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Food and Drug Administration
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June 11, 2002 K/Kob/Vn

DIOSNA Vertical Centrifugal Coaters

Dear Sirs,

Referring to Florian Zielinski's e-mail of June 5, 2002 we are sending you enclosed two sets of the following information about our DIOSNA Vertical Centrifugal Coater VCC:

- Technical descriptions VCC 5/25, VCC 75/150/300
- Drawing (VCC 25)
- Leaflet VCC
- Lecture of Dr. h.c. Herbert Hüttlin
- Reprint "Pharma + Food"
- CD-ROM (film)

To add our Vertical Centrifugal Coater (VCC) into the SUPAC-IR/MR Manufacturing Equipment Addendum.

Branch: coating equipment
Class: pan coating
Subclass: perforated coating system

Our US-distributor is SERVOLIFT L.L.C., 270 Route 46, Rockaway, NJ 07866, Tel.: +1 973 586-3708, Fax: +1 973 586-3731.

95D-0349

[redacted]

Lot 2

If you need any further information, please contact us by e-mail (koberg@diosna.de).

We would be glad, if we would be admitted to the SUPAC-list as soon as possible.

Best regards

DIOSNA Dierks & Söhne GmbH
i.A.

Gabi Koberg

Diosna

Vertical Centrifugal Coater VCC

Shortening of process times (50 % and more)

Lowering of energy and material costs

High, reproducible quality standards

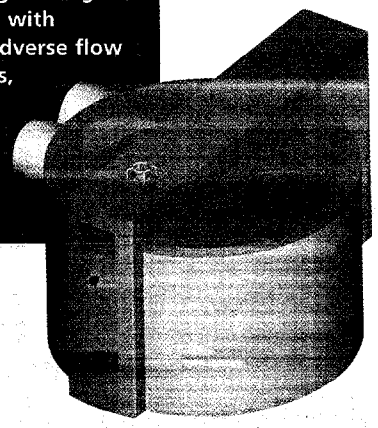
For more details:
www.diosna-vcc.de

Innovation and Quality.
Made in Germany.

Revolving around your success.

The profile.

The vertical centrifugal coater DIOSNA VCC gives a new definition of coating technology - leaving behind many of the well-known disadvantages of conventional coaters. The flexible concept of the VCC offers various ways of application with water and organic based spray liquids and stands for convincing coating results - even with products of adverse flow characteristics, special shape or less hardness.



VCC 150

Vertical Centrifugal Coater VCC 5

Vertically rotating, perforated bowl

Transparent glass cover

Compact size, space-saving design

Filling rates from 20 to 100 %

Application of coating liquids in the bowl center

Even, controllable coating with DIOSNA spray nozzle

Linear scale-up

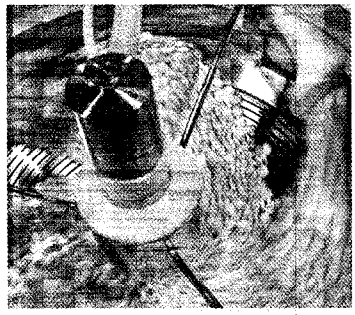
Washing-in-place

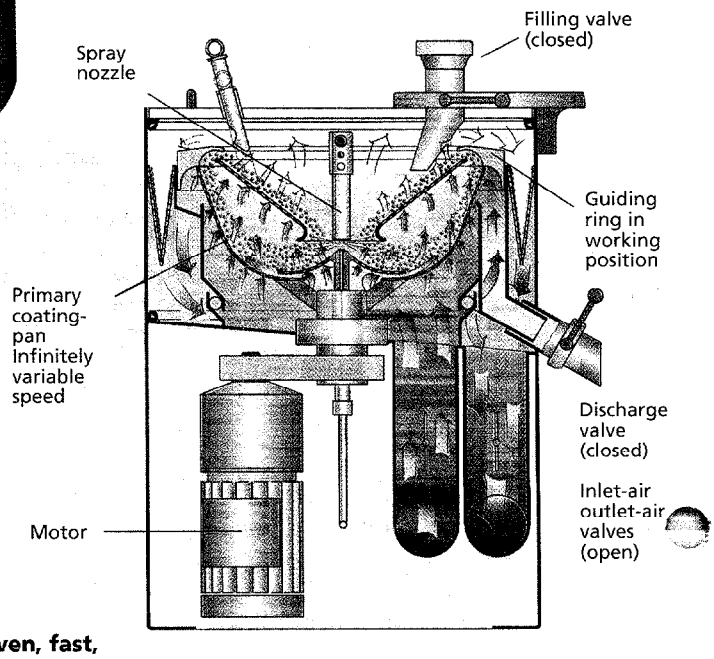
View into the bowl: Gentle product movement

Controllable, gentle product movement using centrifugal action

Homogeneous and fast adsorption - almost without loss of spray liquids

Short drying times





Even, fast, efficient: Coating with the DIOSNA VCC

For more information:

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Sandbachstr. 1 · 49074 Osnabrück
Phone +49 5 41 3 31 04-0
Fax +49 5 41 3 31 04-2 15
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www.diosna.de

Revolving around your success.

Product bowl
The product bowl is arranged to rotate around the vertical axis and its shape is a perforated truncated cone. To optimise the distribution of the spraying liquid and give the best spray pattern, compressed air is supplied through a hollow drive shaft (see separate item „nozzle"). The shaft bearing is situated in the bottom of the air distributor chamber below the product bowl. The shaft of the bowl is driven a geared motor using a frequency converter to obtain variable speed. The bowl can be lowered together with the drive shaft pneumatically for discharge.

Lid
The machine housing is covered by a full diameter hinged lid made of safety glass with a hose-type silicone seal gasket. A sampler is integrated into the lid. A limit switch prevents product bowl rotation when the lid is open.

Product guidance ring
A non-rotating guidance ring which is connected to the apparatus lid is installed above the product bowl. This ring directs the flow of cores rising from the spinning product bowl back into the inner return cone.

Return cone
The return cone is non rotating and is a perforated truncated cone and fastened to the product guidance ring.

Spraying nozzle
The nozzle is installed centrically from above in an adjustable holder. It provides a flat circular spray pattern The spray head is positioned so that the spray coats the product as it falls from the inner static return cone into the rotating product cone. The nozzle is equipped with compressed air connections, one for the atomizing air, the other for the supporting air.

Machine housing
All the above items are located in a moveable, self-supporting machine housing. For cleaning, all parts can be dismounted and remounted without tools.

Supporting air fan
The supporting air is supplied through the drive shaft of the product bowl.

Air preparation unit
The air preparation unit consists of a pre-filter, ventilator, steam heat exchanger to heat the process air and a fine dust filter. The filters are equipped with a differential pressure gauge (display local). The air flow is measured and regulated by varying the speed of the supply fan (frequency converter). The air temperature is regulated by mixing heated and unheated air (bypass regulation).

Discharge channel
The product bowl is surrounded by an inclined discharge channel which is equipped with a pneumatically actuated stop flap and a pneumatic vibrator. The channel is sealed against the air distribution chamber by an inflatable seal, and it is easily dismountable for cleaning.

Exhaust air ring channel
The exhaust air channel is is installed circularly around the discharge channel. It is equipped with a pneumatically actuated stop flap for air as well as a drainage valve.

Exhaust air filter
The exhaust air filter is designed as cartridge filter and equipped with a local differential pressure gauge. (local display)

Exhaust air fan /Under pressure regulation.
The exhaust air fan is controlled by a frequency converter. The pressure inside the coater will be monitored and the exhaust fan speed adjusted to maintain the correct under pressure within the machine.

Measuring of exhaust air temperature
The exhaust air temperature is measured and indicated at the operating panel.

Control
The operator control panel is a stainless steel enclosure incorporating a Touch screen 115.6 mm x 87 mm and an emergency stop. The control system is housed in electrical/pneumatic cabinets in the technical zone. Protection class is IP 54. A Siemens S7 p.l.c. (model 314) is used. The parameters for 20 different cycles can be stored. The process cycles are divided into a number of steps for which different times, speeds, temperatures, air quantities etc. can be pre-defined. Automatic cycles (where the machine moves from one step to the next without stopping) or manual cycles (where the operator controls each step indvidually) are also incorporated. The cabinets contain all the controls items (frequency converters, transformers, contactors, relays, pilot valves, etc.)

Air distributor chamber
Below the product bowl is an air distributor chamber. The air inlet into this chamber is provided with a pneumatically actuated butterfly valve. A drainage connection is installed at the lowest point of the inclined base of the chamber.

Materials
Stainless steel product-contact parts are made of material no. 1.4404/1.4435 (AISI 316 L). These parts are grinded Ra ≤ 0.4 and polished mechanicalls. Stainless steel non product-contact parts are made of material no. 1.4301 (AISI 304). These parts are grinded Ra ≤ 1.6. The product guiding ring consists of aluminium with a hard-coat®-surface finish. All polymers in contact with the product are FDA acceptable grades of silicone rubber, PTFE and EPDM.

Installation
The machine is designed for installation in a process area with a technical area immediately adjacent to it. All the equipment is located in the technical area except for the coater itself which is installed in front of the separating wall to the technical zone. The operator control panel is embedded in the wall to the technical zone. All other construction elements (air handling equipment, switch cabinets) are mounted in a technical room.

Documentation
Detailed documentation in English language (2 copies) will be delivered along with the machine. It includes operating instructions, maintenance instructions, safety regulations,

installation plans, circuit and terminal plans, RI diagram, selected drawings of assembly groups (e.g. seals, pneumatics) and a spare part list.

Items not included

Our scope of supply does not include any items not specified above. In particular we draw your attention to the following items:

Supply and exhaust lines for steam, condensate, water, waste water, compressed air and an electrical supply. These have to be provided, installed and connected by the customer according to the guidelines supplied by Diosna.

Electrical and pneumatic connections between the individual plant parts (operator control panel, machine and technical area items).

Process air piping between the technical area and the machine.

Building works, such as the provision of openings in the ceiling and the wall, pedestals, foundations and supporting constructions.

Offloading, transport into the building and location of the equipment. made by the customer.

Safety

The complete equipment corresponds to the European safety standards and is delivered with a manufacturer's certificate according to the European machine guidelines (CE-certificate).

K/Kob/Ut
21.05.02

Technical Specification 1-451-001

DIOSNA-Vertical-Centrifugal-Coater VCC 75, VCC 150, VCC 300

Product bowl
The product bowl is arranged to rotate around the vertical axis and its shape is a perforated truncated cone. To optimise the distribution of the spraying liquid and give the best spray pattern, compressed air is supplied through a hollow drive shaft (see separate item „nozzle"). The shaft bearing is situated in the bottom of the air distributor chamber below the product bowl. The shaft of the bowl is driven by two geared motors using a frequency converter to obtain variable speed.

Lid
The machine is closed by a lifting swivelling lid. The lifting movement is controlled automatically. The swivelling movement is effected manually. A feeding socket, a sample taker and an inspection glass with light are integrated in the lid. An exhaust air socket is installed centrically; it is connected to the exhaust air pipe via a pneumatic seal. A limit switch prevents the machine from being operated when the lid is open.

Product guidance ring
A non-rotating guidance ring which is connected to the apparatus lid is installed above the product bowl. This directs the flow of cores rising from the spinning product bowl back into the inner return cone.

Return/discharge cone
The return cone is non rotating and is a perforated truncated cone and fastened to the lid. The opening of the cone can be closed by a closing cone which causes a collection of cores in the cone. After lifting and swivelling the lid the product is discharged into containers at site.

Spraying nozzle
The nozzle is installed centrically from above. It provides a flat circular spray pattern The spray head is positioned so that the spray coats the product as it falls from the inner static return cone into the rotating product cone. The nozzle is equipped with two compressed air connections, one for the atomizing air, the other for the supporting air.

