

Custom Kilo-Lab for Process Development in Pharmaceutical Industry



HIGHLIGHT

Pharmaceutical | Case study

Client Introduction & Requirement

In the highly competitive pharmaceutical industry, every leading Pharma company must continuously adapt, be alert and continue Research and Development. To stay ahead of the competition, companies rely on equipment that is capable, reliable, adaptable, and regulatory compliant.

For decades, GMM Pfaudler Group has been a trustworthy partner for all its Pharma customers. We demonstrated this same commitment when approached by an Indian pharma giant with their requirement for a Kilo-Lab regarding the development of a polymeric material, which is used as an excipient for making drugs.

The Requirement

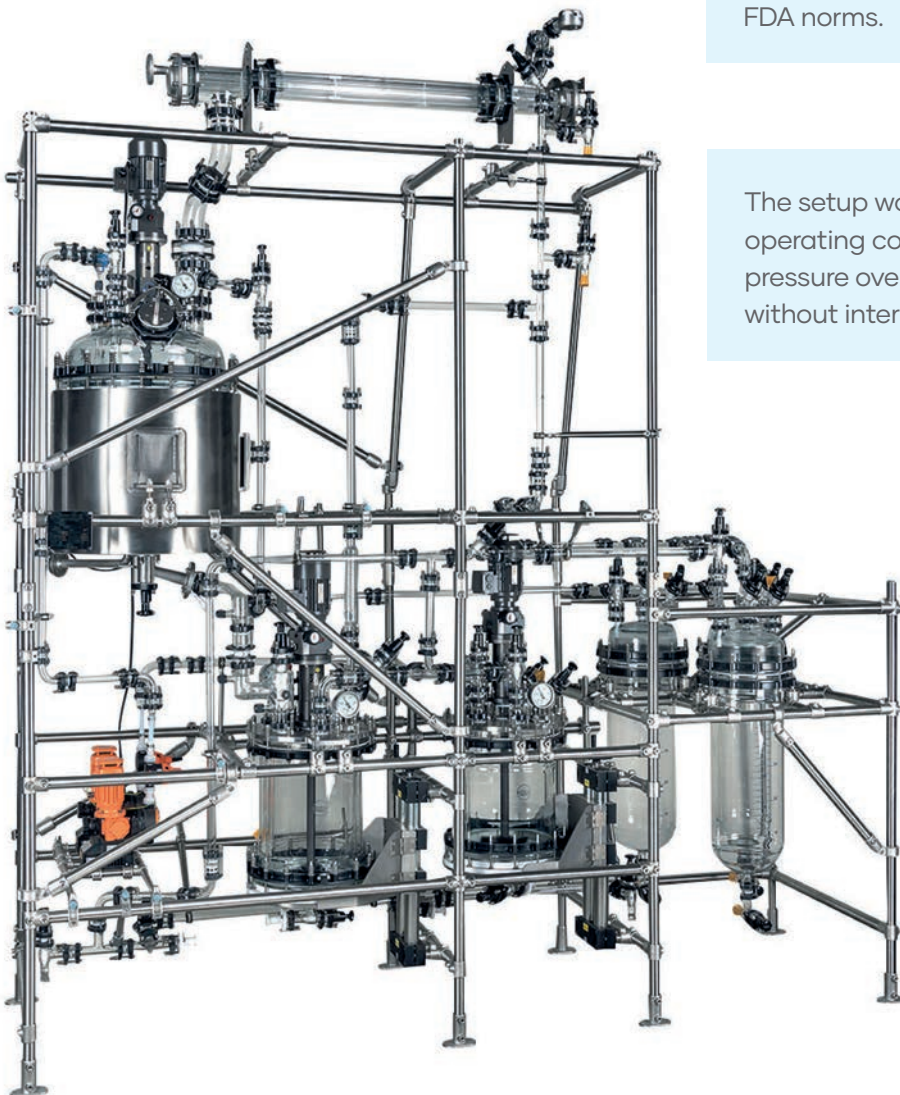
A 63L mild steel glass-lined pan with borosilicate glass cover & overhead assembly.



The reactor would have a heating-cooling arrangement (-50°C to 250°C), high capacity vacuum pump and an automated operation including a 21 CFR part 11 compliant control system, as per FDA norms.



The setup would host a batch with varying operating conditions of temperature and pressure over a period of 30 straight days without interruption.



Our Approach

1.

Our team of engineers and technicians visited the customer to understand their requirements and the parameters that were critical to them.

2.

One key requirement was to accommodate the equipment into an existing cleanroom environment where space was a challenge. GMM Pfaudler Group overcame this feat by incorporating flexibility in the setup supplied by its team.

3.

A second requirement was low temperature application outside of the standard range for glass-lined equipment. We utilized a low temperature carbon steel base coated with a special enameled glass-lining to meet the desired parameters, -35°C to 220°C .

4.

The reactor pan was attached to a flameproof lowering device which can lower the pan by 200mm for easy maintenance and cleaning. In cases of various reactions and mixing requirements, two separate agitator assemblies were also provided to allow necessary flexibility to the customer.

5.

We completed the setup with an all-glass top for the GL reactor pan, overhead condensers (primary and secondary), feed tanks and reflux divider, all supplied by Normag, our high-quality brand of glassware.

6.

The glass assembly needed to be fit with flexible joints to accommodate frequent temperature changes and some manual operations, while keeping the high vacuum intact without any leaks. Our Group achieved this using Normag's PF couplings that allow for minor angular deviations without causing any leaks. The supporting structure for all glass components was provided with cleanroom compatible SS304 hollow pipes.

Factory Acceptance Tests & Commissioning

1.

Integration of all glass parts, instrumentation, automation, testing, etc. were carried out under the supervision of our production department.

A separate protocol was prepared for this unique system by our quality assurance department with support from the end user.

3.

Upon successful FAT, the setup was carefully dismantled, packed and sent to the customer's site where our highly trained service team, completed assembly in the customer's clean room. The unit was then commissioned to carry out site acceptance tests and initial trials.

2.

Several tests including vacuum hold test, running trials of the reactor with water, automation review as per defined test protocol, were conducted.

4.

After completing the tests and trials, the unit was handed over to the customer's operators.

Final Remarks

GMM Pfaudler Group's primary objective is to provide customer satisfaction. Our broad portfolio and skills are instrumental in this endeavor and when it came to the design of this system, we achieved that and a little bit more.

Without any deviations from the required functionality, complete adherence to the FDA norms and, an explosion-proof construction and support, we demonstrated complete commitment to the project and to the customer's needs.

Starting with a "back-of-the-envelope" drawing to commissioning at site, our capable team provided a solution that was flexible, adaptable, and compliant to all regulatory norms, leaving our customer happy and satisfied.



GMM Pfaudler

To learn more about
the case study:
sales-us@pfaudler.com

Find out more at:
www.gmmpfaudler.com

