



Collette



Innovation through Experience



Collette NV was founded in Antwerp in 1892 as a manufacturer of mixers and kneaders for the bakery industry. Over the years the equipment range expanded to cover equipment for other industries, such as the automotive industry and from the early fifties on, the pharmaceutical industry.

From the experience Collette NV has gained in more than 100 years of equipment manufacturing of which more than 50 years for the pharmaceutical industry, constant innovation and improvement has become Collette's trademark. As a reward for our constant focus on quality. innovation and service. Collette NV was awarded the ISO 9001 certificate in 1997 which has been renewed in 2000.

The quality of the equipment, constant innovation and improvement with a focus on service are Collette's major assets. but other factors play an important role in the success of the company. For example our location in Wommelgem, close to the port of Antwerp and the airports of Antwerp and Brussels, allows easy access for customers and easy shipping of equipment. As part of the Niro Pharma Systems Group, we are able to offer many





Process Development Center: Customer Service beyond the Technical Side



A major role in the success story of Collette NV is played by the Process Development Center (PDC).

This fully equipped laboratory offers our customers the opportunity to benefit from years of experience in wet granulation, pelletising and drying processes in high shear mixers and one-pot processors. The staff of the PDC consists of very experienced and dedicated people with a background of engineering, chemistry and pharmacy. They will assist our customers with all questions concerning the process in our equipment. At all times, an Ultima 75 one-pot processor is at the disposal of our customers to test our equipment with their own products. An Ultima 25 one-pot processor is available for rent for customers who prefer to do these tests in their own facilities. Apart from the high shear mixer-processors, a wide range of analytical equipment is available.











Experience: The Gral Range



First introduced in 1975, the Collette Gral high shear mixer granulator is a fine example of the Collette experience in manufacturing high quality equipment for the pharmaceutical industry.

Although the original design is already more than 25 years old, the Gral is still the first choice granulator of many important pharmaceutical companies. The reason for this is that Collette NV has continuously improved its design over the years to make the Gral compliant to the stricts regulations.





Top drive

chines

The basic design of a Gral features a top driven mixer and chopper. This concept, together with the unique bowl shape, ensures a very good rope-type movement of the product in the bowl, offering excellent granulation characteristics. The Gral is available in all sizes from lab-scale to large production ma-

Available capacities

The Gral range offers several options to optimize pharmaceutical production and operation.

Movable head

- · Low position for filling, high position for discharging
- Available on 300, 400 and 600-L machines

Removable bowl

· Fast changeover between batches, low downtime for cleaning

Stand alone or through-the-wall installation

- The through-the-wall installation: Space saving (reduction of expensive production area), GMP (maintenance interventions outside the production area)
- In the stand-alone execution, all mechanical parts are completely covered and sealed, so the machine remains GMP compliant

One-pot system with vacuum drying

Gral in processor execution



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Linking the Gral

For years, Collette NV has experience with integrating its equipment with other process units. Common integrations involve linking a Gral and a fluid bed dryer or an IBC material handling system.

With the incorporation of Collette NV into the GEA Niro Pharma systems group, this service has been expanded by collaborating with the other companies of the same group, who deliver other key technologies such as fluid bed dryers, tablet presses, material handling systems, transport systems and high containment valves. The advantage of being able to offer a complete processing line from within the same group is obvious: one supplier, identical control systems, single point of contact, all of which benefit the end user.







△ Gral 300 movable head linked with Gallay IBC system

Innovation: The Ultima Range

Following our philosophy to be always one step ahead, Collette NV has decided to re-evaluate the Gral design.
As a result, a completely new design of

As a result, a completely new design of equipment has emerged: the Ultima range.

This range can be split into 2 groups: the Ultima - Grals, and the Ultima - processors.

The basic design of mixer, chopper and bowl has not been changed from the original Gral design for 2 major reasons.

- This design has proven its efficacy in more than
 years of intensive use within the pharmaceutical industry.
- Gral customers can easily switch to the Ultima design WITHOUT revalidation.



▲ Ultima 75 swinging bowl
 ▼ Vacuum loading of Ultima 25

 Available capacities

 Size Ultima (liter)
 25
 75
 150
 300
 400
 600
 900
 1200







Innovation: The Ultima Range

The Ultima - Gral

The Ultima is designed in such a way that all outside surfaces are very smooth and thus easily cleaned. All necessary connections, tubes and cabling are completely covered and sealed, to avoid places where dust

collect.
The design of the discharge valve has been modified to allow better and more complete discharging of the product AND the cleaning solutions. This has

further improved the

Ultima range.

WIP/CIP program for the

and contaminations can

The Ultima - Gral can also be linked to other equipment such as fluid beds, as is done with the Gral.



