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January 7, 2003

To: Public Docket: #95D-0349.  
Dockets Management Branch (HFA-305 )  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852  
Reference: SUPAC-IR/MR Equipment Addendum

We would like to be consider for the following:

SUPAC-IR/MR Equipment Addendum: Coating Equipment

Nature of the proposed change: Addition of Equipment

Proposed class and subclass of the equipment

- Class: Pan Coating
- Subclass: Perforated Coating System

Proposed equipment listing: L.B. Bohle

Pictures and descriptions of the equipment are included

See Description, Brochure.

Sincerely

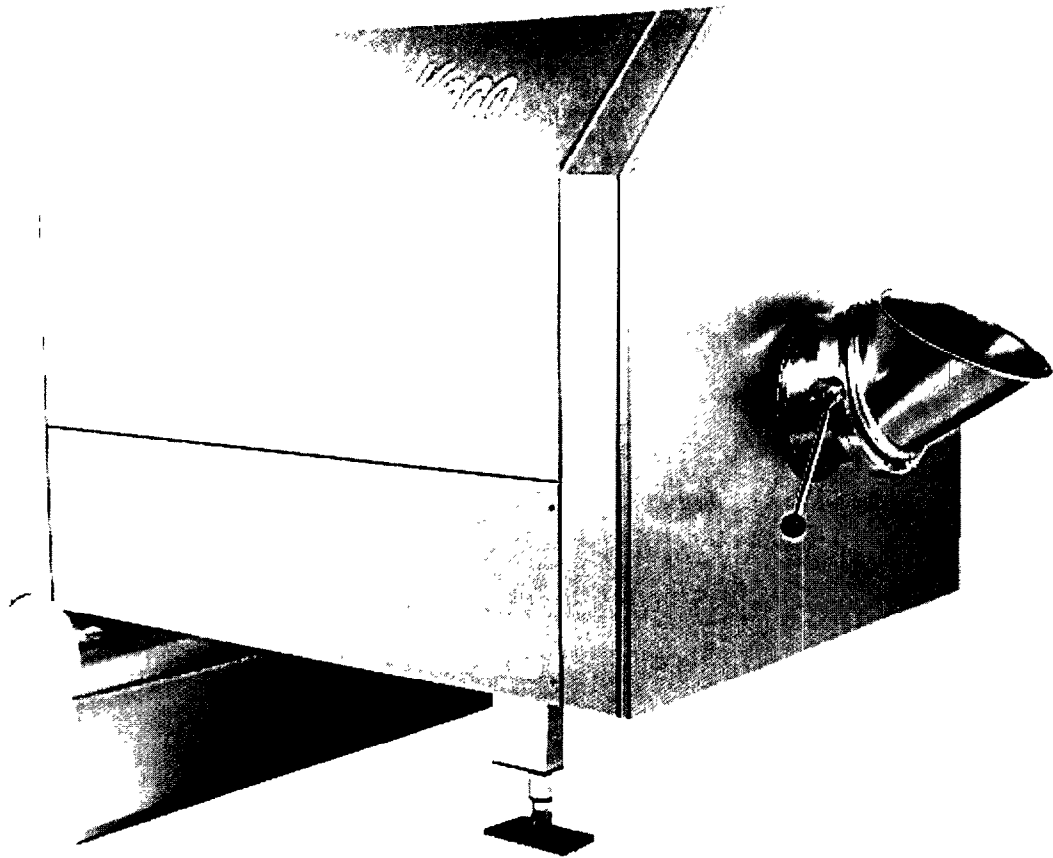
Rafael Navarro  
Project Manager

95D-0349

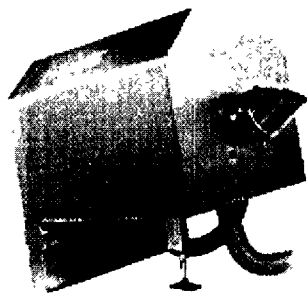
RPT11

# LB BOHLE

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## Bohle Film Coater-BFC



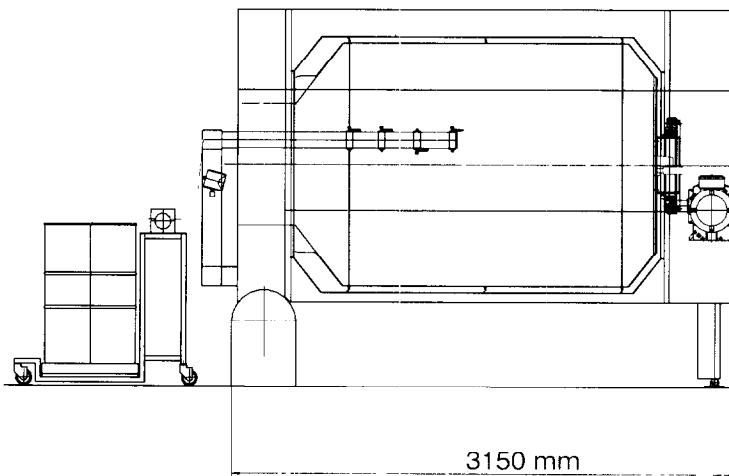
- Able to coat batches from 300-600kg of tablets
- Completely contained coating process
- Self-cleaning nozzles insure no exposure to the operator
- Patented Spiral ribbons guarantee homogeneous mixing and uniform coating, with no twinning
- Laminar airflow through the bed results in minimal solution loss
- Complete CIP of drum
- Adjustable inclination of the pan allows optimization of coating for all shapes of tablets

### Design

The entire coating module is mounted on a movable axis that allows the inclination of the entire pan by tailoring the inclination for the different shapes and dimensions of the cores.

The bed thickness can be controlled to provide optimum results.