Machine housing
All the above items are located in a machine housing.

Supporting air fan
The supporting air is supplied through the drive shaft of the product bowl. The supporting air is taken from the process air.

Technical Specification 1-451-001

DIOSNA-Vertical-Centrifugal-Coater VCC 75, VCC 150, VCC 300

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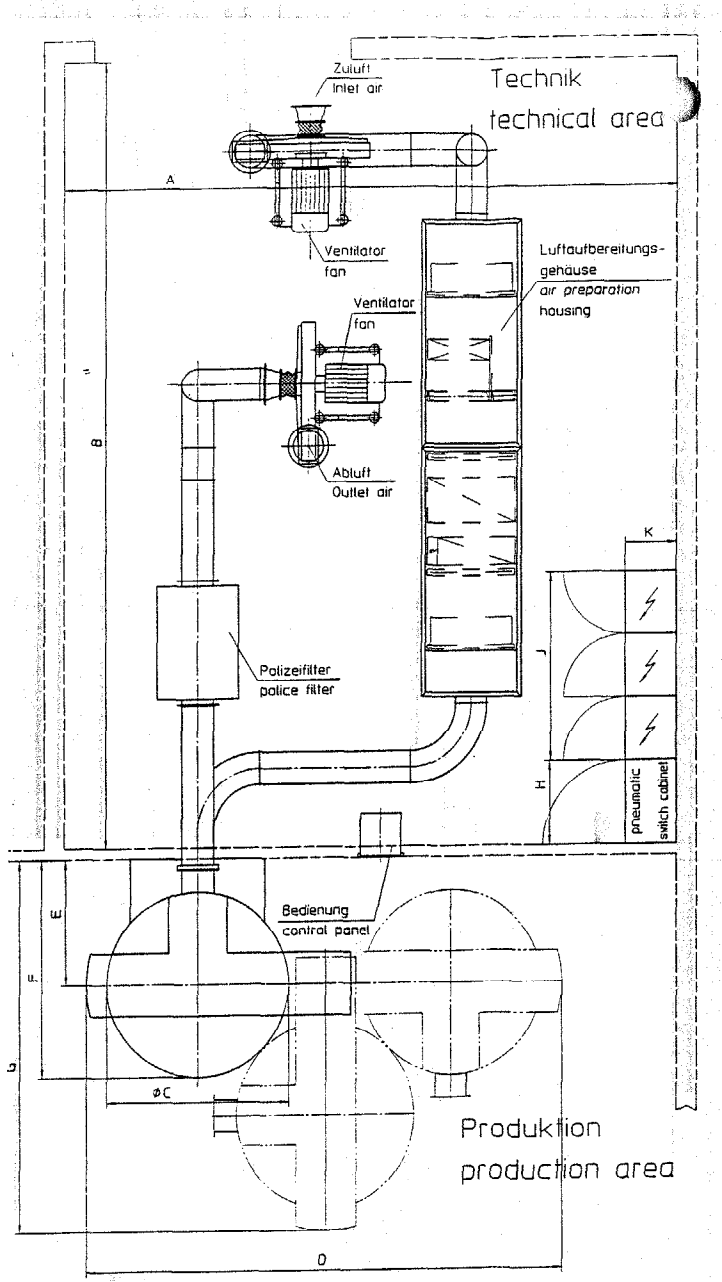
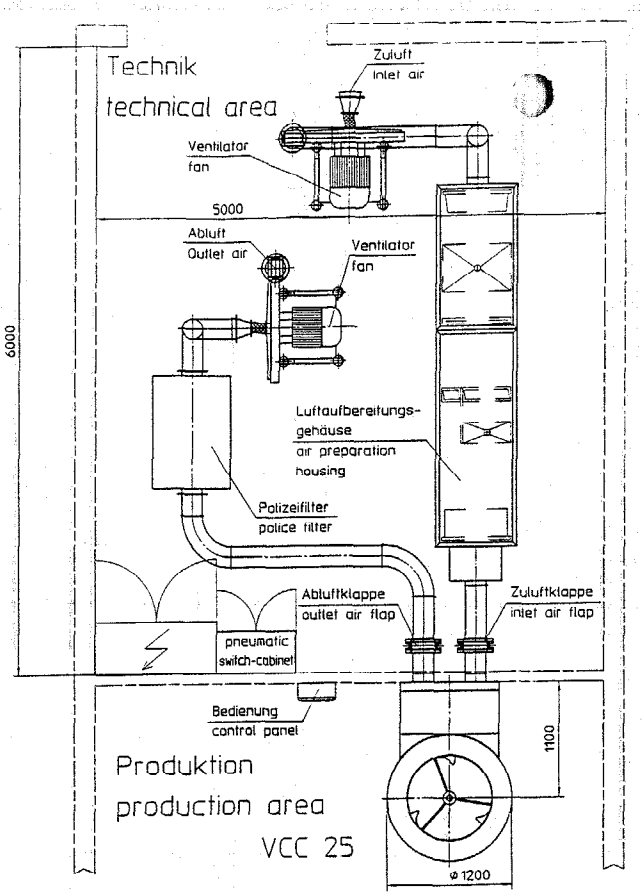
Process air piping between the technical area and the machine.
Building works, such as the provision of openings in the ceiling and the wall, pedestals, foundations and supporting constructions.
Offloading, transport into the building and location of the equipment. made by the customer.

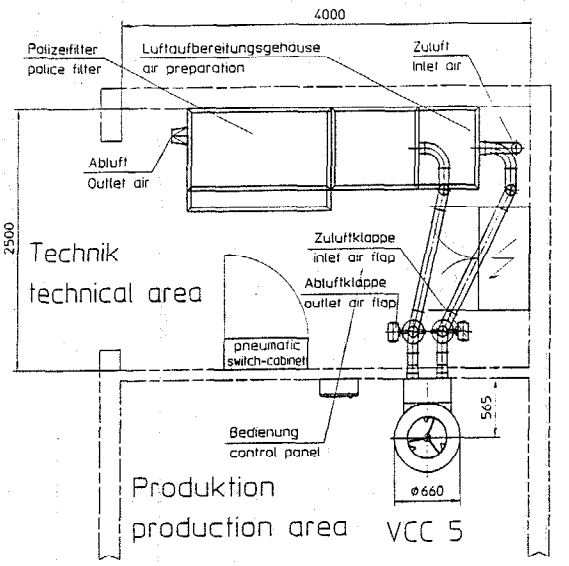
Safety

The complete equipment corresponds to the European safety standards and is delivered with a manufacturer's certificate according to the European machine guidelines (CE-certificate).

K/Kob/Ut
07.05.02







nlagengrößen imensions	A	B	ØC	D	E	F	G	H	J	K
:C 75	5500	7000	1450	3900	1000	1725	2930	800	1200	500
:C 150	6000	7500	1760	4660	1200	2080	3530	800	1800	500
:C 300	7000	8500	2150	5840	1550	2625	4470	800	2400	500

Theoretische Werte!
Alle Abmessungen können sich durch Zusatzausstattungen, örtliche Gegebenheiten oder prozeßbedingt ändern.

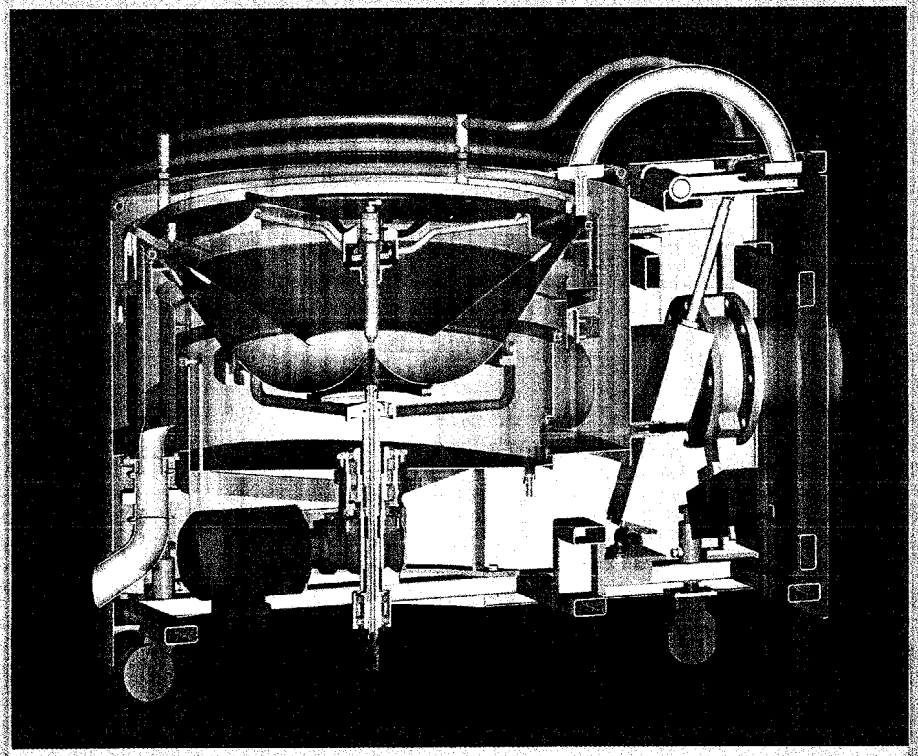
Theoretical values!
All dimensions due to additional equipment, local conditions or the process.

DIOSNA
DIERKS & SÖHNE

Dimensionsheet VCC

1-45N-000-KE01

DIOSNA
Vertical Centrifugal Coater VCC



VCC 25

Revolving around your success.

Speech on the occasion of the
Sales Representative's Training at
DIOSNA on 21/22 November 2001

The DIOSNA Vertical Centrifugal Coater patent / licence INNOJET Technologies

new technology for more efficiency in organic and aqueous coating processes

- by Dr. h.c. Herbert Hüttlin -

INNOJET
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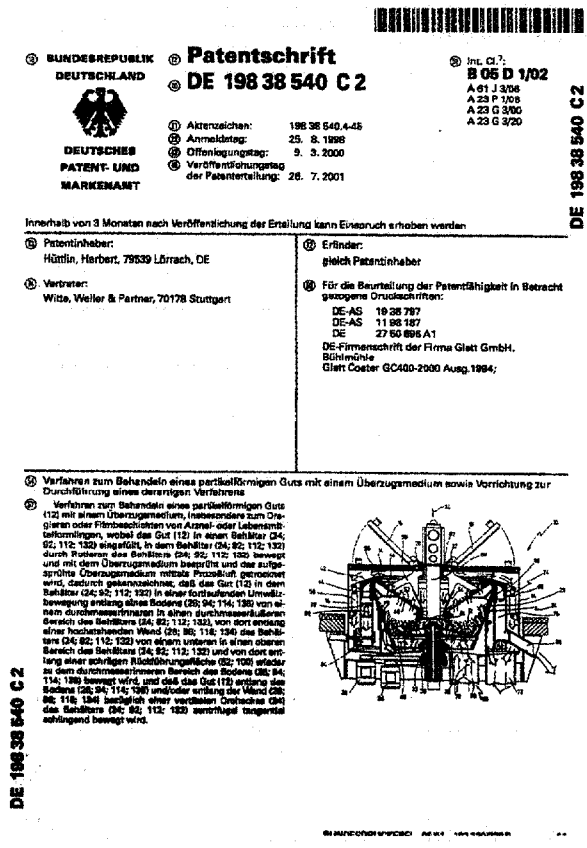
Picture 1 Patent documents



(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENT- UND MARKENAMT

(12) **Patentschrift**

(10) **DE 198 38 540 C2**

(51) Int. Cl.⁷: B 05 D 1/02, A 61 J 3/06, A 23 P 1/08, A 23 G 3/00, A 23 G 3/20

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Innerhalb von 3 Monaten nach Veröffentlichung der Erteilung kann Einspruch erhoben werden

