GMP Peeler Centrifuges Multipurpose Solutions

The Chemicals and Pharmaceuticals Industry has encouraged the development of Peeler Centrifuges because of their configuration and mechanical arrangement. Fine Chemicals and particularly the pharmaceuticals industry needed a machine which allows separating the processing area from the rest of the machine.

The evolution of these industries, the specialization and required versatility of the varied production requirements, pushed the progress of these types of machines. They must not only provide separation of the processing area, but also be able to change batches or products insuring non-contamination of every batch or product. These are the Multipurpose Solutions in GMP Peeler Centrifuges.

Technical solutions and advantages.

In the third generation of RINA Peeler Centrifuges a range of achievements have been researched and included, all focused to only one aim: to enable change of batch or product with a single machine with full guarantee of non-contamination. These machines are fitted with many other safety provisions which, besides insuring the right mechanical performance of every part, minimize the risk of contamination of the products being processed.

At the same time, because of their concept and modern arrangement, any eventual mechanical technical service out of the processing area can be accomplished if required, without affecting the processing area itself.

Moreover, in view that the location of these machines is closely linked to Clean Rooms which are particularly sensitive to any repairs and mechanical services (clean rooms are delicate and they are often built around this type machine once it has been permanently installed on site), the user will get a machine readily suitable for any required action/service on every part, with some additional options to minimize the eventual impact that such a kind of action can have on it, as for example the feasibility of removing the bearing box from the rear side of the centrifuge, and to uphold and remove the basket without needing to set up an lifting device in the process area.
Design guidelines. The three main sections of the machine.

Third-generation GMP Peeler Centrifuges stand out by their global design and they can be clearly split into three well-differentiated areas/zones:
The process zone, the zone where all services assisting the process zone are located, and the rear zone with driving and ancillary equipments of the Machine

The process zone:

The process zone or front part is the “clean” part of the machine where centrifugation of products is accomplished and, if located in a Clean Room, this is the part within the room that will be reachable to the machine operator. The following items are found there: the casing -fully accessible, hydraulically opened/closed and tightened by an inflatable seal (other kind of seals can be mounted subject to particular circumstances in each case) and double-effect hydraulic locks-, the basket, all machined in every surface (100%), the feeding pipe with adjustable outlet section, the washing pipe and the sightglasses for internal viewing. The discharge pipe is also located in this area as well as all services and elements required for the safe control of this part of the Centrifuge.

The services zone:

In this zone, outside the Clean Room, all services assisting the process zone are found and conducted, thus allowing a quick visual checking of a large quantity of elements, guided by a concept of a rational and simple arrangement of all parts of the Centrifuge.

The following items are found here: the hydraulic circuits, the lube unit with its two circuits, the inlet of all cleaning systems towards the process zone, N\text{2} inlet/outlet, the connection and devices for the proper operation of the antagonic blowing system (in those units provided with this device), the liquids outlet pipe, the vibrations sensor, the piping of pneumatic circuits, sightglasses for lubing control, the lip seals and labyrinths check-up provision, etc...
**Rear zone:**

This zone supports all the required elements for the proper operation/driving of the machine. They are devices that due to their own characteristics must be located out of the process zone but in no way are these less significant; located here are the junction boxes with all required electric and pneumatic inlets. The following other elements are also found: the main driving motor, the complete transmission system to the bearing box, the tachometric and static electricity removal system, and the lube unit with its accumulator to ensure the right pressure to the hydraulic circuits at all times.

RINA 700F Series – Rear/Side view

---

**Washing systems for the process area.**

In the process area of the machine we can clearly find two types of washing provisions. Washing of product in process and washing of the machine itself to receive a new batch or a new product.

**Washing the product in process.**

These GMP Multipurpose machines have the required devices to enable the proper washing and discharge of products being processed, consisting of a washing pipe with nozzles covering the complete basket height, the scraper for discharging the centrifugate either assisted by compressed N₂ or not—for a higher efficiency on scraping- and the antagonic blowing of the cake from outside the basket for easy heel removing of those products readily falling-off.

**Washing the machine to start a new batch or a new product.**

These Centrifuges are equipped with several elements and provisions for a fully-guaranteed cleaning of the process area to enter new batches or new products for processing.

Inside the casing there are a set of rinse nozzles and CIP balls to enable its cleaning in the process area. These machines can also get its casing partially filled up (1/3) at the time the basket is turned at a low speed (automatic process programmed at the PLC).

