

## Case Study: Ranbaxy Laboratories Ltd.

GEA Pharma Systems supplies top-end containment line to Ranbaxy in India for anti-cancer drugs

GEA Pharma Systems has supplied a complete containment line to Ranbaxy Laboratories Limited of Gurgaon in India for the manufacture of anti-cancer drugs with an OEL 1-10 micro gm/cubic meter. The new equipment has allowed the company to develop niche oncology products in a contained environment that protects its workforce and the wider environment from toxic compounds.

The concept began in 2007 when Ranbaxy started to evaluate containment products for use in the manufacture of these highly potent drugs. It was essential that the process prevented any cross contamination in the production area and limited operators' Real Daily Intake (RDI) of hazardous substances to well within the Acceptable Daily Intake (ADI).



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### Selection criteria

During the selection process there were several key features that were essential in the chosen equipment:

- All units had to provide full containment;
- The entire process had to be contained in a single machine to avoid contamination and limit material handling;
- The technology had to be sufficiently flexible to adapt to different products and batch sizes;
- The control systems should allow the process to be monitored using NIR technology during operation;
- Materials should be easy to handle;
- The process should provide the maximum possible yield with minimum wastage;
- There should be a clear and straight-forward documentation procedure.

In addition it was essential to Ranbaxy that its personnel had an in-depth understanding of both the equipment and the relevant containment aspects of the process: the equipment was required to perform well and be cost-effective without unnecessary features or over engineering.

### Single Pot Processing

To meet the requirements for production, containment and whole-life costs, Ranbaxy chose two Collette™ Single Pot processors from GEA Pharma Systems: the UltimaPro™ 10 and the UltimaPro™ 75 (10-L and 75-L processing bowl respectively).

Single Pot technology allows granulation, drying and sizing to take place all within the same vessel. The drying technology is based on vacuum drying at safe low temperatures with optional help of microwaves or Transflo™ (gas-assisted vacuum drying); end point determination is achieved through a torque sensor for granulation & NIR for end humidity; a built-in camera allows operators to view the process without opening the lid; the machine incorporates an in-line Co-mill; and cleaning is performed by a comprehensive fully validatable CIP system.

GEA Pharma Systems has been supplying Single Pot Processors to the pharmaceutical industry for over 25 years and has numerous references for this technology. We have a leading position and a proven track record as system integrator for high containment projects with single pot for oncology and hormone applications.



Figure 1: The UltimaPro™ 75 at Ranbaxy Laboratories Ltd.

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### Operational benefits for Ranbaxy

Since installation the equipment has been performing to the predicted levels of production, containment and operational efficiency. In addition a spokesman said that there had been some areas of performance that had been exceptional including: very effective microwave drying for aqueous feeds; more consistent granule sizes; and much less operator intervention than had been anticipated.

In a recent interview, Lalit Sood, Projects Director for Ranbaxy said that the reduction in the unit cost had opened up the market for the company sufficiently for it to provide a hard-to-resist proposition worldwide. "The GEA technology has allowed us to enjoy security of outcome with the guaranteed quality and consistency we need."

Navin Lakhanpaul the Business Unit Head in India for GEA Pharma Systems said that he was delighted with the project especially as it comes at a time of increased activity for the company in the region. "Ranbaxy represents a very prestigious reference site for us in India," he said. "We are pleased to be working with one of India's premier organisations."

### Ranbaxy Laboratories Ltd

Ranbaxy Laboratories Limited is one of India's largest pharmaceutical companies. It specialises in producing a wide range of high quality, affordable generic medicines, trusted by healthcare professionals and patients worldwide. The move into the manufacture of niche, high-value, low-volume oncology products is a new development for the company, one that would have been impossible without the use of the high-quality equipment supplied by GEA.

GEA Pharma Systems  
Keerbaan 70  
2160 Wommelgem  
Belgium  
Tel. +32 3 350 12 11  
Fax +32 3 353 20 55  
Collettet@geagroup.com



[www.geapharmasystems.com](http://www.geapharmasystems.com)  
[collette@geagroup.com](mailto:collette@geagroup.com)