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(72) Erfinder:
gleich Patentinhaber

(56) Für die Beurteilung der Patentfähigkeit in Betracht gezogene Druckschriften:
DE-AS 19 38 787
DE-AS 11 98 187
DE 27 50 695 A1
DE-Firmenschrift der Firma Glatt GmbH, Böhlmühle
Glatt Coater GC400-2000 Ausg.1994;

(54) Verfahren zum Behandeln eines partikelförmigen Guts mit einem Überzugsmedium sowie Vorrichtung zur Durchführung eines derartigen Verfahrens

(57) Verfahren zum Behandeln eines partikelförmigen Guts (12) mit einem Überzugsmedium, insbesondere zum Dragieren oder Filmbeschichten von Arznei- oder Lebensmittelformlingen, wobei das Gut (12) in einen Behälter (34; 92; 112; 132) eingefüllt, in dem Behälter (34; 92; 112; 132) durch Rotieren des Behälters (34; 92; 112; 132) bewegt und mit dem Überzugsmedium besprüht und das aufgesprühte Überzugsmedium mittels Prozeßluft getrocknet wird, dadurch gekennzeichnet, daß das Gut (12) in dem Behälter (34; 92; 112; 132) in einer fortlaufenden Umwälzbewegung entlang eines Bodens (39; 94; 114; 139) von einem durchmesserinneren in einen durchmesseräußeren Bereich des Behälters (34; 92; 112; 132), von dort entlang einer hochstehenden Wand (28; 86; 116; 136) des Behälters (34; 92; 112; 132) von einem unteren in einen oberen Bereich des Behälters (34; 92; 112; 132) und von dort entlang einer schrägen Rückführungsfläche (52; 100) erneut zu dem durchmesserinneren Bereich des Bodens (39; 94; 114; 139) bewegt wird, und daß das Gut (12) entlang des Bodens (39; 94; 114; 139) und/oder entlang der Wand (28; 86; 116; 136) bezüglich einer vertikalen Drehachse (34) des Behälters (34; 92; 112; 132) zentrifugal tangential schräg bewegt wird.

DE 198 38 540 C2

BUNDESREPUBLIK DEUTSCHLAND

URKUNDE

über die Erteilung des

Patents

Nr. 198 38 540

IPC: B05D 1/02

Bezeichnung:
Verfahren zum Behandeln eines partikelförmigen Guts mit einem Überzugsmedium sowie Vorrichtung zur Durchführung eines derartigen Verfahrens

Patentinhaber:
Hüttlin, Herbert, 79539 Lörrach, DE

Erfinder:
gleich Inhaber

Tag der Anmeldung: 25.08.1998

München, den 25.07.2001

Der Präsident des Deutschen Patent- und Markenamts

In Vertretung

Hammer

The world will always need new and – above all – better technologies in order to meet or to satisfy the constantly growing demands of our times.

Previously the question of technical feasibility had to be answered. Today the economic and environmental soundness, i.e. questions of economical and ecological aspects must find an answer – apart from the aspects of quality, safety, reproducibility, handling and washing.

This statement already represents a rough outline of the catalogue of rules and regulations new technologies have to live up to if they are to stand out clearly from prior art.

But what is prior art?

What can the new technology be compared with?

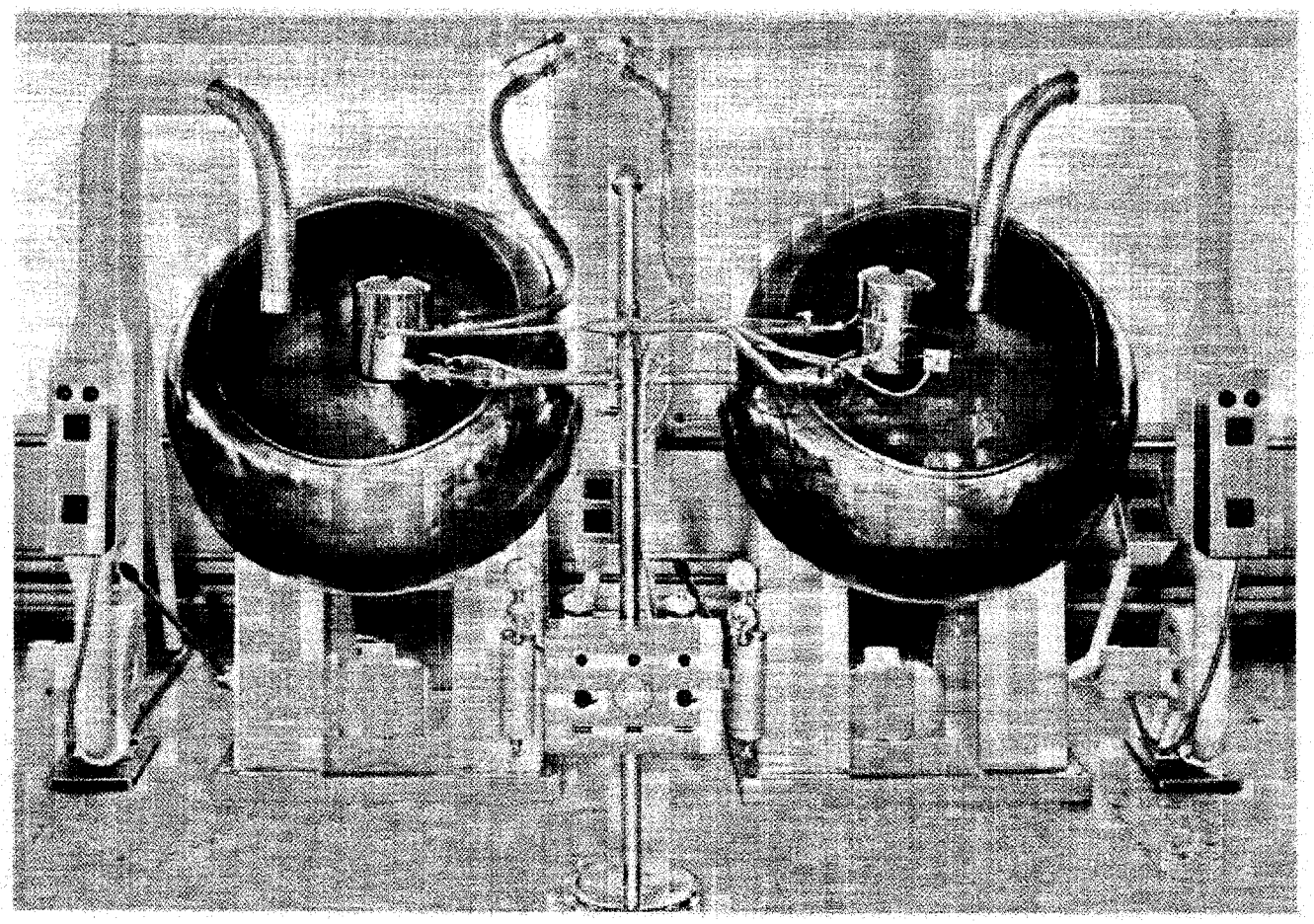
In order to describe what is "new", one has to know what is "old"!

This is why we first want to take a look at the coating systems you will encounter out there in your customers' world. Only if you are familiar with the pros and cons of the existing systems will you be able to illustrate the pros and cons of this "new" technology.

I want to let you in on this secret right at the beginning in order to **motivate you as much as I possibly can**:

The INNOJET Centrifugal Coater, or the Vertical Centrifugal Coater, as it is called at DIOSNA, features a whole line of advantages which are unheard-of in the coating world and may, therefore, be called truly innovative.

Picture 2 Moorish dome pan



History, back to the beginning:

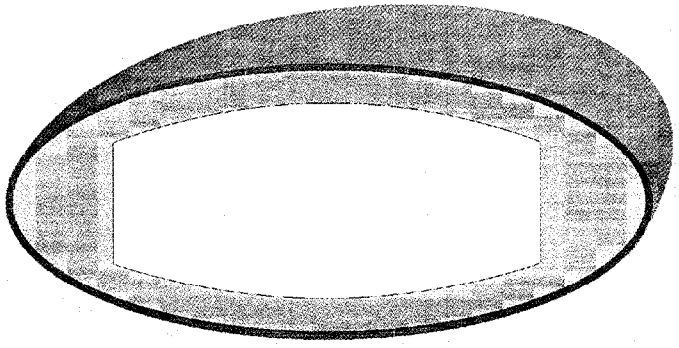
In the beginning, there were the confectioners with their slanted, Moorish dome-shaped copper pans in which they made delicious sweets by coating almonds, peanuts and walnuts with sugar and/or chocolate.

It is likely that the pharmaceutical industry copied the process of coating tablets with sugar or a suspension from confectioners.

A large number of such conventional Moorish dome pans is still employed in the production of pharmaceutical confectionary and in the food industry world-wide.

At first, they were content to apply a mostly sticky coating mixture in cycles by means of a ladle and to distribute it in a rotating pan with subsequent patient drying under the mere influence of ambient temperature. In the sixties, however, great efforts were made, particularly to accelerate the drying cycle or to shorten the drying process by blowing in hot and dry air.

Picture 3 Cross section of a sugar-coated dragee



A coating consisting of sugar and/or a talc suspension can only be applied, distributed and dried in cycles. Continuous application, distribution and drying, all at the same time, is not possible due to the high viscosity of the coating mixture. In this case we refer to the process as "sugar coating" or "suspension coating".

It goes without saying that sugar coating requires 25 –100 individual coatings - depending on the formula - to achieve a total coating mass of up to 100 % of the core weight. This process will take several if not many hours.

First, the application of coating liquid by means of a ladle was replaced by a high-pressure spraying system in sugar coating processes. As early as the sixties, efforts were made to increase the effectiveness of the drying process by blowing in conditioned process air and thus shortening sugar coating processes and even automating them.

An entire individual cycle of a sugar-coating process always consists of three individual cycles:

Sugar-coating cycles

- application of liquid (ladle or spraying) approx. 0.50 minutes.
- distribution of the liquid applied 1.5 – 3.0 minutes
- drying 8 – 12 minutes

total: min. 10 minutes, max. 15.5 minutes.

Bearing this in mind, it becomes apparent that the problem of long process times is due to the drying cycle.

Picture 4 Immersion sword publication 1

Aus der Pharmazeutischen Produktion der Sandoz AG, Basel (Schweiz)

Zuckerdragierung und Filmcoating mit dem „Tauchschwert-Verfahren"

2. Mitteilung

Von D. Lenkeit, H. Hüttlin*), R. Koller und S. Contini

Zusammenfassung

Ein automatisches Dragiersystem, das sowohl für Zuckerdragierung als auch für Filmcoating verwendet und in handelsüblichen Dragierkesseln verschiedenster Größe und Bauart adaptiert werden kann, wurde zur Serienreife entwickelt.

Mit diesem System werden eine optimale Feststoffausnutzung der Dragiersuspension und minimale Dragierzeiten erreicht.

Summary

A large scale automatic coating system for film coating as well as sugar coating has been developed for use with normal sugar coating pans of different sizes and types.

Optimal utilization of solids in the suspension, together with minimal coating times was achieved by this system.

1. Einleitung

In Zusammenarbeit mit der Firma W. Glatt, Binzen (Deutschland), wurde von der Abteilung Technik der Sandoz AG, Basel, auf Grund der Idee von H. Hüttlin eine neue Dragiertechnologie, das „Tauchschwert-Verfahren" realisiert [1]. Ermuntert durch die positiven Resultate mit einer Prototyp-Anlage im konventionellen Rundkessel (60-kg-Maßstab) wurde das System inzwischen auch in größeren Rundkesseln und Horizontalkesseln (Pellegrini) erprobt und zur Serienreife entwickelt.