The **BFC-600** coater system has a larger length to diameter ratio than traditional coaters, by inclining the pan the thickness of the bed is controlled and kept from becoming too deep. In traditional coaters a thick bed of tablets results in a fast moving ring of cores on the outer layer and a dead zone (or very slow moving cores) in the center. These central cores tend to stick to each results in less static pressure on each tablet and having very good movement of the product insures quality. The inclination is precisely measured and controlled; the angle can be set as a recipe parameter guaranteeing a repeatable process.



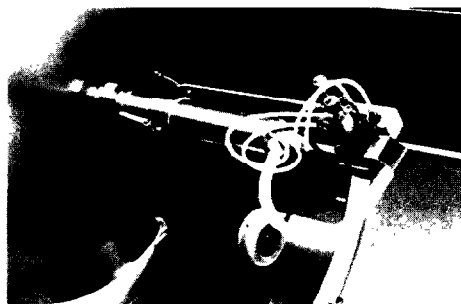
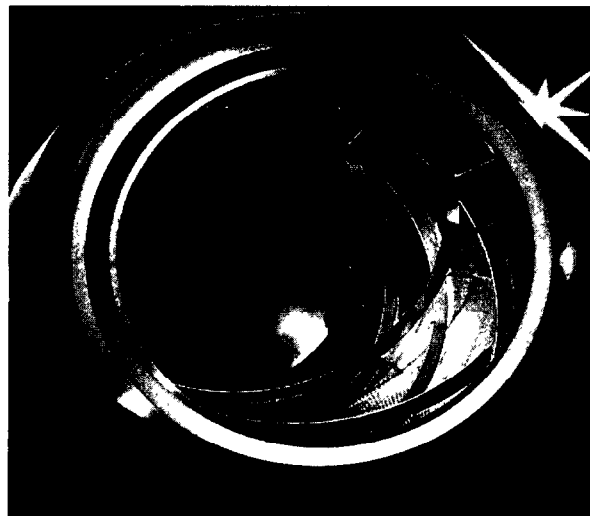


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### The Pan

Heart of the BFC is the coating pan with a conical shaped cylinder at both the beginning and the end. Spiral ribbons guarantee a gentle movement in the kernel bed. These ribbons are highly polished to prevent solution and cores from adhering to the surface and to allow easy cleaning during the CIP process. The lower set of ribbons is continuously welded to the interior surface thus no material can be trapped between the ribbons and the pan surface. The two sets of ribbons achieve rapid, but gentle movement of the cores in a continuous blending motion each tablet is brought into the spray zone with great frequency. This allows Bohle to use fewer spray guns and achieve faster coating. During discharge the drum is rotated in reverse and the spirals gently discharge the product.

Complete discharge can be achieved rapidly if desired.

