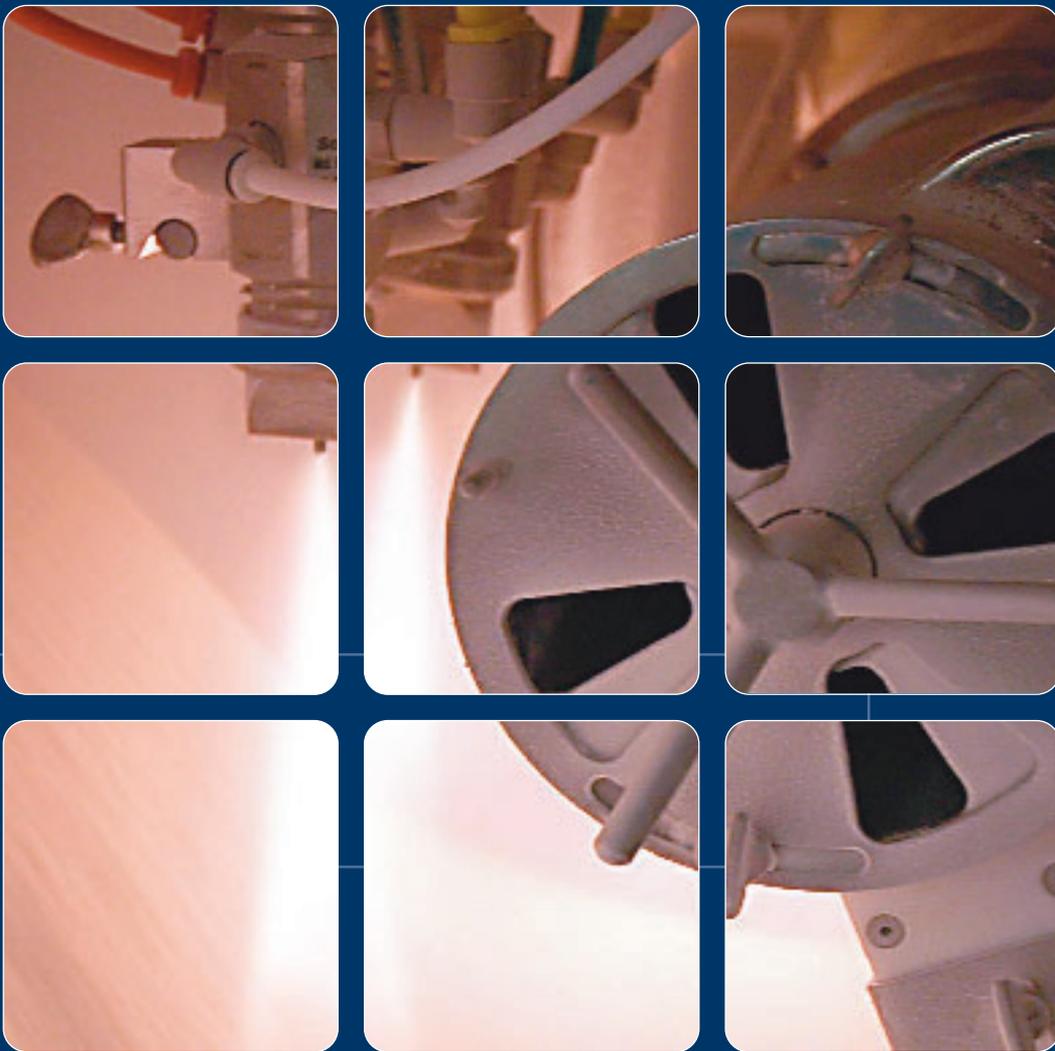


NCS - Nicomac Coating System

COATING POWER



N I C O M A C

NICOMAC COATING SYSTEMS...

THE MOST ADVANCED SYSTEM FOR PHARMACEUTICAL PRODUCTS

The **Nicomac Coating System (NCS)** combines a unique design with unmatched coating performance and versatility for today's ever-evolving processing field. NCS system has achieved worldwide success in both the Pharmaceutical and Confectionery industries. NCS guarantees high-quality products with accurate batch repeatability.