Die Tauchschwert-Anlage ist mit einer Steuereinheit für alle beim Zuckerdragieren bzw. Filmcoating notwendigen Arbeitsschritte ausgerüstet.

Damit steht zum erstenmal ein automatisches, zur Serienreife entwickeltes Dragiersystem zur Verfügung, das

— in verschiedensten handelsüblichen Dragierkesseln verwendet werden kann und

— sowohl eine rationelle Zuckerdragierung als auch Filmcoating von Presslingen verschiedenster Art ermöglicht.

Außerdem wurden Tauchschwert-Anlagen als Kabineneinheiten entwickelt, die auch in unausgebauten Räumlichkeiten als geschlossener Dragierraum aufgestellt werden können. So besteht die Möglichkeit, eine extremsten GMP-Anforderungen genügende Dragiereinheit in nicht voll ausgebauten Räumen aufzustellen und dadurch wesentlich Kosten zu sparen.

2. Beschreibung des Tauchschwert-Systems

In unserer ersten Mitteilung [1] wurde der Prototyp der Tauchschwert-Anlage im konventionellen Rundkessel beschrieben. Im folgenden geben wir den Aufbau der zu einem hohen Perfektionsstand weiterentwickelten Anlage im konventionellen Rund- und Horizontalkessel wieder.

2.1. Dragiereinheit

Sie besteht im wesentlichen aus einem perforierten, in das Kernbett eintauchenden Zweikammersystem (Tauchschwert, s. Abb. 1 u. 2).

Das Aufbringen der Dragiersuspension erfolgt durch ein perforiertes Stahlrohr, den sogenannten Einlaufrechen (Zuckerdragierung) oder durch Düsensysteme (s. a. 3.1.2. und 3.1.3).

*) Planungsbüro Hüttlin, D-7853 Steinen.

Alle mit dem Produkt in Berührung kommenden Teile sind aus Chromstahl gefertigt und hochglanzpoliert. Tauchschwert-System, Dragierkessel (Rundkessel resp. Horizontalkessel) und Abdeckung bilden zusammen eine geschlossene Einheit (s. Abb. 3 u. 4).

2.2. Steuereinheit

Die Steuereinheit steht alle für die Zuckerdragierung und für das Filmcoating notwendigen Arbeitsschritte vor. Diese werden im automatischen Betrieb von Zeitgliedern ausgelöst. Dazu kann der Prozeß in jeder Phase auch manuell gesteuert werden.

Die geschlossene Dragier- bzw. Filmcoating-Einheit (Dragierkessel, Tauchschwert-System und Abdeckung) wird durch den mit der Steuereinheit automatisch geregelten Unterdruck im Kessel sichergestellt. Speziell beim Filmcoating mit organischen Lösungsmitteln kommt diesem Detail größte Bedeutung zu (Arbeitsplatzhygiene, GMP, Ex-Schutz usw.).

2.3. Lüftungseinheit

Die Versorgung der Tauchschwert-Anlage mit Trocknungsluft und Abluft übernimmt ein eigens darauf abgestimmtes Kompakt-Lüftungsgerät (Monobloc-Einheit).

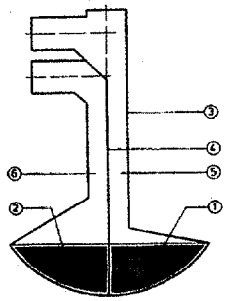


Abb. 1: Tauchschwert zu konventionellem Rundkessel. 1 Zuluftkammer, 2 Abluftkammer, 3 Koaxialrohr, 4 Trennscheibe, 5 Zuluftquerschnitt, 6 Abluftquerschnitt.

3

The first automatic sugar-coating processes were performed in 1973 by the GLATT immersion sword, licensed by Herbert HÜTTLIN (immersed in a conventional Moorish dome pan).

By the way, the immersion sword was **my first invention** / my first patent in the field of pharmaceutical technology to go down in history (at least after the successful work of GS Bologna).

Picture 5 Immersion sword publication 2

W. GLATT), K. WEHRLE*) und H. HÜTTLIN**)*

Zuckerdragieren mit dem Tauchschwertverfahren

ein neuzeitliches, rationelles Verfahren in der Zuckerdragierung

Zusammenfassung

Ein automatisches Zuckerdragiersystem, das mit handelsüblichen Dragierkesseln verschiedenster Art und Größe kombiniert werden kann, wurde zur Serienreife entwickelt.

Speziell in Verbindung mit Dragierkesseln größeren Nutzinhaltes tritt die Leistungsfähigkeit des Tauchschwert-Systems deutlich hervor. Neben den Vorteilen eines automatischen Zuckerdragierprozesses wird eine wesentliche Verkürzung der Dragierzeiten und eine optimale Ausnutzung der Überzugsmasse erreicht.

Einleitung

Die konventionellen Zuckerdragierverfahren haben ihre Leistungsgrenzen erreicht. Der Zwang zur Rationalisierung bei gleichzeitiger Sicherung hoher Qualitätsansprüche machte es zur Aufgabe, mit neuen Ideen eine zeitgemäße Entwicklung zu betreiben.

Neben den Aspekten der Wirtschaftlichkeit wurden noch Belange des Umweltschutzes und der Arbeitsplatzhygiene in die Entwicklung mit einbezogen.

Unter diesen Maximen wurde nach der Idee von H. Hüttlin**) das Tauchschwertsystem durch die Firma Glatt-Binzen/BRD entwickelt und bereits mit großem Erfolg in vielen Firmen eingesetzt.

Die nachfolgenden Erläuterungen geben einen Überblick über den technischen Aufbau des Tauchschwert-Systemes in seiner Gesamtheit.

Beschreibung

Das Herzstück der Anlage bilden zwei, in die Dragiermasse eingetauchte Zweikammer-Tauchschwerte nach Abbildung 1 und 2.

Die beiden perforierten Endstücke für Zu- und Abluft der Tauchschwerteinheit befinden sich in der Dragiermasse. Über die Zuluftkammern wird aufbereitete Trocknungsluft direkt in die Dragiermasse eingeblasen und nach erfolgtem Wärmeaustausch von den Abluftkammern wieder abgesaugt.

Die optimale Ausnutzung der Trocknungskapazität bringt eine Verkürzung der Trocknungszeiten auf etwa die Hälfte im Vergleich zu konventionellen Verfahren.

*) Firma Werner Glatt, D-7861 Binzen

**) Planungsbüro Hüttlin, D-7863 Steinen

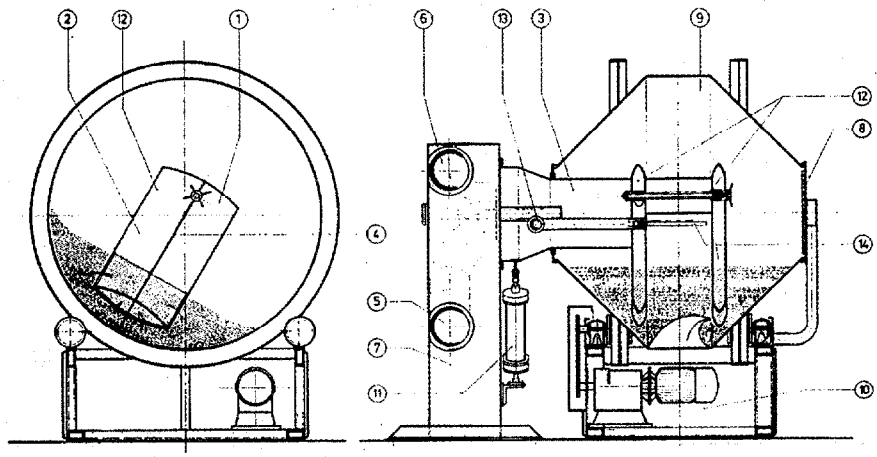


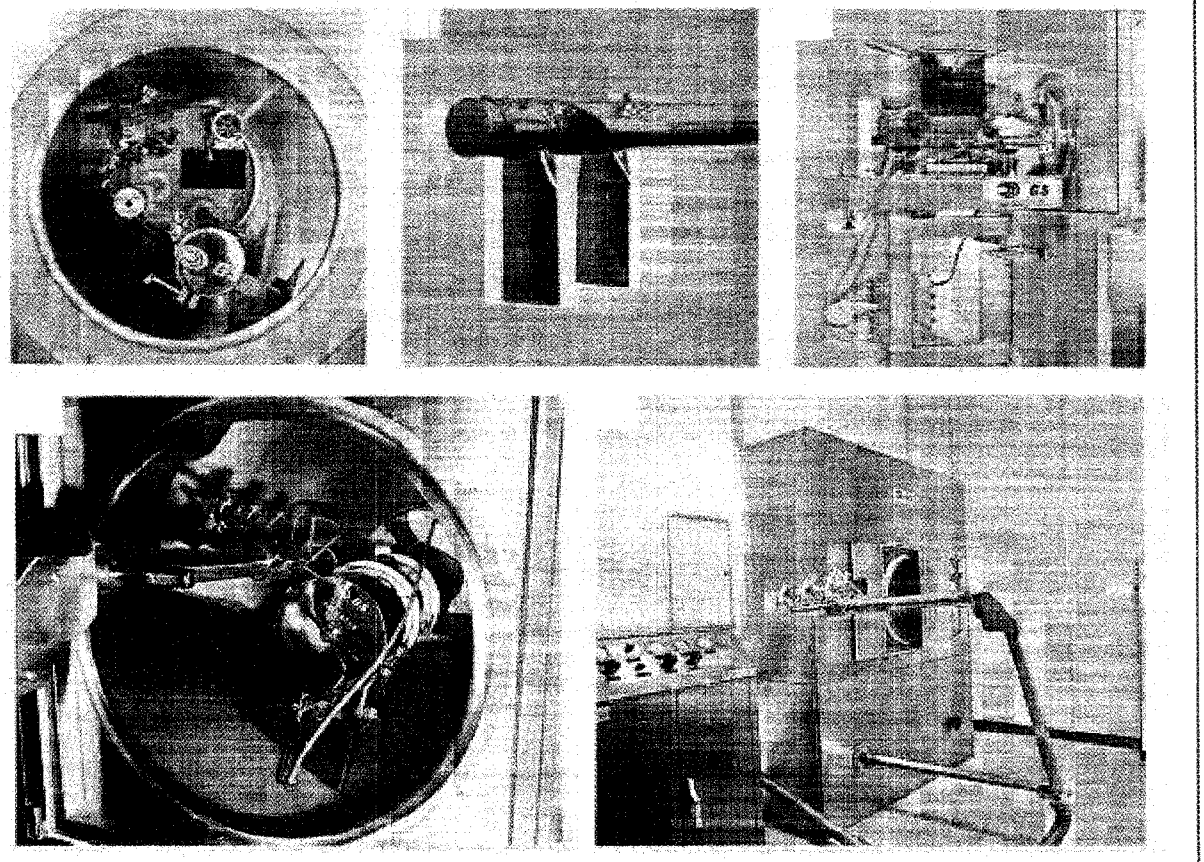
Abbildung 1 *Abbildung 2*

Abbildung 1 und 2 Tauchschwert-Einheit mit Horizontal-Dragierkessel beliebiger Größe

1 Zuluftkammer, 2 Abluftkammer, 3 Koaxialrohr, 4 Trennscheibe, 5 Zuluftquerschnitt, 6 Abluftquerschnitt, 7 Stativ, 8 Kesselabdeckung, 9 Horizontal-Dragierkessel, 10 Antriebsblock, 11 Ausschwenkvorrichtung 12 Tauchschwert 13 Flüssigkeitszuführung 14 Einlaufrechen

The GLATT immersion sword was identical with the GS-Coater in terms of construction (without any cutbacks in function and design).

Picture 6 GS coating system



GS was renowned for this system world-wide, however, hardly anybody talks about the GLATT immersion sword anymore. Copyists or pirates were faster and better.

