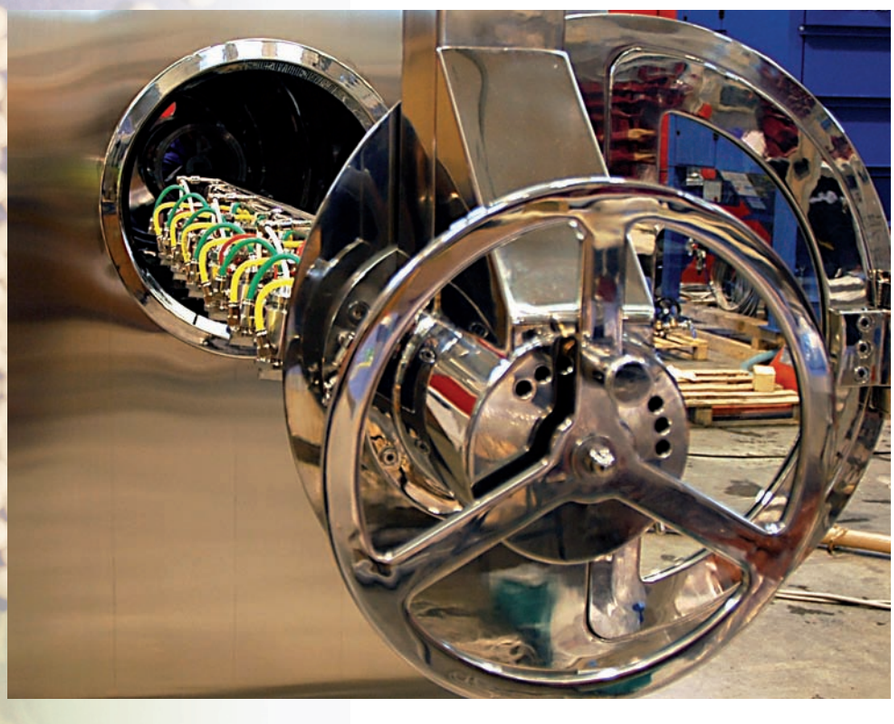
PSC NICOMAC PERFORATED SUPERCOATER

The Nicomac Perforated Super Coater (PSC) combines a unique design with unmatched coating performance.

The PSC is a highly innovative technology with a new design concept that is able to move the coating process, within a perforated drum, into a new era.



Perforated, side-vented pans were developed when pharmaceutical manufacturers moved from sugar and organic solvent-based coatings to aqueous coatings. The first side-vented pan that was launched in the market in the 1970s, was based on a design patented by Eli Lilly in the USA. Since then, this type of technology has become very popular all over the world, its success largely due to the higher drying efficiency created by increasing the interaction between the product being coated and the drying air responsible for removing the aqueous solvent.

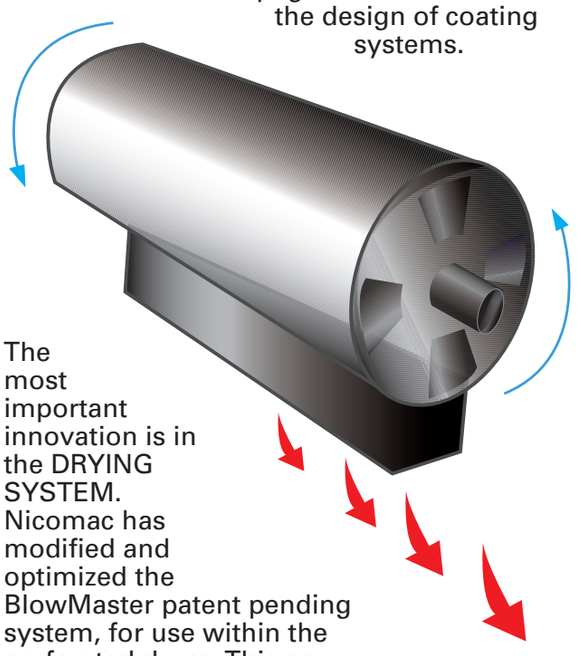
To achieve such a high drying efficiency, compromises must be made. Conventional tablet coating equipment with a perforated drum is designed to use large volumes of air for high-efficiency drying and providing repeatable results. The largest concern when utilizing this technology is the loss of inlet air which is passing through the perforations instead of passing through the core bed, because the air flow is following the path of least resistance. In order to reduce this loss, some use a high negative pressure within the drum to try to redirect the air flow, as much as possible, through the tablets. This engenders higher product loss during the process and a more difficult cleaning operation. Another issue to be considered is the varying position of the core bed throughout the different process phases. In general, the tablets will be in a higher position early in the process, and as they are coated they will slowly fall down to a lower position, the degree depending on the size and roughness of the tablets. As a direct result of this, there is a large waste of inlet air in a fixed system, which will be far away from the core bed throughout a large portion of the process. Moreover, the resulting turbulent airflow can interfere with spray patterns producing uneven coverage and dosing, and again making the cleaning process difficult. This is why it is very difficult to work with a low batch capacity within a conventional perforated drum. In an attempt to compensate for this, many suppliers will offer to change the drum even though this makes the operation very costly, difficult and complicated for pharmaceutical operators.