WIDE RANGE OF MODELS

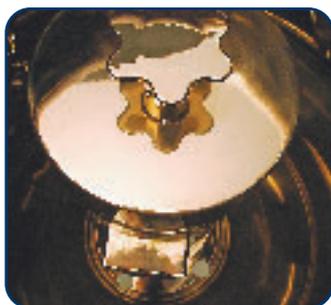
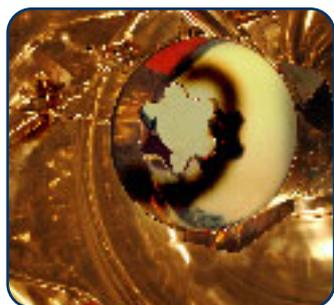
1 kg to 2 tons capacity

NCS 2300 the largest coating machine in the pharmaceutical field.



INNOVATION - PATENTED SYSTEM

Nicomac is constantly working hard to stay "one step ahead" of the competition. NCS commitment to innovation is confirmed by the release of new Patent designs every year as well as several unique devices for Nicomac coating system.



QUALIFICATION AND VALIDATION

DQ (Design Qualification)

IQ (Installation Qualification)

OQ (Operational Qualification)

SQL (Software Qualification)

Calibration and documentation are available for complete validation of the equipment. Nicomac has extensive experience and knowledge in validation services.



CUSTOMER SERVICE

Our qualified and experienced coating specialists are available to supply process training service on-site or in-house trials. Nicomac can supply trials, research, development, formulation optimization, small scale production and production batches up-to 600 kg. Nicomac office provides spare parts and service for our entire line of equipment and can dispatch sales or service engineers as needed at a moment's notice. Nicomac, maintains a technical support hotline and is available for on site or "on line" technical assistance consistent with the Nicomac philosophy of prompt service.

SOLID WALL COATER

Solid Wall Coater Nicomac coating systems employs a smooth, electropolished, nonperforated, solid wall pan. This allows technical advantages not seen in competing coaters.

VERSATILITY

NCS is capable of performing a variety of functions within one machine; these include: sugar, aqueous, and organic film coating, without any parts being changed. NCS can coat with high quality: tablets, losanges, minitabets, pellets, granules, and sugar seeds.

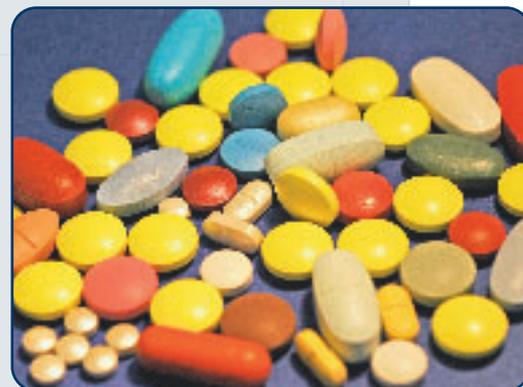
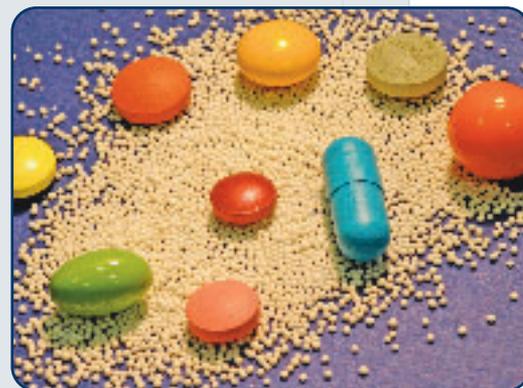
UNIQUE PERFORMANCES Thanks to NCS specially designed NCS drum and drying system, NCS can be loaded with 10-15% of drum capacity without any modifications with the same quality of the finished product.

The solid wall design combined with NCS unique drying system has unsurpassed coating performance. In addition, the solid wall pan allows easier and faster cleaning and perfect mixing that avoids any possibility of Cross Contamination.



SHARK FIN BAFFLES *IT. PATENT N° MI 2004A001949*

Nicomac "3D Shark Fin Baffles" were developed from years of experience and testing through electronic models and trials. NCS combines the highest mixing efficiency with very gentle product handling that guarantees an even distribution of spraying solution, thus reducing overall process time, and guaranteeing high yield and the finest product quality.