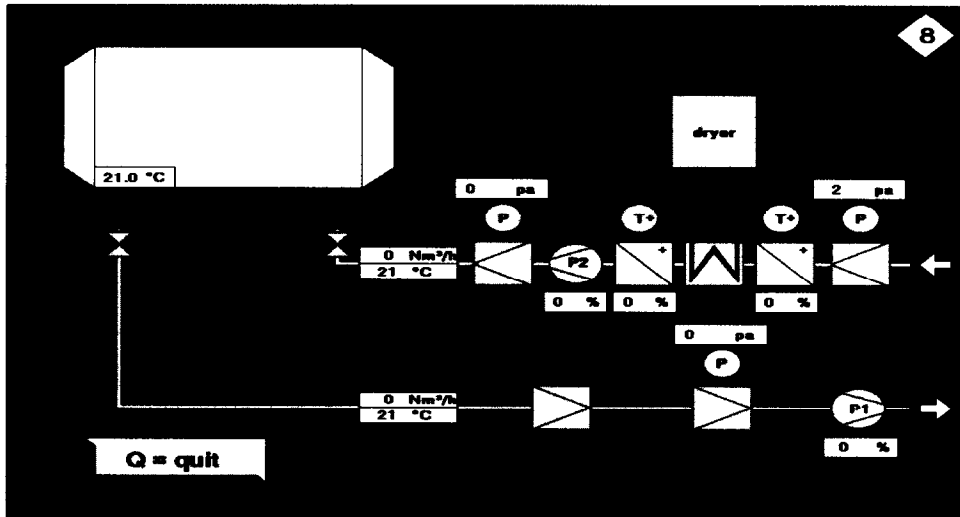


### The Spray System

Another unique and patented item in the Bohle Film Coater is the spraying system.

A binary nozzle delivers coating solution accurately and with repeatable precision to the tablet bed. Again, because we control the bed thickness by varying the angle and speed of rotation, the distance from the nozzle to the tablet bed is

constant for different batch sizes and products. The nozzle does not have to be re-calibrated between batches resulting in homogeneous coating for all products regardless of batch size or tablet shape, each nozzle is equipped with a self-cleaning mechanism, which keeps the nozzle free from solution build-up without any operator exposure. The recipe can be programmed to automatically clean the nozzle based on time or a change in flow rate of the solution. The isolator pin is dropped in the nozzle to stop solution flow, a mechanical scraper, constructed from stainless steel strands arranged as a small brush scrape across the face of the nozzle. At the same time a vacuum line is activated to remove any particles scraped from the nozzle. The pin is retracted and the coating continues. The entire cleaning process takes only seconds. A peristaltic pump transports the suspension through a mass flow rate measuring system. Spray rates can be designed to suit customer needs. The normal accuracy for that system is  $\pm 1\%$  of weight load. If desired, it is also possible to deliver a higher accuracy for an additional charge. Normally one pump is sufficient to deliver the solution to all nozzles; however, a pump for each nozzle can be designed if desired.



## Air Handling System

A complete *Air Handling System* can be included with the BFC. The system is completely integrated and mounted on a skid for easy installation. This is a great cost saving to the customer, as the only connections are utilities and the ducting to the coater itself. The system includes a pre-filter, supply fan, HEPA filter, heating elements, dehumidifier coils, exhaust fan, and exhaust HEPA filter.



## Sample Air-Handling Screen

With the entire air-handling system integrated on a skid (As shown in the picture on the left) installation and maintenance cost for the unit are greatly reduced. The unit can be easily moved with a standard forklift. All cabling connections between the switchgear cabinet and the skid are provided so only utilities and the inter-connecting ductwork have to be installed.

