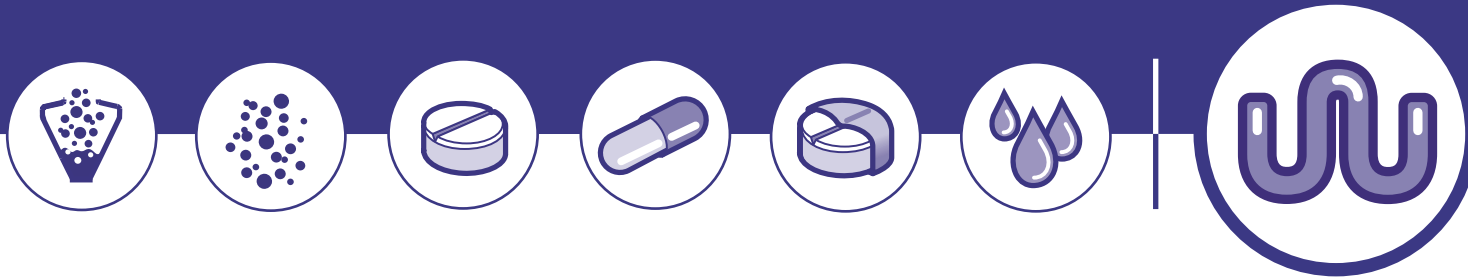


Perfect adaptability for truly continuous production.

IMA enters the Continuous Manufacturing sector with Cromax, a coating machine designed to easily integrate with other machines and guarantee interruption-free production processes.

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Using thorough process control, Continuous Manufacturing (CM) improves production in the pharmaceutical sector in terms of power, effectiveness and safety. According to some estimates, using CM processes enables operational asset effectiveness of over 80% (up to 95-100%). That's a considerable increase in efficiency compared to conventional technologies (20-30%) or lean manufacturing (50%). Even from the point of view of throughput time for pharmaceutical manufacturing (TPT - the time it takes to go from precursor chemical to finished product), the improvements it offers are impressive. Compared to the 2-300 days required by conventional manufacturing methods, CM takes less than 10 days. Yet despite the estimated potential, the market has still not found definitive solutions to exploit this technology. IMA Active, the IMA Group division operating in the design and manufacture of machinery for solid oral products, has entered this sector with Croma, a continuously running coating machine. As explained by Nicola Gandolfi – one of the team of IMA designers that created it – Croma's

key characteristics are modularity, adaptability and truly continuous processing.

What approach did you take when designing Croma?

Let's look at the broader context first. The pharmaceutical industry is certainly pushing for Continuous Manufacturing solutions – due to the advantages highlighted by many studies – but no shared technical solutions and certainly no market standards have yet been identified.

This is a very broad and still largely unexplored scenario. This is why we decided that the main goal of our project had to be adaptability - the ability to integrate easily into a plant - and we based our design on modularity. By that I'm referring mainly to design modularity, which means the machine can be configured to fully meet the customer's requirements.

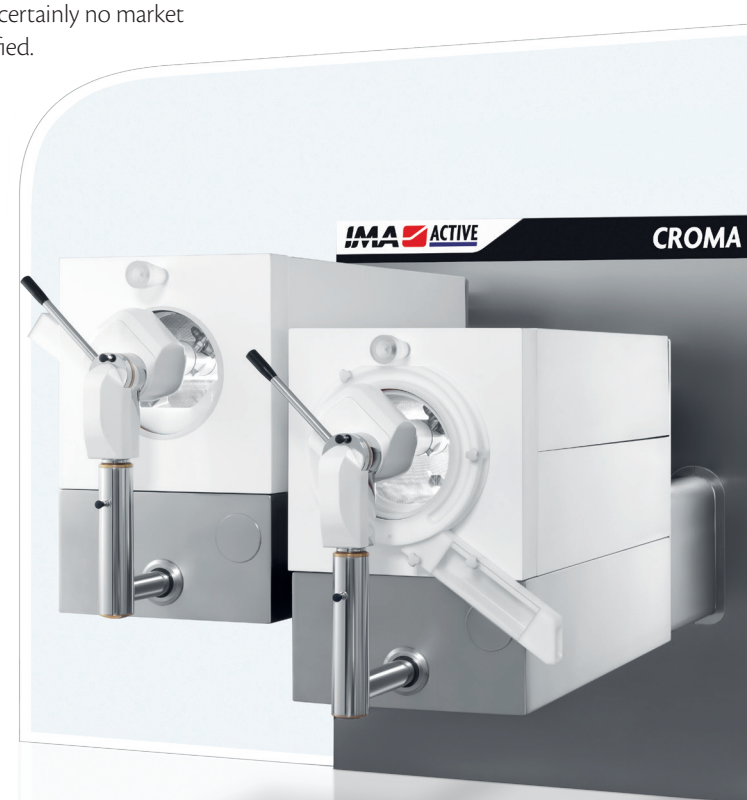
How did you make the machine adaptable?

