capabilities

- Direct compression
- Capsules
- DiffCORE®
- Liquid Dispensing Technology (LDT)

Processes

- High containment
- Wet granulation (high shear)
- Top spray granulation
- Fluid bed granulation and drying
- Continuous granulation and drying
- Dry blending
- Tablet compression (single and multi-layer)
- Tablet coating (aqueous, solvent based, and enteric)
- Encapsulation and high speed inspection
- Tablet printing
- High speed visual inspection
- Roller compaction
- Hot melt extrusion

Equipment and Facilities

Cytotoxic Facilities

Oral High Containment Facility includes dispensing under controlled environmental conditions, compounding vessels (up to 50L) integrated with isolator technology and an automated volumetric capsule filling system operating up to a speed of 40k CPH.

High Potency Facilities

Equipment includes:

- Granulation - high shear granulator 10-50kg
- Compression - IMA tablet press 75,000-150,000 TPH
- Coating - IMA coating pan 50L-200L

Low-Medium Potency Facilities

Equipment includes:

Granulators (including high shear)

- Niro/Lodige 100-800kg
- Fluid Bed Dryers (Glatt and Fielder) 80-150kg; 130-200kg; 275-800kg
- Microwave granulators and dryer - 130kg

Compression (including bi-layer)

- Fette tablets presses, single and double-sided 3090i (90k-150k TPH and 20k-700k TPH
- Courtoy double-sided bi-layer tablet presses (36k-870k TPH)
- Hata tri-layer press

Coating

- Lodige - 225L
- Glatts (60-110kg; 130-400kg)
- Dria and Vector (350-450kg)
- Accela Cota (220kg)

Encapsulation

- Planeta and Futura Capsule Fillers (33k-90k/hr)
- Impressa Hot Melt Capsule Filler (120k/hr)

GlaxoSmithKline	Direct Compression	DiffCORE®	Capsules	High Containment
SOLID DOSE				
Canada	●		●	
Italy				●
Spain	●			
US	●	●	●	

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