Also, and as a remarkable mechanical feature, the hinged casing enables the 100% opening, thus allowing the easy and complete viewing and to reach all elements inside for any eventual action required either in the casing or its parts.

Nevertheless, CIP System of RINA Peeler Centrifuges is checked by applying the riboflavin test under homologated procedure for final certification of washing system to cover 100% of surface and elements.

Page 4 of 7
**Easy product change.**

The design of these machines, the full access to inside, and the easy (dis-)assembly or replacing of the required elements for a product change, give the most versatility to the whole machine assembly, thus allowing to process different products or batches with a simple, quick and easy operation.

The easy product change is a basic feature of the third-generation Peeler Machines and its complete design is guided to this aim, although in-depth actions can be handled if required as multiple devices and pipes can be disassembled.

![RINA 700F-1000 located in 10000 class clean room](image)

**Safe operation, Complete automation of process.**

Third-generation Peeler Centrifuges are fully automatic machines. That means they allow performing the complete centrifugation cycle, and other operations and functions, without requiring a human action. At the same time, they are provided with all the required safety and control elements that enable the proper operation without needing any action or control on the spot.

GAMP 4 and 21 CFR (part 11) are normal guidelines and standards that automatic Peeler units must accomplish for validation.

Standard built in control systems for the RINA models, the following ones can be outlined:

Pressure control of the hydraulic system acting on the cylinder for opening/closing the casing and lockings. These Centrifuges have an adjustable accumulator tank to maintain the pressure of the circuit without needing to keep the hydraulic unit on. This device ensures the pressure of the circuit and starts up the hydraulic unit when needed.

As for the lube unit the following parameters are permanently kept under control: pressure in the circuit, temperature and flow rate, thus ensuring the proper circulation of oil. There are some visual elements as a thermometer and sight glasses for a quick observation by the operator.

Separate temperature controls of both main and rear bearings, controlled from PLC.
Visual control of the status of dynamic labyrinths and lip seals. These machines allow checking at any time the right status of labyrinths and seals, and they detect any oil leaks before affecting the process zone, and any eventual solvent leak on the bearings thus avoiding getting them damaged. This is an exclusive feature of the third generation of machines.

Pressure control of the N\textsubscript{2} circuits. Also the pressure in the pneumatic circuits is controlled as well as the pressure of the inflatable seal to ensure the proper locking of casing and housing.

Vibrations control. These centrifuges are fitted with a vibrations detector device recording from 0% to 100% admissible vibrations.

All these devices above, joined in unison with the conventional ones, complete the safety system provided for these machines and lead them to the top safety level, at the time they are fully guaranteed as for the fulfilment of all control and safety regulations in force.

**Mechanical safety.**

Safety, reliability and mechanical resistance of all the components is an issue accurately treated in these third-generation Peeler Centrifuges. Not only as for the strength of each part and structure but also for their accurate manufacturing and design and for the adherence of all the elements to the most severe quality controls.

The third-generation of RINA Peeler Centrifuges not only meets all the requirements for GMP processes, but they have only been envisaged for the operators to handle these machines. That means, attention has been paid not only to the control and operation requirements in the process zone (total access, possibility and provision to act on any element, easy cleaning, etc...) but particular care has been applied also in all the issues to provide an easy access, operation, and control.

As a remarkable element, as for safety of these machines, particular mention must be made of the system provided to check the status of lip seals and labyrinths in the bearing box, by means of some intermediate chambers and pipes between the locking system and the main bearing thus enabling to detect any eventual leakage occurring either of oil to the process zone or of product or solvent from process zone to bearings.

**Conclusions.**

Without losing sight of the constant technical and mechanical improvement of these machines, the third generation of Peeler machines meet and exceed the most stringent requirements as for concept, design and GMP requirements, and consequently they are suitable for application in all branches of the chemicals and pharmaceuticals industry. Moreover, because of their configuration, these are extraordinarily improved and reasonably simplified machines, thus making that an apparently simple machine contain all the required elements to accomplish its aim with the highest standard.
Moreover, the easy driving, running, operating and handling actions make these machines be very capable and particularly advisable for processing any kind of products with a single unit and with full guarantee.

However, we can not obviate that, as in all fields, the human factor still remains on the basis of everything, therefore despite here above a fair example of advanced technology has been widely described, we must go on working and hopefully such a factor will give rise to an even better fourth generation...if that is possible...