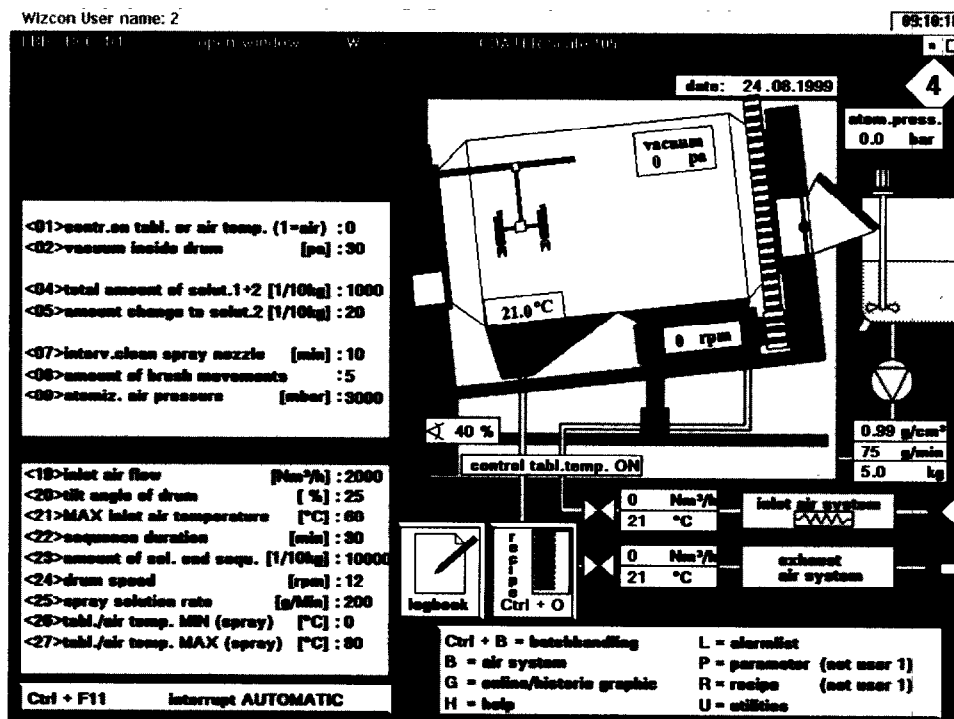
## The Control System

A complete computerized control system for both automatic and manual operation of the coater is provided. A state-of-the-art PLC controls all functions of the entire coating system while a PC-based graphical interface provides the operator with all process parameters displayed in useful graphs, tables and pictures.

There are four basic security levels, which can be expanded if required:

- Operator – Access to automatic functions (Run a Recipe), display graphs, historical information, etc.
- Maintenance – Manual Mode operation, run system manually with all interlocks still active
- Engineer – Create and edit recipes, define access
- System administrator – Can exit program and manipulate all aspects of PC

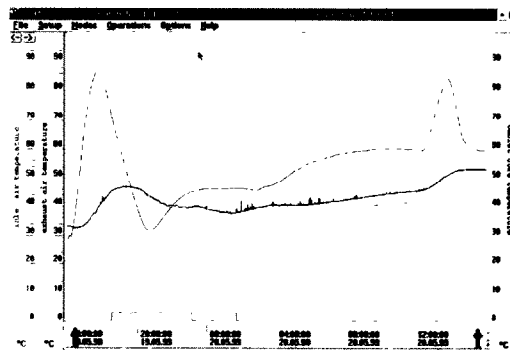
## Sample Screens:



Typical Screen in Automatic Mode

## Documentation

All process parameters given in the recipe are registered automatically at the end of the batch. These are the air supply temperature, outgoing air temperature, core bed temperature, additional air quantity, and negative pressure in each system, spraying rates and total spraying quantity. This requires the parallel recording of all actual values in the case of more than one coating drum and thus a continuous control comparison with the chosen set values. This process defining parameters are stored on the system hard disk, printed out if desired or transmitted over a serial interface, to a superior control unit for data protection. In order to limit the data, only possible deviations are shown – apart from the respective recipe.

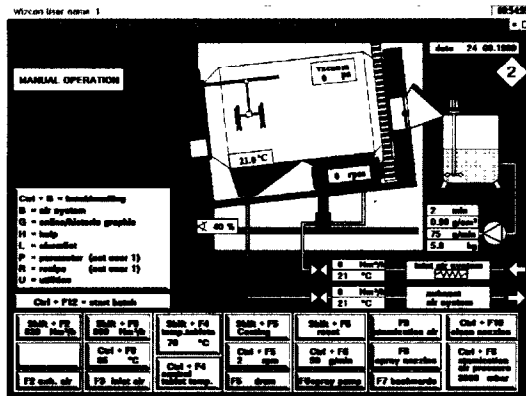


## Sample Help Screen



- **ACTIVE TAB-BUTTON :**  
If the TAB-button does not work, it must be activated with the keyboard-button "W".
- **MESSAGES :**  
By incorrect operator-handling the system generates messages. The message-window can be closed by pressing the ERROR button on the control-desk or will automatically close after 10 seconds.
- **ERROR MESSAGES :**  
On error a message-window will open and show informations about the error. The error can be cleared by pressing the FAILURE button on the control-desk. The window will close then.  
If the error cannot be cleared, the window can be closed by pressing "ALT + A"  
By using the button "L" a list with all errors will appear on the screen.
- **HELP :**  
This help-window will close by pressing "Ctrl + H"

The standard operator interface package is equipped with an extensive help library for all errors and functions of the program. This greatly reduces the learning curve for new operators and avoids mistakes and delays in production.