The characteristic feature of the immersion sword or the GS coating system is a perforated hollow part made of special steel blowing dry, warm and also conditioned process air from the "bottom", so to speak, onto the moving bulk, and sucking the air off again at the same point.

The spaces between the tablets permit the drying air to penetrate the bulk deeply and finally to escape via the outlet air chamber of the perforated hollow part.

In another variant of the design, the outlet air escapes via the surface of the flowing core bed into an outlet air nozzle which also forms part of this technology.

But we do not want to spend too much time on prior art. This was merely to inform you on the basic achievements.

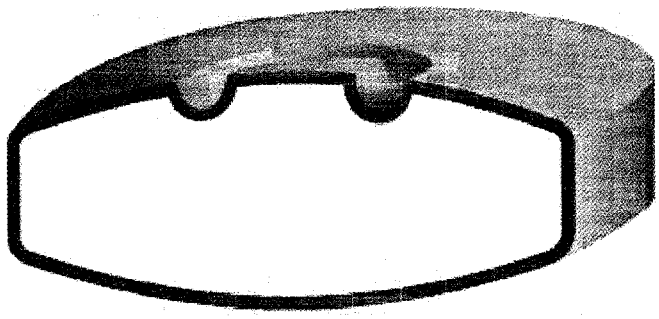
The former drying periods of the conventional coating cycles took 8 – 12 minutes and were reduced to 4 – 6 minutes, i.e. by about half.

This constituted a tremendous progress!

Film coating

Despite this progress, at least in the pharmaceutical industry, a change of paradigms in process engineering took place in the course of the seventies.

Lacquering or film coating began to attack sugar-coating and suspension-coating.



Picture 8 filmcoating tablet

Particularly the pharmaceutical industry investigated the capabilities of film coating intensively, since it was immediately thought to achieve increased long-term stability - especially in countries with hot and humid climate.

In the same manner, pharmacists slowly realised that sugar or suspension coating could not meet the demands of controlled release of the active substance in the gastro-intestinal tract of human beings and animals.

From then onwards, the inclusion of a defined resistance against the different intestinal juices was endeavoured for the coating layers.

In these cases we refer to them as "functional layers".

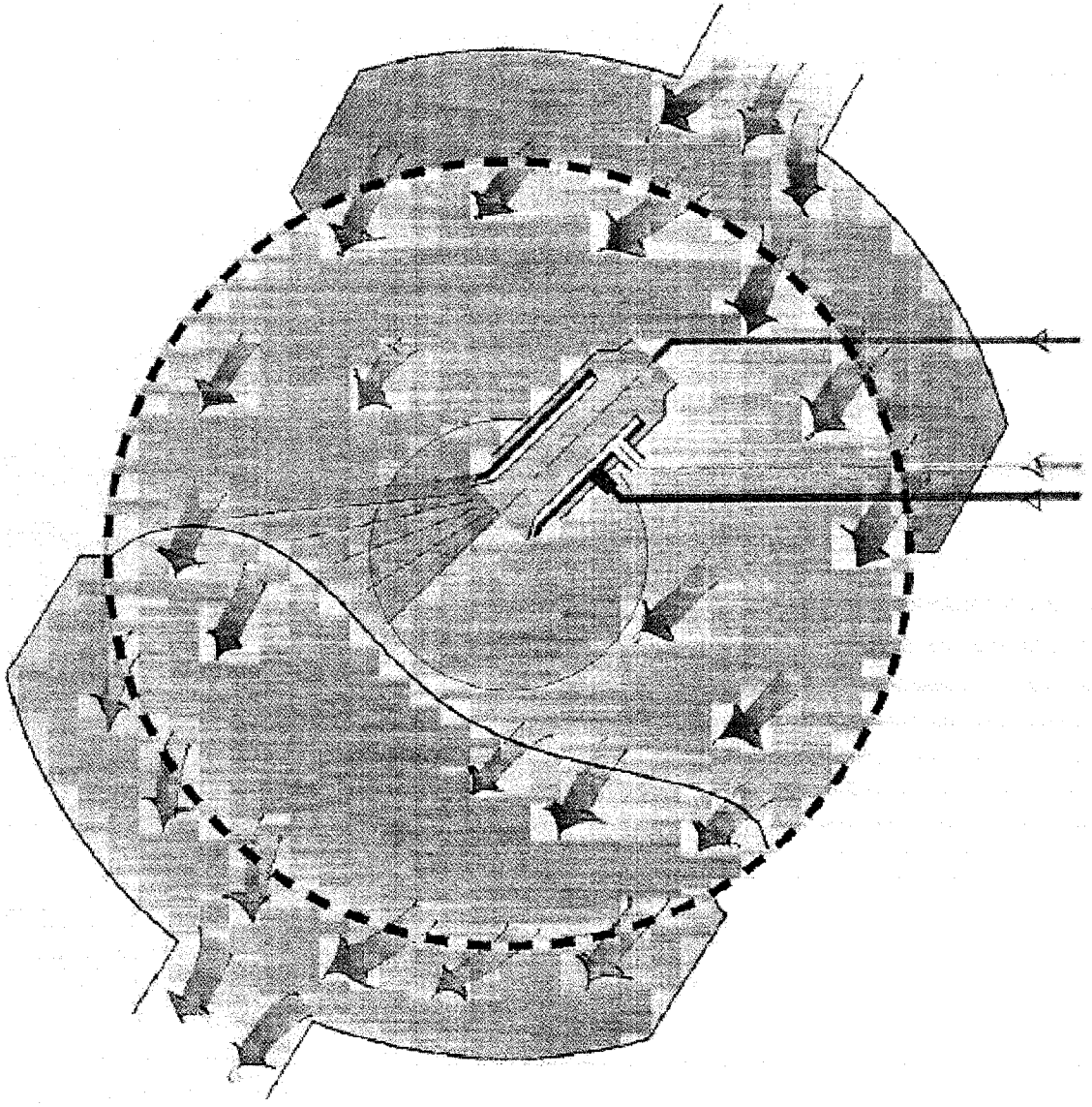
The first polymers, plastic film coatings were produced by RÖHM Darmstadt (EUDRAGIT)

Polymer derivates and cellulose derivates are now starting their triumphal march world-wide. In this context, the products of COLORCON London, SEPPIFILM Paris, and several others should be mentioned in addition to RÖHM Darmstadt.

When the first film coating took place, also the first horizontal pans equipped with the corresponding spraying and drying devices appeared. The PELLEGRINI pan, for example.

Attempts to shorten the processing times even more finally resulted in the perforation of the pan body in such horizontal pans.

Picture 17 Section diagram of a perforated pan

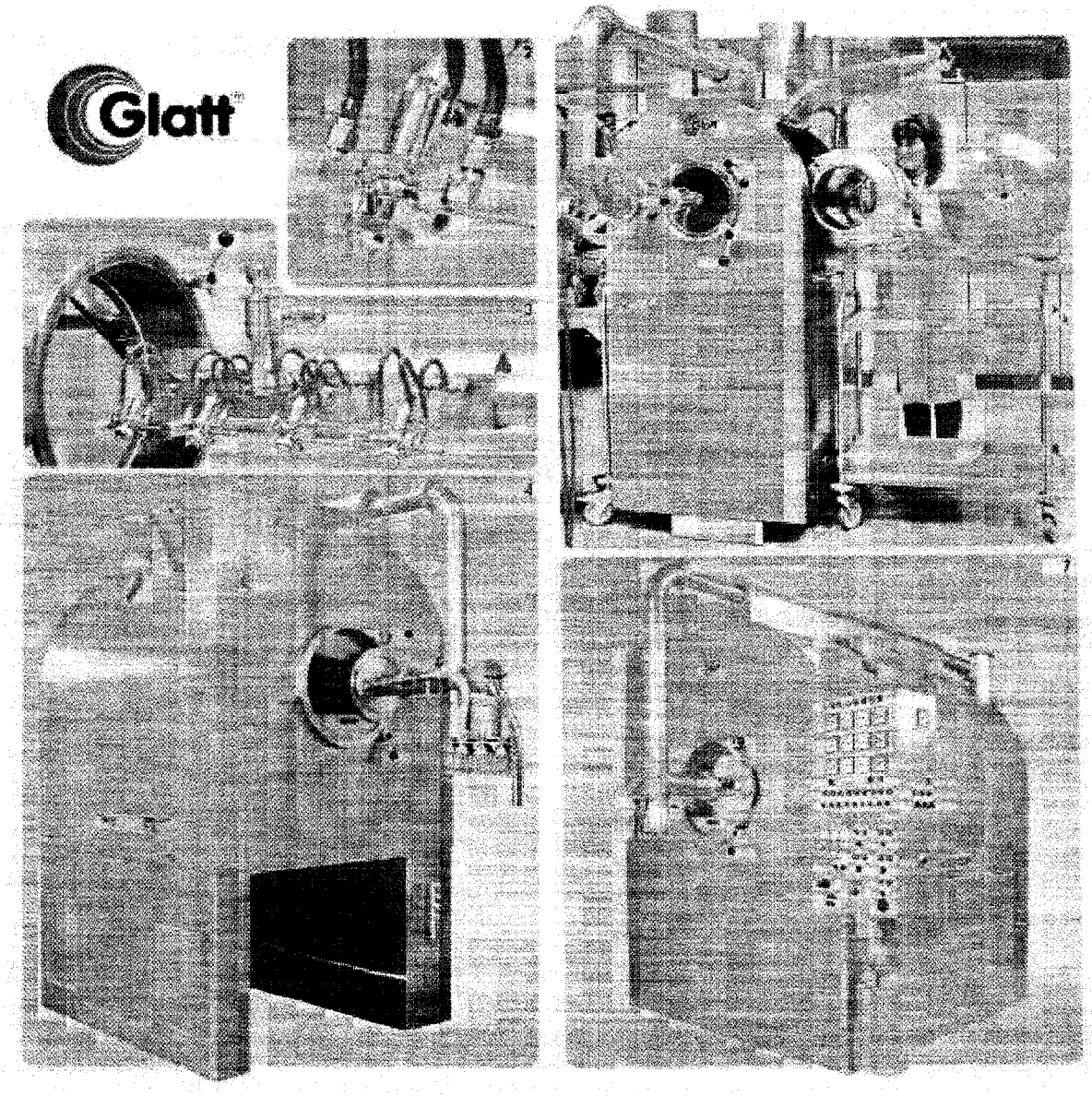


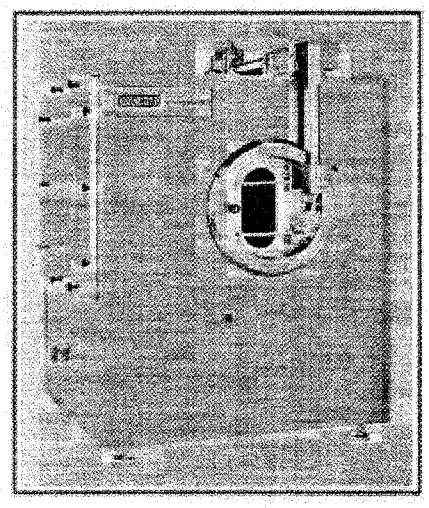
The next change of paradigms for processes and facilities in terms of sugar-coating and other coatings of tablets was introduced with the perforation of the pan body.