Another point to be considered is that when a manufacturer was producing pellets, the pellets were passing through the perforations, resulting in the use of the Fluid Bed Dryer as the machine of choice for this process.

To provide an alternative solution to these problems, Nicomac designed and developed their solid wall coater with the BlowMaster, patent pending, air system, as a very good technical alternative to the perforated drum. This system eliminates a lot of the disadvantages described above, and also enables a manufacturer to use a single piece of equipment when working with either pellets or tablets.

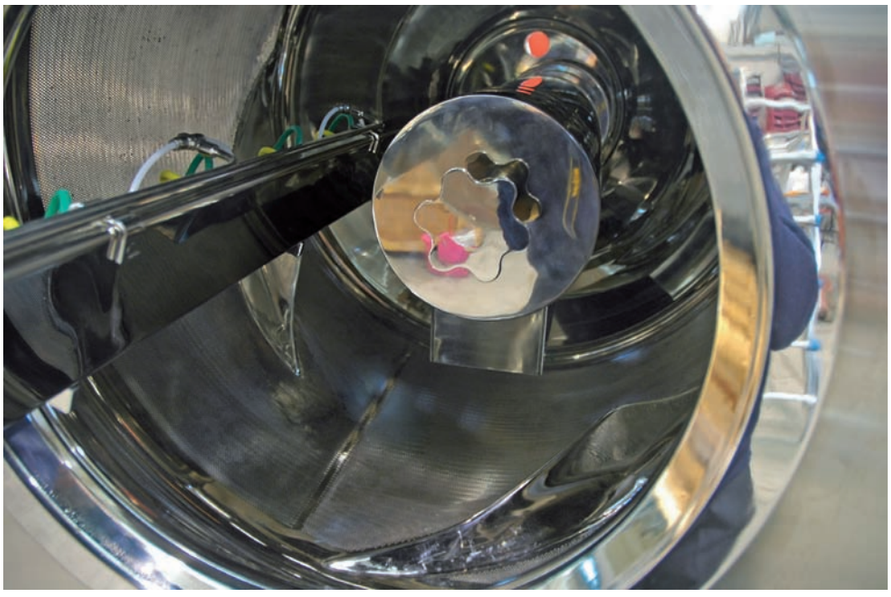
In 2000, when Nicomac developed the solid wall coater with the powder dosing system and BlowMaster – both patent pending – it became an important reference in the market, providing the highest performance technology for both pellets and tablets. However, we must consider that the majority of coater suppliers produce perforated drum coaters. So, for coating tablets, this technology has become predominant in the world market. As a result, many pharmaceutical companies have already validated their product manufacturing using the perforated drum coater, and will only utilize this technology. Over the last four decades, many designers of perforated drum coaters worldwide have introduced machines to the market with some technical improvements, but basically, the technology of air flow has remained the same.

In spite of the success of the solid wall coater, Nicomac, as one of the oldest companies in the field of manufacturing coaters is responding to market demand. In 2009, Nicomac has designed a completely new perforated drum coater. They have drawn from their long experience in this field, and have overcome the problems presented by this technology. The results are impressive, and most probably a new page has been written in the design of coating systems.



The most important innovation is in the DRYING SYSTEM. Nicomac has modified and optimized the BlowMaster patent pending system, for use within the perforated drum. This new device, patent pending N°MI2009A001281, is able to completely change the conventional concept of blowing inlet air within a perforated drum. The BlowMaster is a central air diffuser able to force 100% of the tightly controlled, heated inlet air directly through the product bed itself, just before the spraying area. Air dispersion through the perforations not covered by the tablets, typical of conventional perforated coaters, has been completely eliminated. The angle of the BlowMaster can be programmed and adjusted throughout the process, allowing the flow of the air to be directed to the optimal location on the core bed, in an active response to the position, batch size, and process phase of the product.