*In manual mode, all driving motors can be controlled individually. All interlocks necessary for process control are maintained. In automatic mode, a batch is worked automatically and recipe controlled.*

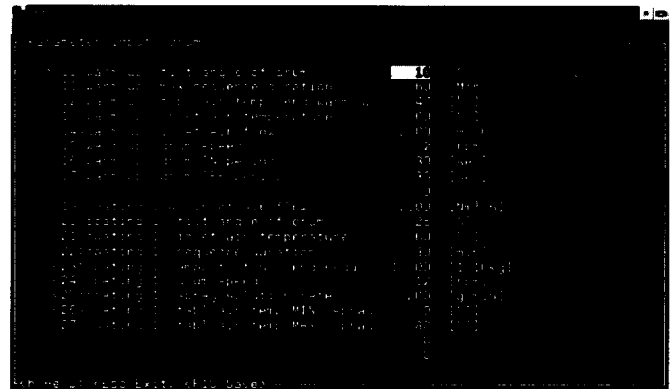
### Recipe administration

A separate program executes the administration of recipes. Up to 999 recipes can be stored by the menu. Extensive help functions and partially pre-defined parameter values make the preparation of recipes very easy for the operator. If desired, the recipe program can be installed on any other PC.

### Batch administration

The batch number may contain between two or twenty alphanumeric characters and is entered at the beginning of the automatic mode. After selecting a recipe, the automatic process will be started. All occurring measuring data and messages related to the batch, will be stored in the PC and can be called up on the screen later. At the end of the batch, the system generates a log with all-important data. In order to analyze the batch, the operator selects the desired batch from a list and watches or prints the important data as recipe, log, fault list or measuring graphics. All batch data are recorded twice for safety reasons. This data can be copied on a ZIP data carrier or filing. If desired, the data can be automatically filed on the customer server after connection with the customer's PC-network.

### Recipe Entry/Edit Screen



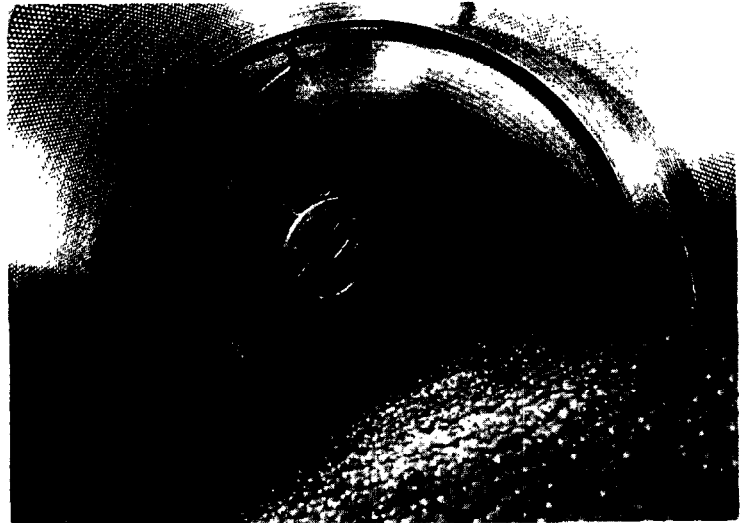
As a standard L.B. Bohle utilizes Siemens PLC and WIZCON Software running on an OS/2 Platform or Windows NT.



## View from the video Camera

### Video System

To allow the operator to view the coating process on-line without any risk of exposure. L.B. Bohle installs a color video camera and light source inside the coating system. The camera and light are isolated from the product and give the operator an extra dimension of process control with a clear picture of the coating process.



### CIP System

The CIP systems utilizes a remote skid to handle the delivery of the rinse water, CIP solution and final USP Rinse. The liquid is delivered through spray nozzles located inside the coating system and exhaust duct. Solution is also delivered through the spray nozzles through a diverter valve system that maintains a separation of cleaning solution and coating solution piping. The drum is rotated through out the entire cleaning process. The bottom of the coater is designed to free drain completely to a central return point where the wastes water can be pumped to drain, pumped to a neutralization system, or in the case of the Wash cycle, recirculate to the pan.

### Typical CIP Skid

- Without detailed cleaning data about specific products it is difficult to specify the CIP skid. A typical system consists of:
- Frame Work shall be minimum 2x2x11 gauge tubing, 150 Grit finish, T304 stainless steel.
- All CIP tubing shall be 16 gauge, 180 grit mechanical ID/OD polish, electro-polished ID, T316L stainless steel. All welds will be ground and polished on ID where accessible.
- The atmospheric 200-gallon CIP Batch tank will be insulated and clad with stainless.
- The 200-gallon USP water surge tank will be insulated and clad with stainless steel.
- The CIP Heat Exchanger will be a double tube sheet shell and tube unit. The T304 stainless steel shell will house a T316L tube bundle.
- The chemical feed system will consist of a free standing T304 stainless steel frame design for chemicals supplied in 55-gallon drums.

