



NICOMAC

10 West Forest Ave, Englewood NJ 07631
Phone: +1 201 871 0916 Fax +1 201 871 1720
www.nicomac.com e-mail: SalesUSA@nicomac.com

Quality Implementation Staff (HFD-357)
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science
5600 Fishers Lane,
Rockville, MD 20857

Public Docket # 95D-0349

Dear Sirs,

We are writing to ask the revision of

" Guidance for Industry -SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms"- Manufacturing Equipment Addendum - January 1999 rev. 1"

which is listing the Coating System, manufactured by **Nicomac Srl**, Italy and distributed in USA by **Nicomac, Inc.** in Englewood, NJ, in the subclass of the table 1 of the section VIII only as a perforated system, while the option of a "conventional" system is also available.

Therefore we are asking to have the **Nicomac** listed in the subclass of

The **Table 1 Unit Operation - Coating Equipment**

also as manufacturer of coating system defined in the subclass of

"Conventional system".

Technical Details

Beside the design of coating system using perforated devices which gained the listing in the **perforated coating system** subclass, Nicomac also developed a system, based on the conventional solid wall pan technology, as per the picture on the right hand of this page.





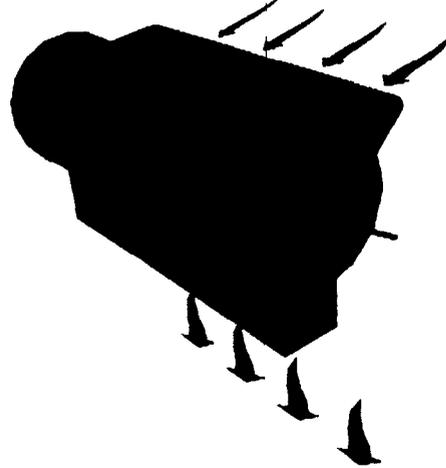
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The drying system in our coating equipment is designed to freely blow the air on the surface of the product .

A telescopic device consent to have the blowing mouth always as close as possible to the product, while a step motor allows for the air direction to be always perpendicular to the product to be dried, while the product bed changes position during the coating process.

The system, using perforated devices, is still available, for particular process or for regulatory related issues.



Feel free to contact me for any further information you may require,

With Best regards,

Francesco Nigris
Nicomac Inc.
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Fax +1 201 871 1720
www.nicomac.com
e-mail: SalesUSA@nicomac.com

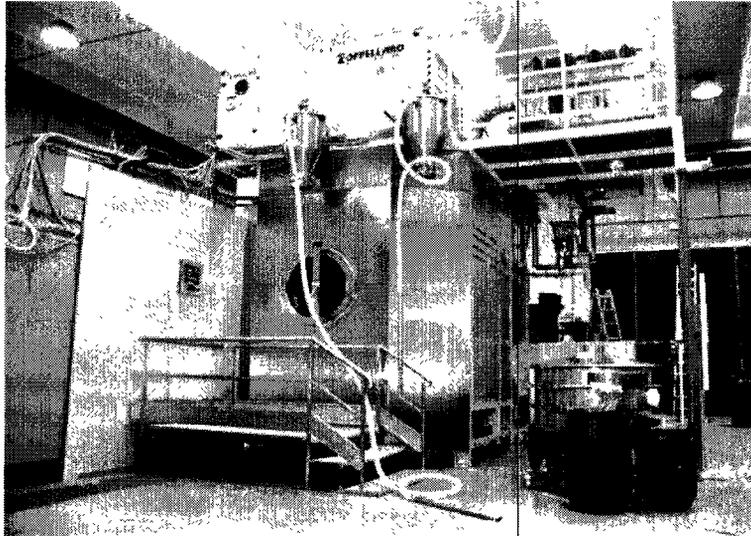


via Cuneil, 12 - 20060 Liscate (MI)
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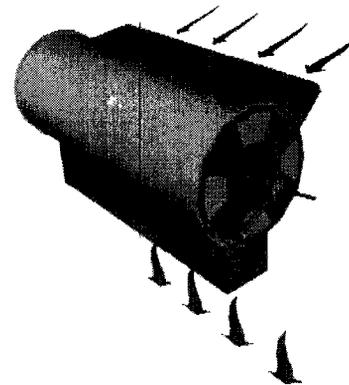
Nicomatic Coating Systems...
THE MOST ADVANCED SYSTEM FOR CONFECTIONERY PROCESSES