THE BEST MIXING FOR A COATING PROCESS

Mixing is one of the most important issues for coating processes. NCS has the best mixing performance for a coating process. Nicomac unique baffle design is suitable for any type of product, any batch size or process. No spare baffles are required.

DRYING SYSTEM

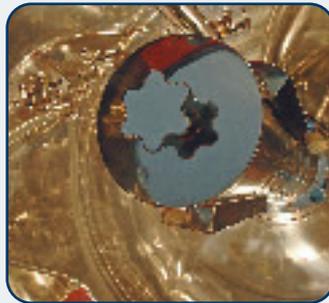
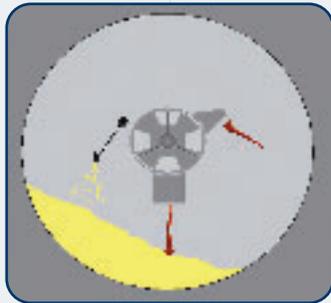
BLOW MASTER

It. Patent Drying System *IT. PATENT N° MI 2003A002542*

Blow Master is a unique highly efficient drying system using 100% of the tightly controlled process air through the product bed itself for unbeatable performance.

Outlet air placed in the opposite side avoids any kind of air turbulence in the spray zone and allows the best air flow and the best drying efficiency.

Drying flow is automatically oriented to the core's bed according to the batch quantity, shape of product and phase of process thus guaranteeing uniform distribution of air flow, low air speed, high yield, high flexibility for inimitable performances.



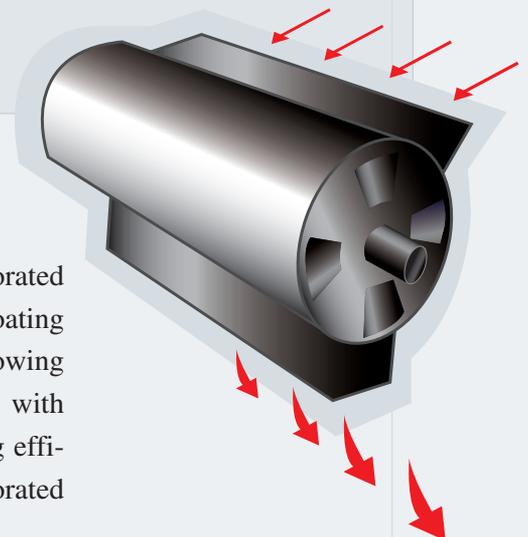
DRYING SYSTEM - THE BEST QUALITY

- High Efficiency
- Short Process Time
- Very Low Product loss
- Low Utilities Consumption
- Uniform drying and spraying
- Easy cleaning
- Easy inspection
- Easy dismantling
- No product abrasion through perforation or paddles impact



BLOW MASTER

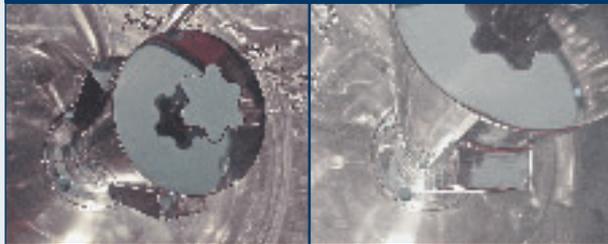
BM has the same performance as perforated drum with less utilities consumption. Coating is not a static process therefore by blowing the top of a core's bed in conjunction with NCS perfect mixing, a very high drying efficiency that is normally seen with perforated drums, is achieved.



EIDON RESEARCH LABORATORY - Udine - Italia 03/02/2003

TEST	Temperature of the product at the end of each test	Absolute Humidity Difference between Inlet and Outlet air humidity (Drying efficiency)
1ST NICOMAC BLOW MASTER AIR DRYING SYSTEM	about 46.2 °C	2.9 to 3.2 gr/kg
2ND PADDLES IMMERSSED IN THE PRODUCT ONE BLOWING ONE EXHAUSTING	about 41.3 °C	1.7 to 1.9 gr/kg

1st Nicomac Blow Master Drying System



2nd Old Drying System



PRODUCT USED FOR THE TEST

SUSPENSION SPRAYED

- Sepifilm 050
- Titanium Bioxide
- Sepifilm green
- Peg 6000
- Talcum
- H2O
- Solid content 14%