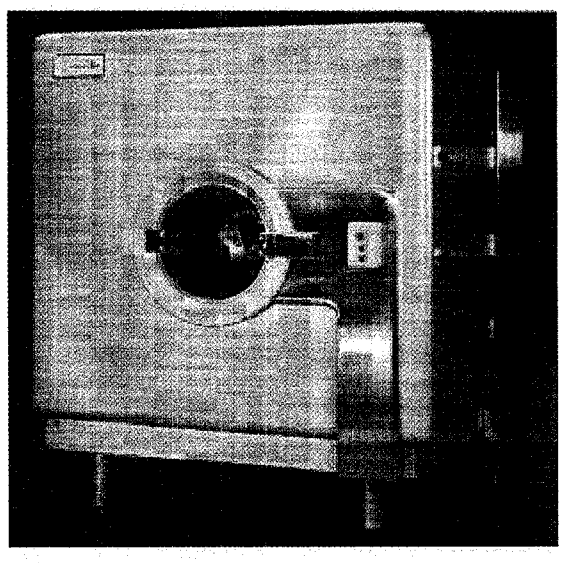
Developments of the past 2 – 3 decades seem to have served the design/optimisation of technical details rather than basic considerations in terms of a clear improvement of performance while, at the same time, ensuring a high degree of product quality, reduction of spraying losses, improvement of handling, the integration of the process steps of "filling" and "discharging" into the design as well as "washing-in-place".

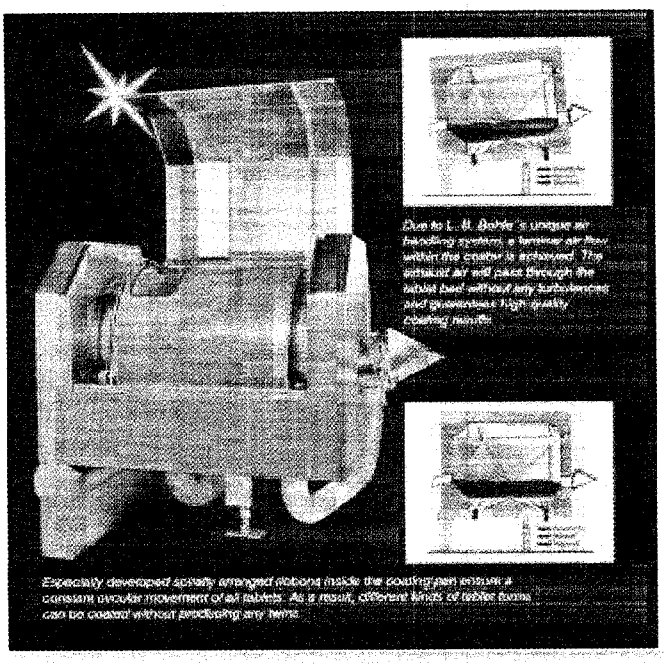
The constantly increasing demand for coating technology and engineering worldwide induced a number of facility manufacturers to deal with the topic of perforated coating pans. Some of them were MANASTY, GLATT, DRIAM, Freund etc.

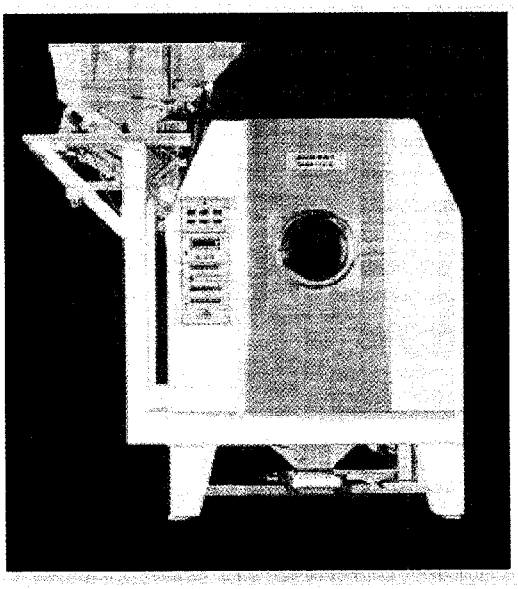
Picture 9 – 15 coating systems, horizontal pans of competitors





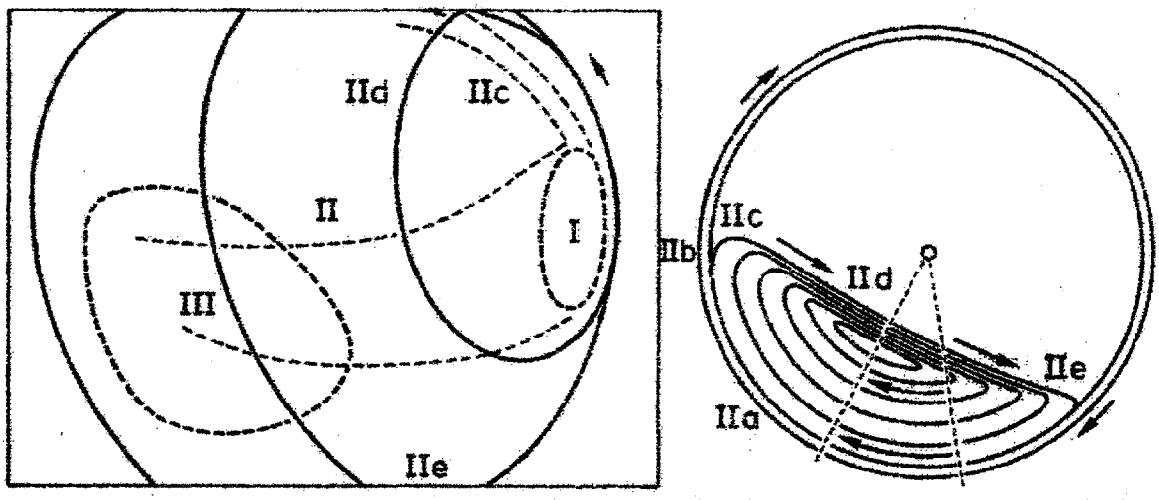






All these systems work as follows: The drying air - in the form of process air - is blown via a corresponding air source onto the descending product, it passes through the product and is finally sucked off on the opposite side via a suction source tightly mounted on the outside of the perforated pan body. This causes a more or less effective heat exchange of the process air with the product.

Picture 16 Product movement according to Prof. Speisser



The seemingly unsolvable problem of the bed core formation in a moving core bed of tablets made it very clear to me that a solution would not be found by merely improving the existing pan shapes and re-designing the carrier shovels and baffles.

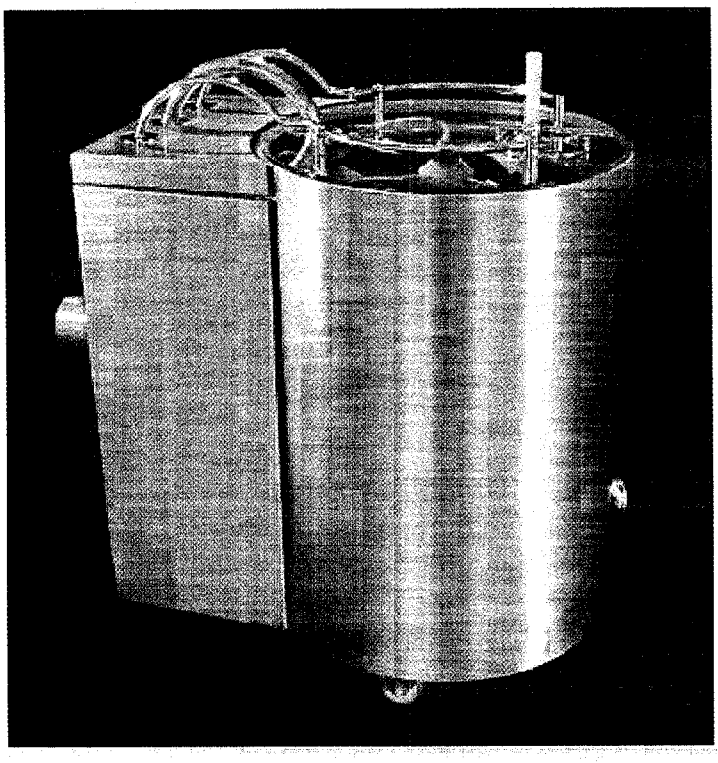
Once the physical preconditions of the process air in respect of the statically available pressure and quantity are given, the space between the individual product particles essentially determines how much process air passes through the bulk of product.

We became aware of the fact that a clearly more modern coating technology was not to be achieved by improving the perforated horizontal pans with their complex spray air and process air facilities.

We needed to find a new technological approach.

Edison's light bulb was not invented by improving the wax candle!

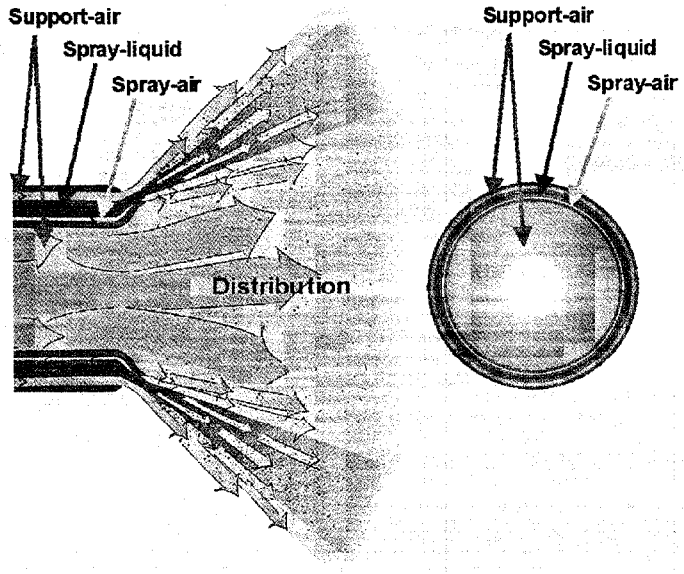
Picture 18 ICC-5 photo



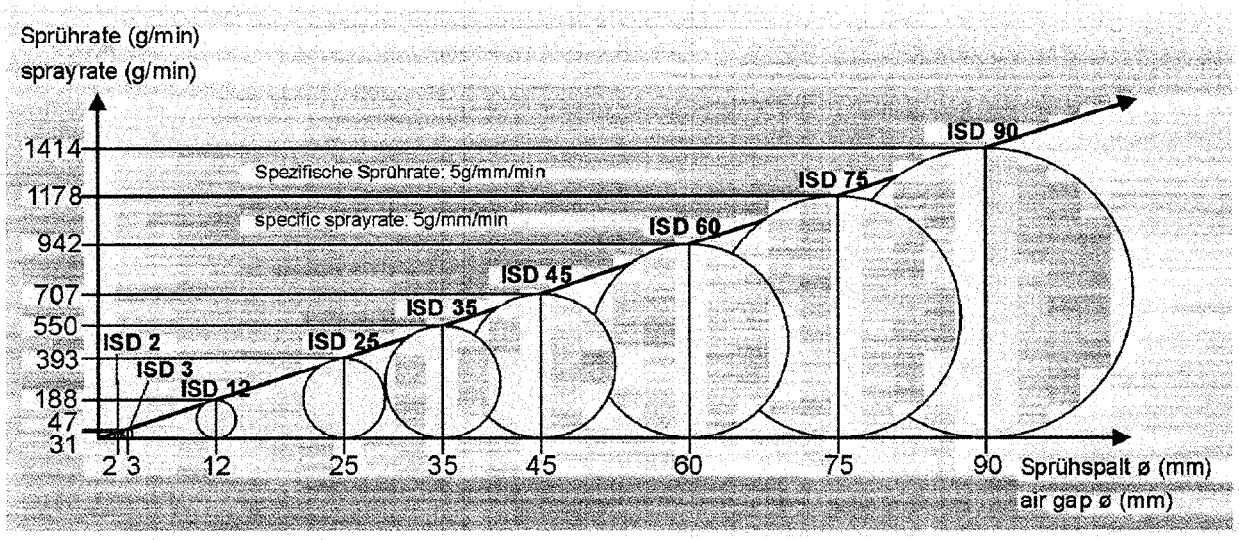
How was the idea of the Centrifugal Coater born?