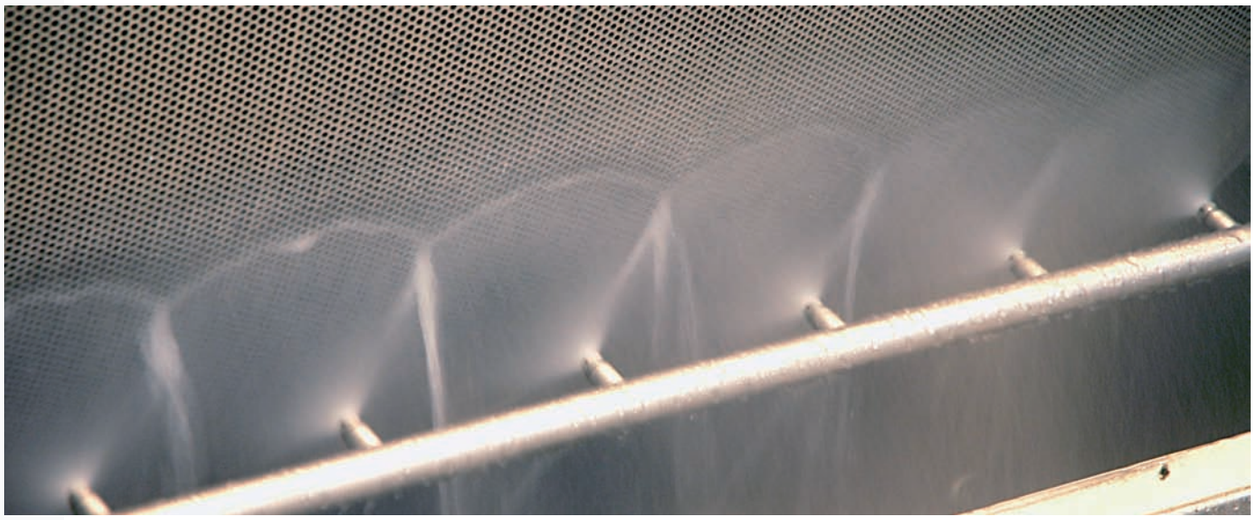
Use of the BlowMaster also provides many other advantages including: a shorter process time; a reduction in utilities consumption of at least 50%; the ability to use the machine at 20% of the batch capacity; a reduction in product loss; and an easier cleaning process.



From the very first trials, Nicomac realized that the performance of the Perforated Super Coater (PSC) was extremely successful in comparison to the traditional perforated, side-vented pans. Please see below the process parameters table of a standard coating process utilizing Opadry II of Colorcon. Nicomac maintained the most conservative parameters in order to get a reliable result that can be improved by even just increasing the concentration of coating solution or increasing the air quantity.
Trials made in the same drum, proves that it is also possible to work with 15-20% of the batch capacity netting the same high performances.

The PSC primary process control was based on a closed loop control of both temperature and relative humidity of the air stream exiting the tablet bed. Depending on the process application, Nicomac chose the most appropriate process control algorithm available. For temperature sensitive products, the bed temperature is closely monitored and controlled.
The Shark Fin ™ baffles, designed by Nicomac in the year 2000, combines higher mixing efficiency with gentler product handling, resulting in perfect coating uniformity. They also reduce overall processing time and allow processing of very low batch capacities.
The spraying system is designed with an easily removable sliding arm from the window that can be automatically driven and folded to reduce the volume of space occupied in the cleanroom. The spray angle can also be automatically adjusted by the control system to suit the process application. Anywhere from 4 to 8 NO clogging guns can be placed, according to the batch size. An EASYMOVE device is fitted to dismantle, the guns' piping for cleaning in a few seconds, without using tools.
At the end of the manufacturing process, a fast and effective WIP-CIP cycle is easily completed. Several spray heads are located inside the coating pan, allowing for maximum flow rates over the entire pan surface, and three different cleaning units are located outside of the drum to guarantee the best and most efficient

cleaning process. Every part can be easily cleaned and inspected, if required, and individual components can be effortlessly removed.
Nicomac's new PSC Perforated Super Coater has been designed to change and twist the conventional thinking of the side-vented pan market. This next generation of equipment is more efficient, effective and valuable, and is ready to leave an indelible mark on the coating process field.



PARAMETERS	NICOMAC PERFORATED SUPERCOATER 400	NICOMAC PERFORATED SUPERCOATER 400
Coating Equipment	350 litres	350 litres
Tablet loaded (kg)	205	56
Solvent Used	Aqueous	Aqueous
Pan Speed (rpm)	9	7
Baffles	Nicomac Shark fin (™) baffles 6	Nicomac Shark fin (™) baffles 6
Tablet bed temperature (C°)	43°-46°	43°-46°
Perforated drum Drying System	Patent pending Blow Master	Patent pending Blow Master
Time to heat up tablets to process temp. Min	7	7
Negative pressure Mbar	0.1	0.2
Spray nozzle (mm)	1.8	1.2
Number Of Spray Guns	6	4
Atomizing air pressure bar (PSI)	3 (43.5)	3 (43.5)
Spray procedure	Continuous	Continuous
Drying air volume m^3/h (CFM)	2000 (1177)	1500 (833)
Inlet air temperature C°	75°	75°
Final Weight gain (%)	2.56%	2.45%
Process Loss	2%	6%
Initial Tablet weight mg	507	507
Final tablet weight mg	519.98	519.43
Tablet diam. mm	11.5	11.5
Spray solution	OPADRY II	OPADRY II
Solid Contents (%)	11.75	11.75
Total Solution in grams	53600	14600
Spray rate (g/min.) average	530	169
Maximun Spray rate (g/min.)	650	175
Technology used to monitor spray rate	Weight loss	Weight loss
Total Spray Process time in Minutes	101	99

NICOMAC

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