TEST FIXED PARAMETERS

Coater	NCS 350
Drum Speed	6 rpm
Spray rate	255 cc\ min
Inlet air temperature	80°C
Atomization Pressure	4 bars
Flat Jet pressure	2 bars
Inlet Air flow	1200 m ³ \hour

Final Consideration:

Blow Master oriented to the middle of the core's bed allows a low speed inlet air in order to blow a large quantity of air very close to the bed. The air system is very well balanced which allows the increase of air quantity and consequently to have a better drying efficiency. The outlet air funnel is always positioned at a fixed angle from the inlet air guaranteeing quick removal of humidity without turbulences, near the spraying area. Air goes where there is less resistance and where it is forced to go. If air finds resistance the drying efficiency consequently decreases.

In the 2nd test the drying efficiency was less because the air quantity consequently decreased: temperature dropped to 41.3°C and tablets started sticking to each other. Humidity was elevated because the spray rate did not change.

The perforated drum uses the same concept as the Nicomac system, blowing the air in a balanced way, but considering that the air flow goes where there is less resistance, a large quantity of air pass through the holes instead of the cores to be dried. Moreover, the big air quantity through the spraying area can cause high loss of suspension. Physical law suggests that the closer you blow the drying air to the product to be dried the better is the drying efficiency.

PELLET COATER

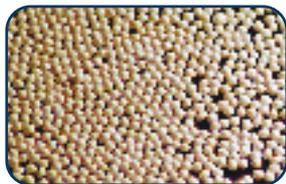
NICOMAC IS THE WORLDWIDE LEADER FOR PELLETS PRODUCTION

These are only some Pellet products that can be produced on the Nicomac coater:

- | | | |
|------------------------|----------------------|-------------------|
| ■ Omeprazole | ■ Ibuprofen | ■ Multivitamins |
| ■ Acetylsalicylic acid | ■ Vitamin C | ■ Pholic acid |
| ■ Sodium Chloride | ■ Potassium Chloride | ■ Nitroglycerine |
| ■ Dicoflenacum | ■ Paracetamol | ■ Pellet seeds |
| ■ Dimenidrinato | ■ Diazoline | ■ Pseudoephedrina |



- Fast aqueous and organic film coating process
- No change over from tablets to pellets



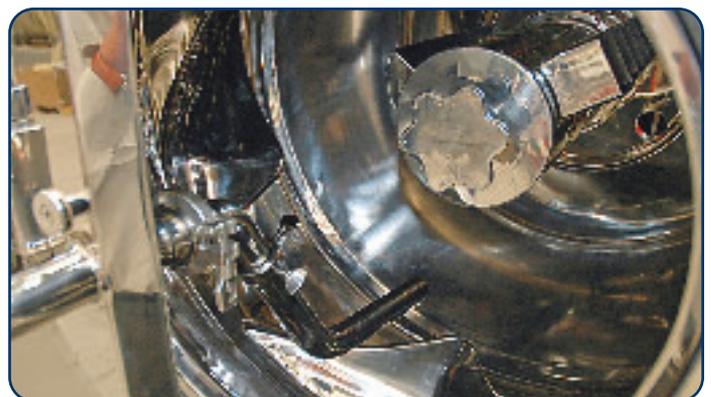
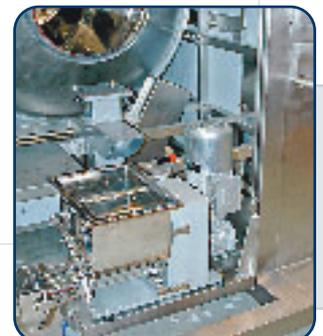
- Unique technology and performance
- High quality
- High capacity



- Long and varied experience
Process consulting
- High yield, uniform size
- Exclusive powder dosing system

AUTOMATIC POWDER DOSING SYSTEM - APDS *IT. PATENT N° MI 2006A000406*

APDS is performed with a combination of pressure and mechanical systems. APDS is a new patented closed system that avoids any powder clogging. APDS is a reliable, efficient, fast, and a controlled system for any kind of powder. APDS is also designed for potent products.