The fact that the INNOJET annular gap spray nozzles showed best results in practical tests and required only a single nozzle to be applied in a new coating system due to the integrated scaling-up design supported my considerations leading to the Centrifugal Coater.

Picture 18 a INNOJET annular gap nozzle



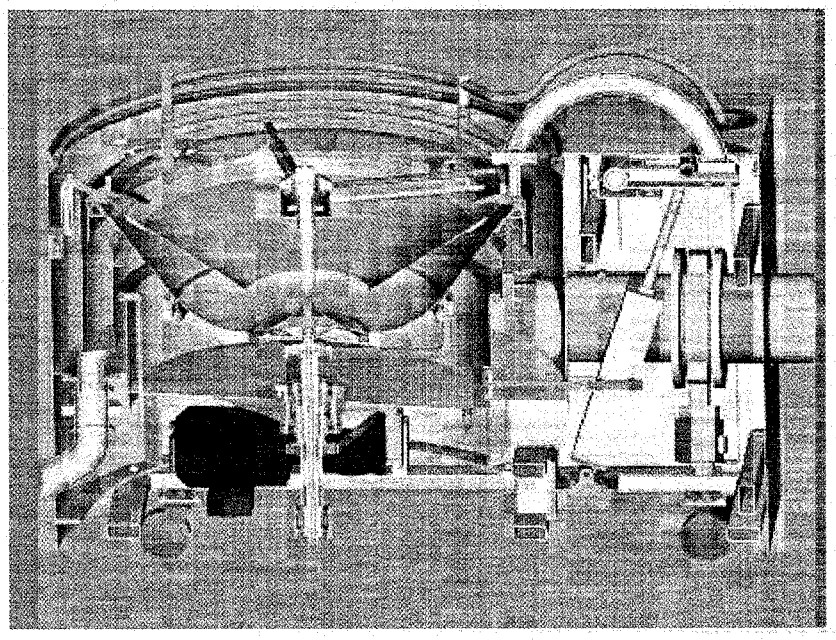
Picture 18 b scaling up of the INNOJET Nozzle



An even layer thickness on the edge, side and calotte of all tablets could only be achieved if all of them passed the spray zone for the same length of time, with the same frequency and were dried over the same distance.

This, however, did not seem possible with the product movement common to nearly all conventional horizontal pans (see section according to Prof. Speisser).

Picture 19 Section ICC 25

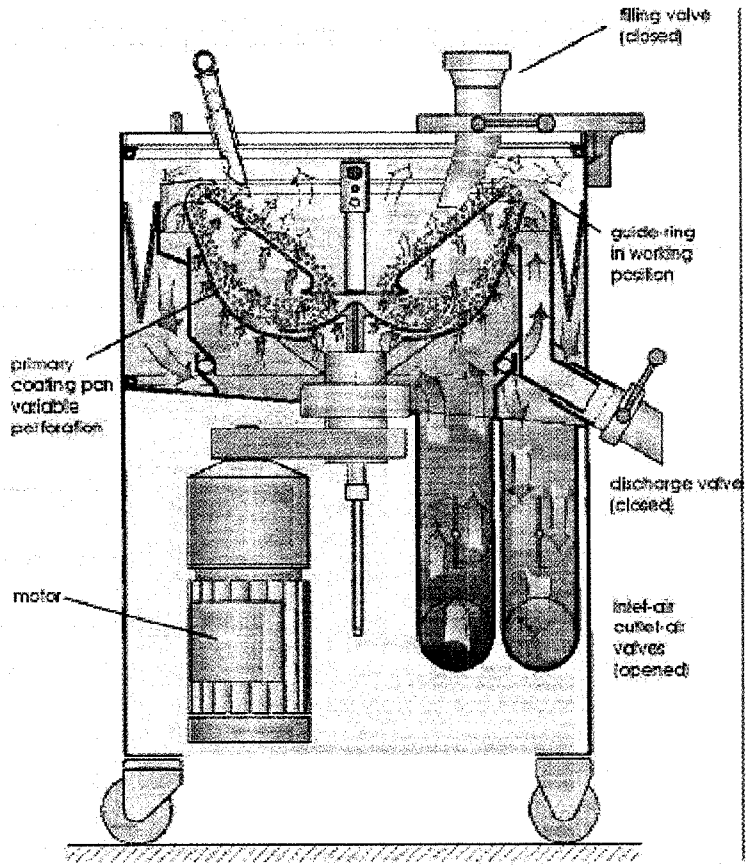


The result of my considerations was to include the centrifugal forces of a pan rotating on a vertical axis, with the simultaneous return of product to be treated via a statically arranged return screen.

This pan rotating on a vertical axis should consist of a body part opening conically towards the top and a doubly arched bottom part which was mounted onto it in the same vertical axis and might be rotated independently if required.

The product moves upwards on the inner surface of the body when the pan turns. It is finally led into a statically fixed return cone via a statically arranged deflecting ring and flows back into the doubly arched bottom part which forms a kind of product tube.

Picture 20 Coating process



The INNOJET annular gap spray nozzle is situated at the lower opening of the return cone within the tube-shaped product flow (on the vertical rotational axis of the pan). It is able to deliver the spraying liquid evenly and nearly horizontally at a 360° angle of contact to the surface of the product flowing vertically downwards in a tube-shaped manner.

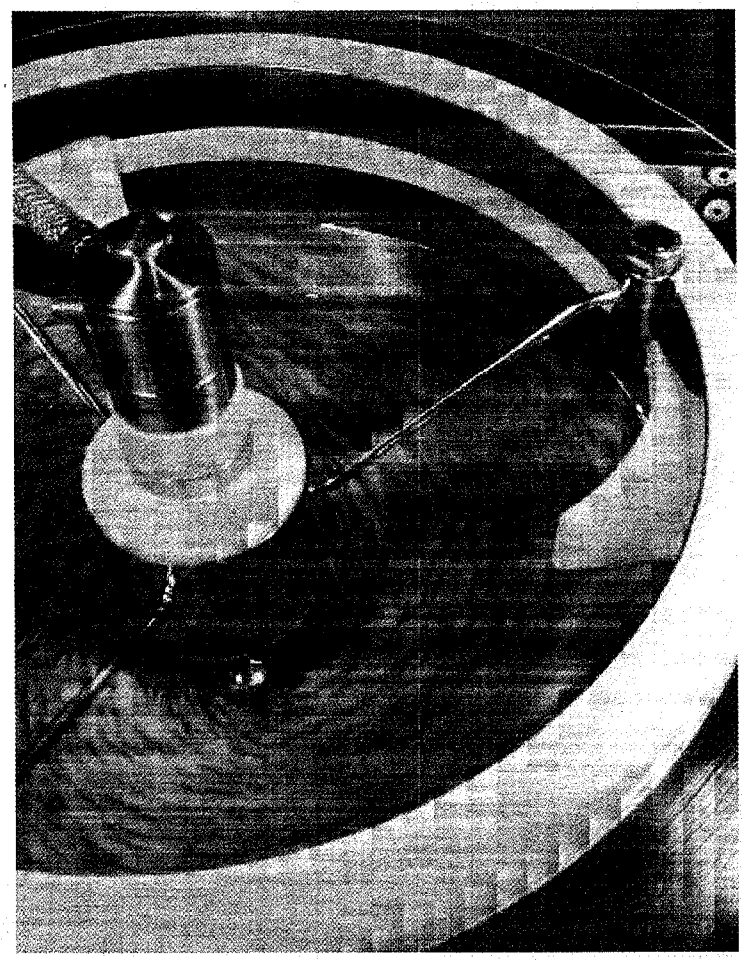
It is self-understood that each individual tablet passes by this application zone in such a defined manner that it receives the same quantity of spraying liquid on its surface.

Immediately after the reception of the spraying liquid, the first drying of the tablet surface occurs (1st drying phase) by introducing accordingly conditioned process air (with defined dryness and heat) via the perforated area of the doubly-arched container bottom as well as the annular gap realised between the outer diameter of the bottom part and the lower diameter of the conical body part.

Process air thus passes through the product in the primary container part, the doubly arched container bottom, for the first time while it flows upwards in a centrifugally gliding motion, and for the second time, while flowing back to the centrally arranged spray nozzle via the return cone.

Two-phase drying was thus created leading to the expectation of a higher efficiency already in the theoretical approach as compared with the systems of prior art.

For the second time in the history of coating technology the drying times were reduced by more than 50 %.

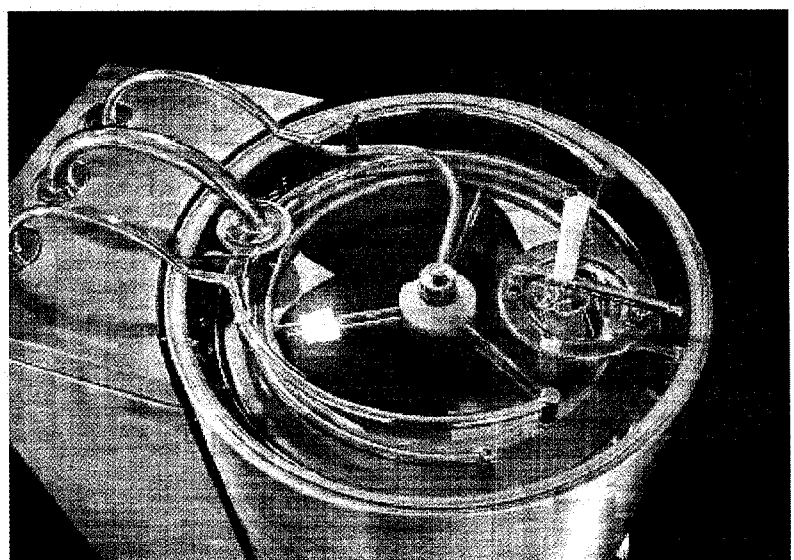


Picture 21 product movement

Centrifugal-toroidal product movement is not only very impressive but also very gentle. It may be applied for all commonly available solid products of the pharmaceutical industry, particularly for tablets of the most varied shapes, sizes and densities as well as filled hard and soft gelatine capsules and for pellets from Ø 2 mm onwards etc.

Optic control

Picture 22 View of glass lid



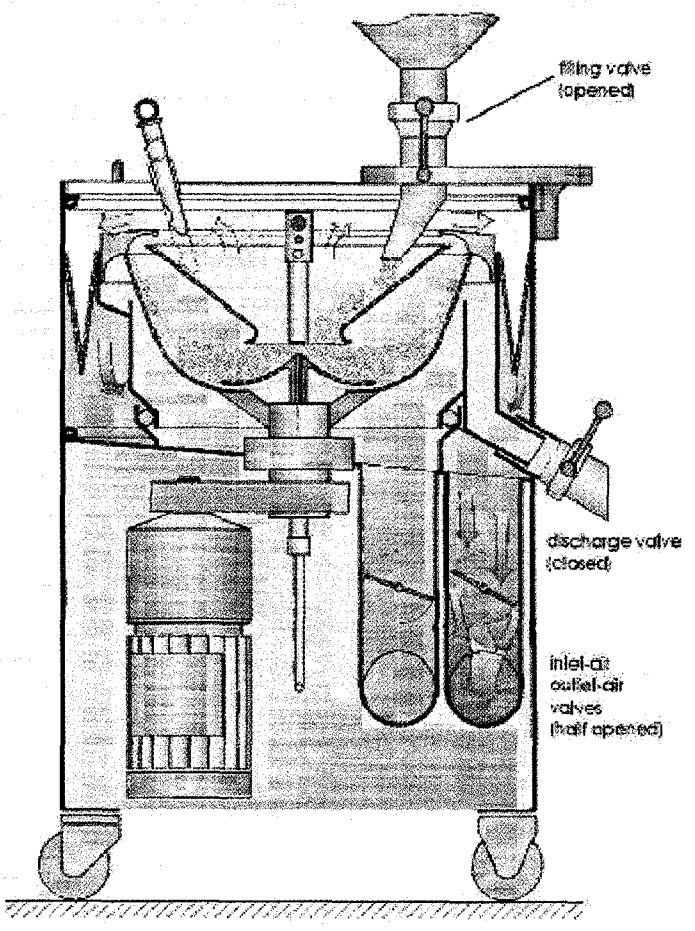
This technology has been designed to grant the operating staff the best possible optic control of the process right from the start.