The Nicomatic Coating System (NCS) combines a unique design with unmatched coating performance and versatility for today's ever-evolving processing field. Our system has achieved worldwide success in both the Pharmaceutical and Confectionery industries. The following are just a few of the significant features that set us apart from the competition:



- **VERSATILITY** - system is designed for use in confectionery applications and can work with soft and hard coating. NCS can perform **sugar coating** processes with different type of products: chocolate core, nuts, almonds , gum, hazelnut , hard and soft cores, small and big size cores Automatic powder dosing is performed when required either by pressure or electrostatic system. Our special design allow to work with 15-20% of full capacity of the drum

CAPACITY - Whatever your capacity requirement may be, we have a model to fit your application. Models range from a laboratory scale capacity of 10 liters up to a full manufacturing scale of 2,300 liters. One of our big advantages is that, thanks to our special drum design, and our unique drying system we can work with 15-20% of full capacity of the drum with the same high efficiency.

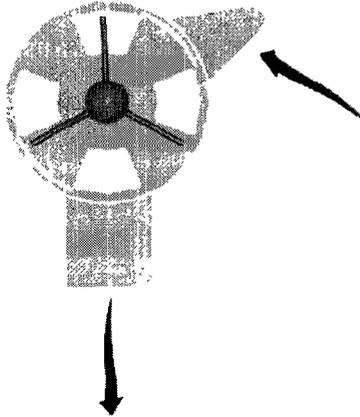




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DRYING SYSTEM - Our Unique highly efficient drying system uses 100% of the tightly controlled process air through the product bed itself for unbeatable performance. Outlet air exhaust slot is placed in the opponent side avoid any kind of air turbulence in the spray zone. To further enhance process efficiency, Drying flow direction is automatically inclined to the core's bed according to the batch quantity, shape of product or phase of the process.. Easy to be cleaned and dismantled. (It. Patent.)

SHARK FIN BAFFLES - Our patented "3D Shark Fin Baffles" combine higher mixing efficiency with gentler product handling to result in improved coating uniformity, thanks to the uniform distribution of spraying solution, thus reducing overall process time.



- **SOLID WALL COATING PANS** - Our coating systems utilize a smooth, electro-polished, non-perforated, solid wall pan. The solid wall design combined with our unique drying system has unsurpassed coating performance. In addition, solid walls make for a more thorough and easier to validate cleaning process.



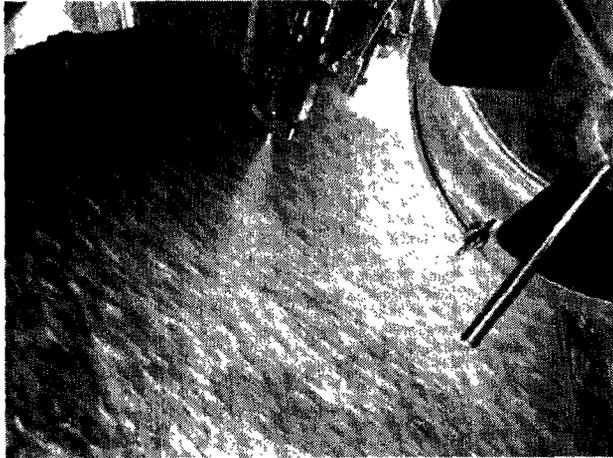
- **MICROLAC CONTROL SYSTEM** - A very sophisticated but user friendly software has been designed by Nicomac. PLC based control system guarantees complete automatic process repeatability. HMI (human machine interface) with touch screen industrial PC for flawless data acquisition and storage. The Microlac software stores up to 40 different recipes with up to 99 discrete phases.



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- **Powder Dosing System** Automatic powder dosing is available either by pressure or electrostatic system. A new patent system avoid any powder clogging while dosing.