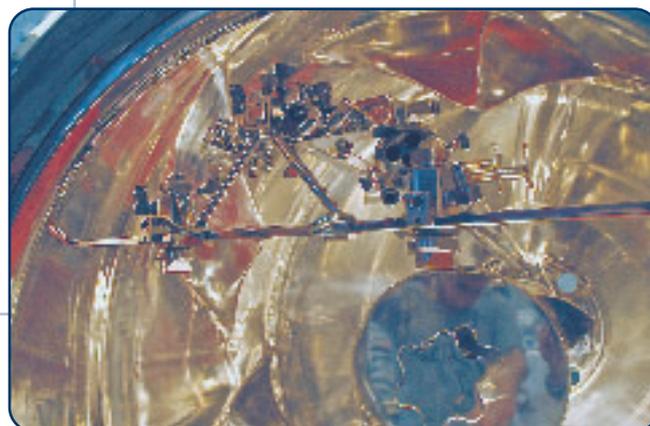
SPRAYING SYSTEM

SPRAYING SYSTEM - *IT. PATENT N° MI 1325793*

Completely stainless steel AISI 316 spraying guns, are used for both film and sugar coating. The distinctive compact design, the accurate and easy controlled spray pattern, the uniform atomization, combined with the Nicomac unique mixing efficiency allows for a smooth coating for the finest quality of the finished product, either tablets or pellets. Exclusive nozzle design to avoid clogging! Spray pattern and gun position are PLC controlled and inserted in the process recipe stored in the SCADA PC. The sliding arm supporting the guns is adjusted by means of electric motors.

HUMIDITY CONTROL

Process control is based on a closed loop of product and air temperature and absolute humidity of the product bed. Depending on different applications, Nicomac sets the proper controlling algorithm. For temperature sensitive products, bed temperature is closely monitored and controlled directly through the delivery of the pump. In continuous process humidity difference can controls the spray rate, in non continuous process, the duration of the drying phase.



THERMOJACKET -

IT. PATENT N° MI 1290010

To avoid any heating dispersion on the external side of the drum. Nicomac has patented a drying system called: "THERMOJACKET". Part of the inlet air is directed to the thermo jacket and heats or cools down the pan drum externally easing the good uniformity of temperature distribution of the cores bed. It reduces any heat dispersions and optimizes the efficiency of the drying phase thus reducing the process time.



MOD	MOUTH LEVEL CAPACITY	USEFUL CAPACITY
NCS	Liters	Liters
LAB 9.9	12	9.9
LAB 15	20	15
LAB 30	45	28
LAB 50	60	46
100	130	103
200	270	202
350	475	357
450	602	451
650	870	658
1000	1350	1012
1200	1616	1204
1500	2004	1503
2300	2500	2009

ACCESSORIES

PLC-PC CONTROL SYSTEM

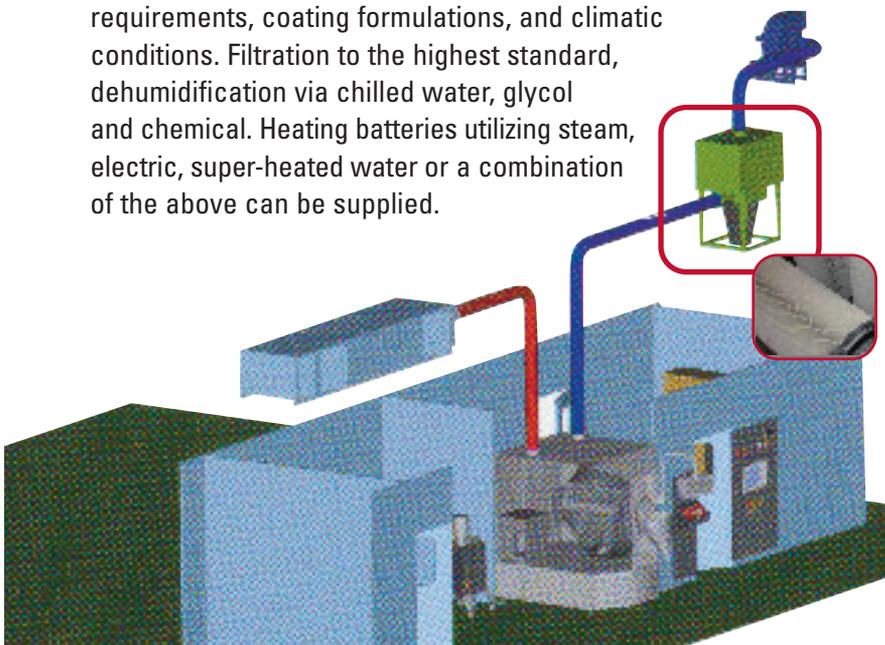
PLC-PC control system Intelligent terminal connected with PLC by means of industrial communication protocol.