▲ Engineering & innovation ▶ Ultima 600





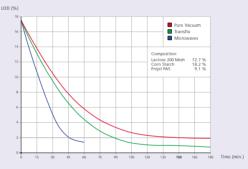


The Ultima - Processor

Due to the current trend in R&D towards more potent drugs, the question of containment has become more and more prominent. High containment levels by use of a one-pot processor enhance both operator safety and product quality and is therefore in many cases THE standard for processing highly potent compounds. The Ultima can be equipped with several drying options to turn an Ultima -Gral into an Ultima processor.

Typical drying curves on Ultima 75

 Influence of the swinging bowl on granulate quality (opposite page)







Innovation: The Ultima Range

Vacuum drying

All Ultima processors are equipped with a very efficient vacuum drying system.

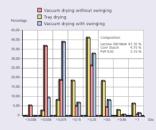
Microwave vacuum drying

This system consists of variable power microwave generators and wave-guides that lead the microwaves to the processor. It is equipped with all safety features and controls to ensure complete safety for product, equipment and operator (e.g. leak tests, product temperature control, arc detection, forward and reflected power

measurement, ...). This drying technique is by far the fastest drying method available in one-pot processors.

Swinging bowl

This feature is the most innovative option of the Ultima-range. During drying, the swinging motion of the processor increases product contact with the heated surface of the bowl. A reduction in drying time, less sticking and better granulate quality due to less agitation from the mixing impeller is achieved. Processing of old formulae with weak granulates is now achievable!



Gas-assisted vacuum drying: Transflo

The **Transflo** system consists of filters located in the bottom of the bowl that are connected to a gas supply (optionally sterile) via transparent, interchangeable tubing (easy inspection, cleaning (optional WIP cycle) and validation). The Transflo system leads to faster, gentler drying.

In short, a full option Ultima - processor is the most complete one-pot processor on the market.





[▲] Transflo system

[▶] Principle of Transflo system

Control Systems



Control Systems

Different types of control systems are available for the Ultima range.

Basic solution

OP/PLC based (standard)
The operator panel
forms a very user-friendly
interface with the machine
and allows you to set any
process parameters and to
check any relevant actual

 For historical trending, a separate paperless recorder, with corresponding software, can be added.

High end version

PC/PLC based, Visual Batch software (available from the Ultima 75 on).



 Software compliant with ISA S88.01 and NAMUR batch processing standards, 3D-process visualization, and unlimited space for storage of recipes.

 The batch information is stored real-time in a relational database.

 This system can be integrated into higher level business and enterprise planning systems such as SAP, etc.



Video camera

 On all Ultima's a video camera can be installed allowing easy visual process monitoring.





Process Technology

Because the Ultima is the most complete one-potprocessor on the market. it does not only execute standard wet granulation and drying processes, but also it offers an enormous flexibility to process and produce difficult products such as:

- Effervescents
- Old formulations (e.g. with starch paste)
- Low binder (thus weak) formulations
- Moisture, heat or light sensitive products
- Vitamins
- Highly potent or toxic drugs
- Etc.

The special features of the Ultima also allow other processes than standard wet granulation and drving, for example:

Steam granulation

 Steam is added via the Transflo filters.

Melt granulation

 Melting of the wax is accomplished by heating of the jacket or by the micro-waves.

Pelletization

 A specially designed pellet mixing arm is available.

Coating

 The liquid addition nozzle is replaced by a special coating nozzle for atomization of the coating agent.

Crystallization processes

Etc.

Process assistance

For all your solutions regarding processes, the PDC team is ready to help promptly. They will assist with any questions about processes on Collette equipment, either on site

the PDC in Wommelgem. Instances of on site support are process reviews tancy in case of technology upgrades, process conversions and new process launches.





Niro Pharma Systems

Collette NV

Keerbaan 70 B-2160 Wommelgem

Belgium

Telephone: +32 (0)3 350 12 11

Telefax: +32 (0)3 353 20 55 Telex: 33 00 9 Collet B E-mail: info@collette.be

E-mail: info@collette. www.collette.be

Niro Inc. 9165 Rumsey Road Columbia

Maryland 21045, USA Telephone: +1 410 997 7010

Telephone: +1 410 997 7010 Telefax: +1 410 997 5021

E-mail: niro.inc@niro-pharma-systems.com

Total solutions for processing pharmaceutical solid dosage forms from one supplier

Niro Pharma Systems was formed by the fusion of Aeromatic-Fielder, Buck, Collette, Courtoy and Callay. Each of these companies offers you equipment that defines the state-of-the-art. Additionally Niro Pharma Systems is able to guide you in the selection of the process best fulfilling your specific requirements and in the complete realisation of the entire project. Niro spray drying systems and the contract manufacturing capabilities of Atlantic Pharmaceutical Services complete the scope.

