KEMWELL
Keeping You Competitive

GMP MANUFACTURING

Kemwell Drug Substance and Drug Product Manufacturing facilities are audited by reputed global multinational clients, European QPs, former USFDA inspectors and regulatory agencies. A USFDA Pre-Approval Inspection (PAI) for a BLA filing is expected by early next year. As one of India's largest and most preferred contract manufacturer of biopharmaceuticals, Kemwell operates multiple world-class GMP manufacturing facilities for the production of mammalian cell culture based biopharmaceuticals- monoclonal antibodies, fusion proteins, etc.

DRUG SUBSTANCE cGMP MANUFACTURING

Over 4000L of bioreactor capacity is available for both clinical trials and commercial drug substance manufacturing.

Core Competencies

- Mammalian cell culture
- Product types – monoclonal antibodies and other cell culture based recombinant proteins
- GMP cell banking
- Integrated with process development and drug product manufacturing capabilities
- Comprehensive analytical support

Capabilities

- Upstream – Bioreactor train of 80L, 400L and 2 x 2000L stainless steel bioreactors
- Expansion plan for additional 12,000L bioreactor capacity in available shell place
- Harvest – Continuous centrifugation and/ or lenticular filtration
- Downstream – Multiple chromatography and TFF steps; pre-and post-viral segregation – call to action
- Hybrid design – Stainless steel and single use equipment
- Flexible and adaptable to different process requirements
- Designed for purifying high titer cultures
- State-of-the-art equipment with CIP, SIP capability
- Central data management system with 21 CFR part 11 compliance
- Process validation
- Cleaning validation

DRUG PRODUCT CGMP MANUFACTURING

Kemwell provides fully automated final drug product formulation and filling under cGMP conditions as per by the worldwide regulatory agencies including US FDA, EMA, and agencies from other countries or regions such as Japan, Korea, Taiwan, Singapore, Australia and India.

Capabilities

- Both liquid and lyophilization formulation and fill in vials and PFS(planned PFS line)
- Both biologics and aqueous non-cytotoxic and non-antibiotic small molecule parenterals
- Multiple validated container & closure configurations (from 2ml to 50ml)

Liquid Vial Capacity

Vial Size (ml)	Max. Batch Size (vials)
2	42,000*
5	33,600*
10	30,000
20	15,000
50	6,000

Lyophilized Vials Capacity

Vial Size (ml)	Max. Batch Size (vials)
2	29,000
5	15,000
10	13,000
20	8,000
50	4,000

* 1-shift operation; Maximum batch size: 300L (Formulated bulk)

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