- Printer provides batch documentation and data logging.
- Up to 99 recipes with 50 to 99 phases for a fully automated production process.
- 3 password level security system.
- Recipe modifications, under password, are recorded and printed.
- User friendly operator interface with automatic set-up and control of all process parameters.
- Synoptic with graphic and numeric form, real time and set point parameters, different colors for different status.
- Comprehensive sensing and alarm system protects process security.
- Process control by temperature or humidity according to product characteristics.
- Software complies with CFR 21 part 11.



INLET AIR UNIT

The modular Air handling Unit is an integral part of our coating equipment. Each unit is customized by our specialists, and a specific layout is designed according to customer requirements, coating formulations, and climatic conditions. Filtration to the highest standard, dehumidification via chilled water, glycol and chemical. Heating batteries utilizing steam, electric, super-heated water or a combination of the above can be supplied.



LOAD CELL SYSTEM

This system can be provided to check constantly, the drum weight during the process with very accurate tolerances. We can also supply a suspension weight controlled dosing system, where the solution tank is placed on load cells. To compensate the different specification on powder raw materials, Nicomac can provide a Load Cell on the powder dosing system, with a sophisticated and easy to use software which is able to adjust the powder quantity in relation to powder density. The system is designed to avoid vibration influences.

WIP CIP

WIP - C.I.P. - WASHING - CLEANING IN PLACE

IT. PATENT N° MI 2002A000886

Nicomac has developed and installed many truly high performance, flexible validated cleaning systems. Nicomac validated an automatic CIP in a 2 tons NCS2300 coater!

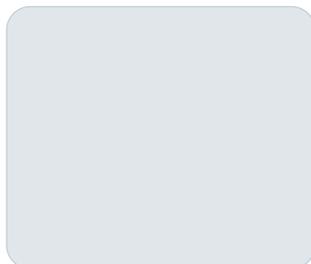
Nicomac combines the advantages of a solid wall drum that avoids any possible cross-contamination with an easy, effective, reliable, fast cleaning system.

Nicomac can supply different automatic and semi-automatic solutions: movable skid, high pressure (up to 80 bars) sanitary pump with low flowrate. A special automatic 4 way washing nozzle fitted on an automatic sliding arm ensures a very strong fluid impact during the washing phase in any corner of the drum and ducts. Tank detergent, high efficient emptying system. PLC Control System can be provided with many configurable recipes where it is possible to set the different washing parameters and phases.



TANKS FOR FILM AND SUGAR COATING

- A wide range of wheeled tanks can be provided with high finish. All parts in contact with the product are manufactured in stainless steel AISI 316, mirror polished with roughness less than 0.3 μ .
- Monoblock built-in control board in stainless steel AISI 304, motor cover protection, speed controlled by AC frequency control.
- Jacketed design tanks for sugar coating, electronic thermoregulator, special cowless stirrer.
- Custom designed tanks can be supplied: 0.49 bar pressure with safety valve, membrane valve, Pall vent filter, level gauge, and so on.



AUTOMATIC LOADING AND DISCHARGING SYSTEM *EXCLUSIVE DESIGN*

Nicomac can supply a patented system that unloads finished products by welded chutes or magnetic, fast connection, unloading chute.

Easy, fast, reliable.

No tooling required.

"Up to last one" tablet unloading with no damaged tablets.

The best system on the market. Safe automatic loading can be provided by a lifting system.



HIGH POTENT PRODUCT

Nicomac developed a safe system interfaced with split valves for high containment of potent products with special sealing.

PERFORATED DRUM NICOATERS

Nicomac is aware about of the advantages of solid wall coating pans, especially with Blow Master drying system. To complete our wide range of technologies and to ease your validation process, we can also provide perforated drum coaters called NICOATERS. As in all Nicomac products NICOATERS outstanding success is based on innovative engineering which has resulted in process cost reduction and process flexibility. Fully integrated Coating System with matched accessories.