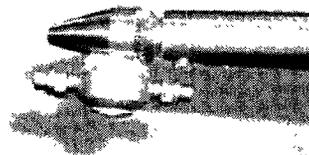
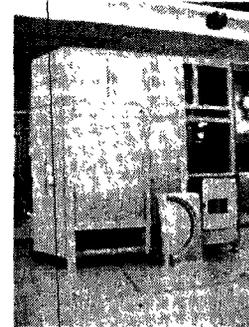


- **It. Patent. SPRAYING SYSTEM** Full body stainless steel guns both for film and sugar coating combined with a perfect mixing guarantee an even and fast distribution of solution on the cores. Guns are provided with intrinsic clogging prevention system. It Patent Sliding arm can be automatically controlled by electric motors with the possibility to preset the

position of the guns in the recipe of the PC.

HUMIDITY CONTROL - Our primary process control is based on closed loop control of temperature and relative humidity of the air stream exiting the product bed. Depending on different application, we have the right process control algorithm available. For temperature sensitive products, bed temperature is closely monitored and controlled. Spraying rate in film coating and Drying Phase in sugar coating can be set on the basis of inlet-outlet Air Humidity

It. Patent THERMOJACKET To avoid any heating dispersion on the external side of the drum. Nicomac has patented a new drying system called: "THERMOJACKET". Part of inlet air is directed to the thermo jacket and it heats or cool down externally the coating pan drum granting a perfect uniformity of temperature distribution into the cores bed, reduces any heat dispersions, optimises the efficiency of the drying phase reducing the process time.

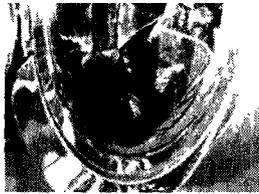


It. Patent CLEANING - Since our coating pans are not perforated, a fast and effective CIP. (clean in place) cycle is easily achieved and cleanliness inspections are easy. A universal skid with 4 ways special spray heads, located inside the coating pan allow the cleaning of every point on the entire pan surface. The high pressure washing pump guarantees a high performance cleaning process. Fast and efficient cleaning is achieved even with enteric and modified release film coating such as Eudragit®. Automatic washing cycle can be stored in the machine HMI (PC).



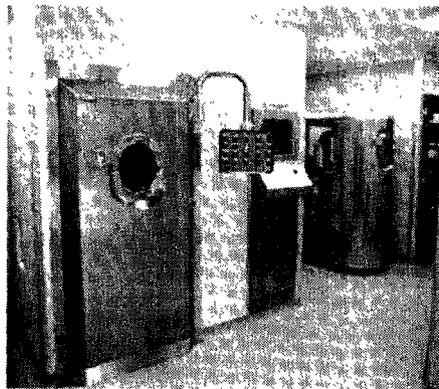
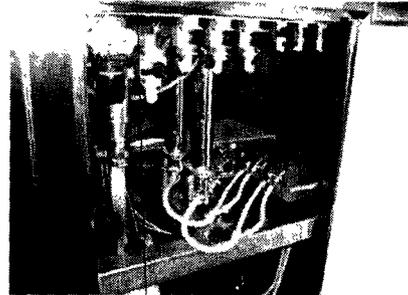
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It. Patent AUTOMATIC DISCHARGE SYSTEM - This patented system unloads finished products as well as CIP fluids by simply rotating the pan via a magnetic, patented, fast connection, unloading chute.

COMPACT DESIGN In order to meet customers requirements and to be able to make better use of their space, we supply customized installation and all process components, as pumps, are contained within the machine enclosure. The unit also has separate operational and maintenance areas.



CUSTOMER SERVICE - Our qualified, service engineers and our experienced coating specialists are available to supply troubleshooting and process training services on-site or in-house trials. We can supply trials, research, development, formulation optimization and small-scale production and production batch up-to 600kg. Critical spare parts are available for prompt dispatch; Nicomac hotline and "on line" technical support are available in the usual prompt "Nicomac way"

ASK ABOUT TRIAL TESTING THE NICOMATIC COATING SYSTEM!