Croma is adaptable from many points of view: from production capacity to the quantity of coating applied to the possibility of working in line with other equipment. Several modules can also be coupled together, in series or in parallel, thereby increasing production capacity or performing different phases

of the process continuously. We calibrated the output using our tableting machine Prexima 300 - an award-winner for its technological solutions - which has an average output of 300,000 tablets/hour for approximately 60-70 kg. Naturally, Croma can also be adapted to other tableting machines on the market.

What other advantages does Croma offer?

One noteworthy advantage is that it is truly



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continuous. Unlike other solutions on the market, Croma allows tablets to move constantly through the machine, both as they are coated and as they feed along the drum axis. Aside from start up and shut down, the product never stops. This allows us to keep the process parameters constant, without sudden changes, and guarantee uniform product quality. Many of the machines on the market, even going back several years, are actually semi-batch machines requiring consecutive loading and unloading, which of course interrupts the process. Croma, on the other hand, offers a truly continuous process and also allows modular production. This overcomes the limits imposed by the finite volumes of batch technologies. It's one of the fundamental advantages of Continuous Manufacturing that is particularly evident in Croma. Together with modularity, truly continuous is the main characteristic we demanded from our project.

What are the key factors to be taken into account?

There are a lot of parameters that need constant monitoring in order to keep the continuous process going and allow regular and even coating. The most important factor from this point of view is the quantity of product in the drum, which must be kept constant at all times. A significant variation in the quantity could compromise product quality. To achieve this, we introduced a technological solution, patented by us, which adjusts the outfeed flow based on the quantity of tablets at infeed. Knowing how much product is coming into the machine, Croma adjusts the amount going out and thus keeps the quantity of tablets inside it constant.

Is Croma already available on the market?

Just to be clear, this is not a standard machine with fixed characteristics. Because of its adaptability, Croma is configured based on the specific requirements

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of each customer. Each project is developed alongside the customer and involves a high level of customisation. In this sense, Cromax is available and we are already working on specific projects with some customers. The machine can be tested in operation in the laboratory based on specific requirements.

What is its cost compared to conventional solutions?

Given the machine's modularity, it isn't possible to give a single answer to this question.

The initial cost may be slightly higher than the technologies already in use, simply because conventional machines are available in standard formats while Cromax is configured to much more specific requirements. However, this type of technology brings significant benefits because the return on investment is relatively short.

How is cleaning managed on this machine?

Cleaning is an important factor in Continuous Manufacturing because it means the plant has to be stopped and continuity interrupted. Parallel systems can be used, allowing operations on one while the other is being cleaned, but this is not an optimal solution.

Instead, we opted to apply the concept of flexibility to cleaning as well: two approaches are available, which means having two product lines. The first has cleaning operations being carried out in a dedicated area. To facilitate this operation, we designed a machine that makes removing parts extremely easy, similarly to the Prexima in fact. The second product line has a system that can be washed - and dried - as much as possible in place. This system therefore has a minimal number of parts to be removed ■