COATING SOLUTION DELIVERY SYSTEM

Controlled and uniform flow rates are achieved with the help of a Single/Multi-head Peristaltic Pump.

Telescopic Spray Nozzle Arm is entirely withdrawn from the pan by pneumatic actuation and then located safely away from the Main Access Door.

Spray Guns can be adjusted individually or collectively for an optimum pattern onto the product bed. Anticlogging guns completely in stainless steel AISI 316 can be provided.

AIR SYSTEM

NICOATERS exploits a balanced thermodynamic process to achieve reduced process time and a high quality of finished product. Temperature, Humidity, Flow and Classification of the air within the tablet in a closed controlled air system is crucial for the coating process and Nicomac NICOATERS provides the best and efficient drying system.

Air Handling Systems are designed to meet the customers' individual needs including Room Layout, Climatic Conditions, and Coating Formulations.

BAFFLES

NICOATERS is available with different types of Baffles to achieve optimum and efficient turbulence in the tablet bed. The selection of Baffle is decided in conjunction with tablet shape, coating process, and customer's need.

- Rabbit Ear
 - Tubular
 - Plate Type Bolted on inside wall of the pan
- All Baffles are removable.

WASH IN PLACE

Built in WIP System consisting of High Pressure Pump, Rotary wash nozzle on the Spray Arm, and solid cone spray nozzles outside the pan. Automated predefined wash cycles controlled by PLC are also available. A sink is provided to collect the wash water and drain the same.

OPERATOR INTERFACE & EQUIPMENT MANAGEMENT

- User Friendly Operator Interface and specially designed Process Control System, managed by PLC provides full details of coating process both real time and historical.
- Configurable operating programs provide maximum batch to batch coating repeatability.
- Comprehensive online Status Reports, Result Summaries and Regime of Alarms/Controls ensures validated coating process has been followed.
- Ability to interface with higher management interface system including SCADA with PC based software meets certain regulatory guidelines.
- Control Systems use Mitsubishi, Allen Bradley or Siemens PLC with Membrane Key Pad or Touch Screen displaying both Graphics and Numeric.



ADVANCES IN PROCESS CONTROL TECHNIQUES

As an option a MICROTECH PLC-PC control system can be provided with software complying CFR21 part 11. Significant process parameters like humidity of air by rh/dew point sensor, volume and velocity of air by velometer, temperature of tablet bed through PT100 sensor immersed in the bed, flow rate of dispensed coating solution through flow meter, healthy condition of HEPA filter through pressure transmitter are online monitored with desired interlocks & alarms.

Three levels password.

Highly automated wash in place system with online monitoring of temperature, pressure and flow-rate of wash water, coupled with interlocks and alarms ensures wash process repeatability.



CONVENTIONAL PANS

Nicomac can supply conventional pans in stainless steel for very special applications.

PRODUCT LOAD AND DISCHARGE

Mobile tilting Lifter is available to lift the tablet container (IPC) and the same are tilted on a chute which feeds the tablet to the pan. These mobile units are suitably designed for load capacity and charging height. The "easy to use" discharge device is connected to the pan by a quick fitting system and discharge is achieved by rotating the pan.

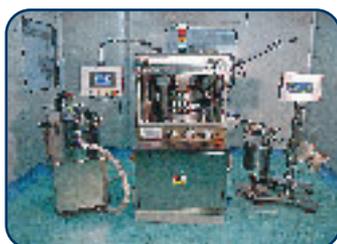
LAB FACILITY

Our technology and our experience are available for any customer need. Qualified specialists with extensive experience are able to supply full process consulting support to improve, optimize and set any kind of formulation.



- Nicomac's 250 m² of CleanRoom facility for in-house trial of solid forms for pharmaceutical and nutritional products includes.
 - dispensing
 - high speed mixer
 - fluid bed dryer and processor
 - multi blender
 - tablet press
 - coaters

State of the art lab equipment, ranging from 1 to 50 kg capacity, with the same features of our production models are available for clinical trials, research & development, formulation optimization scale ups according to FDA guidelines and small-scale production.



Nicomac reserve the right to change the submitted the technical data. Data in this catalogue is not binding.



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