The large transparent areas in the vertically or horizontally swivelling lid

made of highly robust industrial glass grant the best preconditions for this.

Filling

Picture 23 ICC-5 Filling

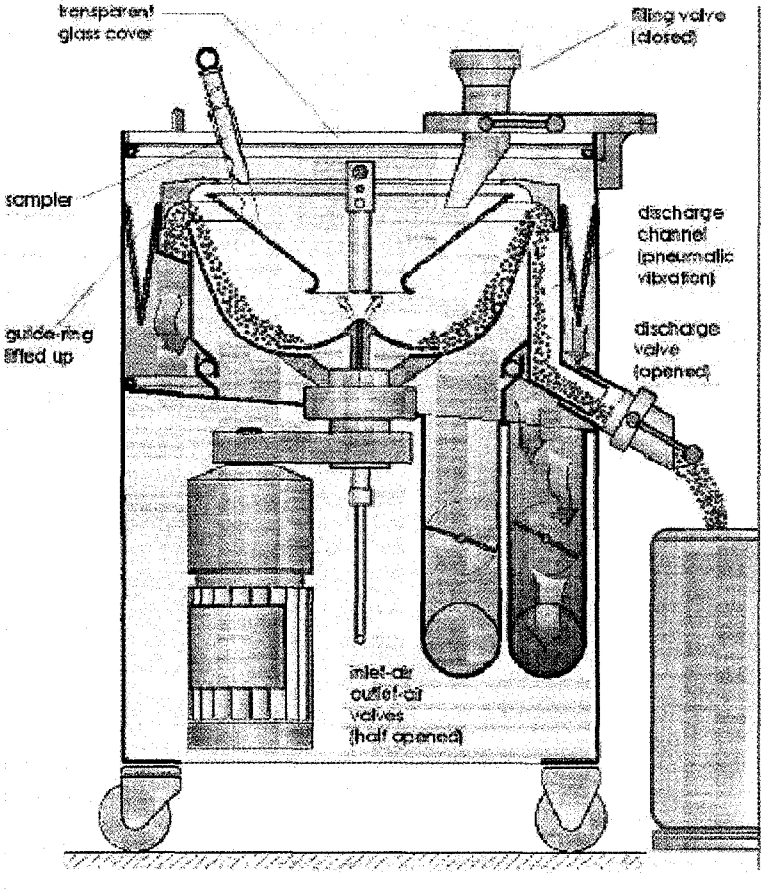


All sizes of the system are gravimetrically filled via a „Müller-Nest" integrated in the lid area.

The raw product vessel enters into a "closed connection" with the „Müller-Nest" so as to allow filling independent of the working environment and under hygienic conditions.

Discharging

Picture 24 ICC-5 Discharging



The centrifugal forces of the product container rotating on a vertical axis also perform an important task in the discharge of the product.

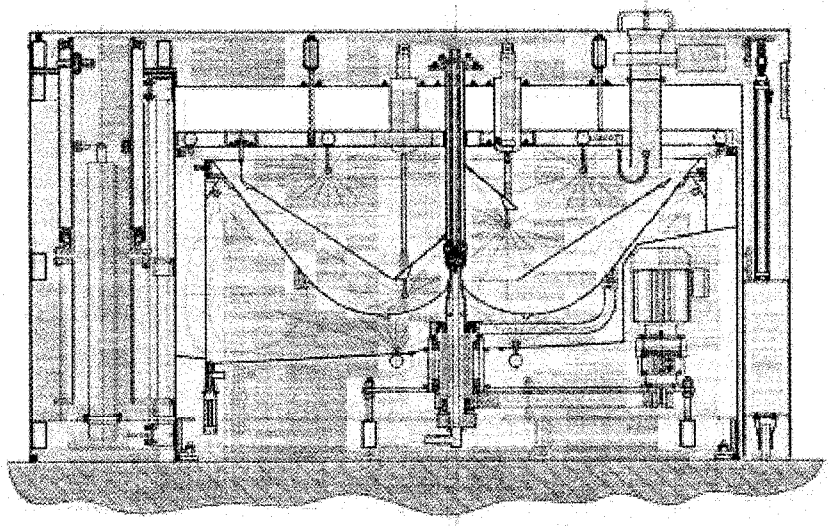
In order to commence discharging, the product container (the same for all sizes) is pneumatically lowered in a vertical direction by a certain value within the main drive shaft.

For smaller devices up to lot sizes of 25 kg, the product centrifugally moving upwards and outwards reaches a discharge duct

integrated in the system which can take in the product and have it released in a downward movement.

The discharge duct forming a ring around the rotating pan is pneumatically vibrated during the discharging process in order to accelerate discharging and to remove even the last tablet safely from the system.

Picture 25 ICC-150 Portal system section 2-D



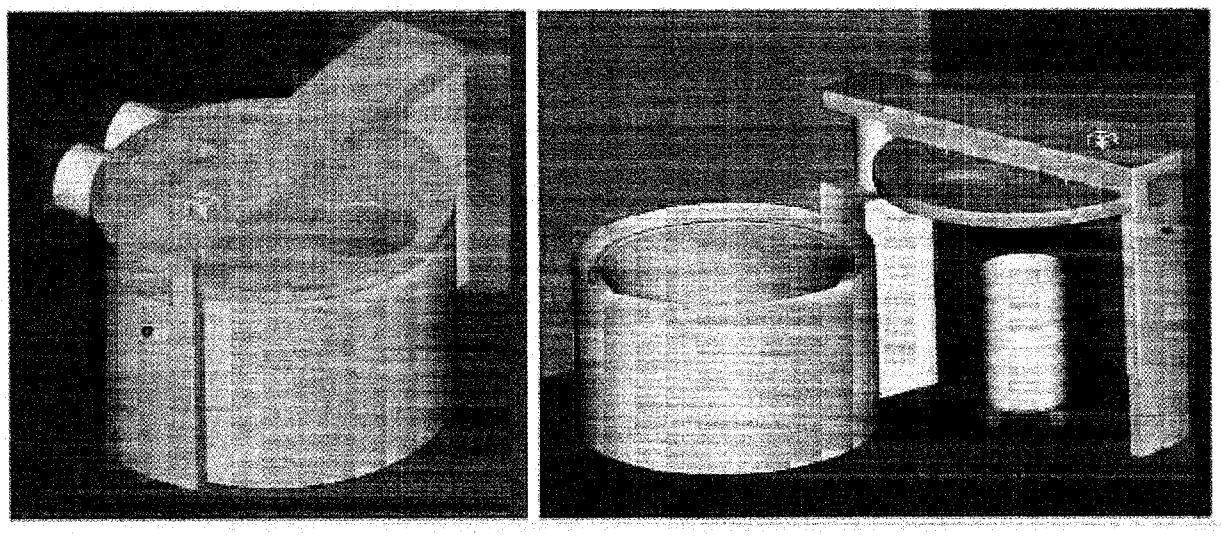
In the case of larger devices from lot sizes of 50 kg onwards, the lid and the complete return cone are carried via a so-called horizontally swivelling portal.

The hat-shaped part which is centrally arranged within the return cone, is pneumatically moved vertically downwards so as to close the lower rim and the throat of the return cone.

The product is still conveyed to the return cone via the deflecting ring during discharging, but from there, it cannot flow out for the time being.

Due to its size and design, the return cone with the closed hat-shaped part can hold the entire lot of the respective device.

Picture 26 ICC-150 Portal system 3-D animation



Subsequently, the swivelling portal is raised vertically by the required amount and is shifted horizontally from the facility.

In this process, the discharging throat of the return cone is centred as well as possible above a corresponding product recipient bin and a closed connection is formed.

To discharge the product, the hat-shaped part is slowly raised vertically by manual control which gradually opens the cross section for discharging the product.

In this case, the product is also completely discharged.

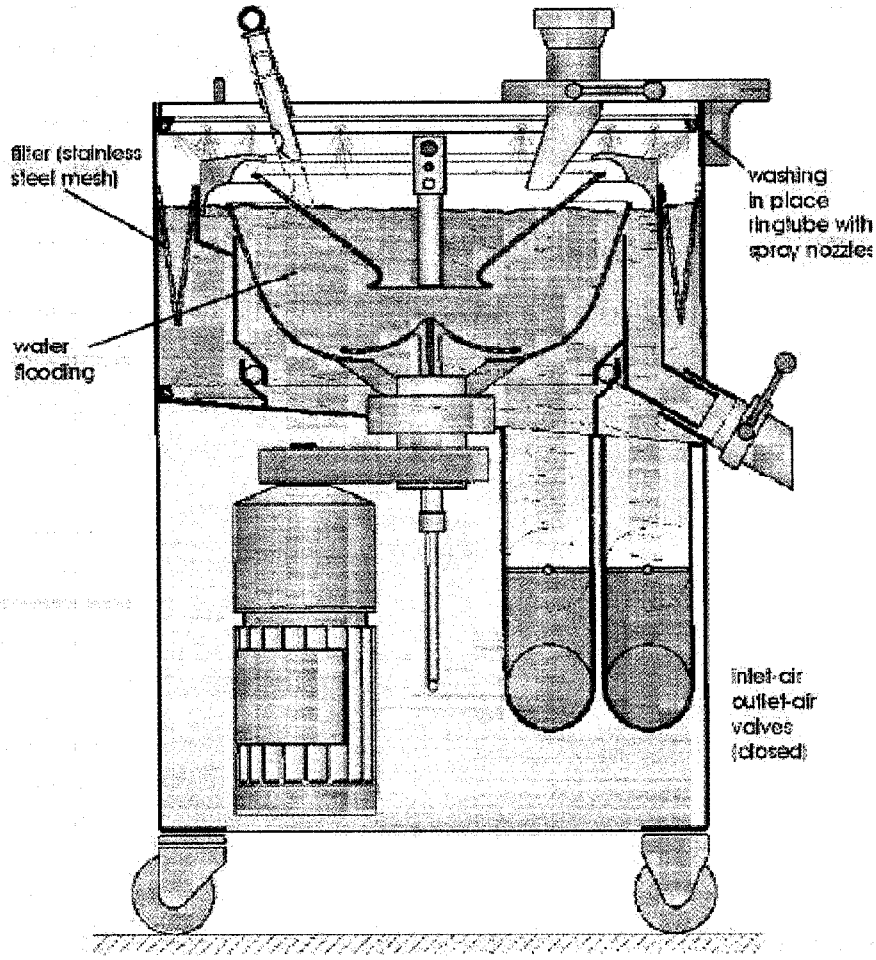
Since coated moulded solids are characterised by the fact that they do not release any active substance particles via their surface, so-called "open discharging" is acceptable in most cases. Not so for the filling process, since the product has not received its protective coating yet which could prevent the escape of active substances.

If we become aware of how awkward discharging of horizontal coating pan facilities still is today, we will realize the tremendous extent of the progress facilitated at this point.

And now for the cleaning of the process device.

Picture 27 ICC-5 Section flooding

Cleaning of pharmaceutical process facilities and their validation, which forms an indispensable necessity and demand, is becoming more and more of an issue for designers and users.



However, to ensure that the result of facility cleaning is not determined by chance, it must be considered already during the design phase as well as during the construction of individual details.

Homogenous internal and external surfaces of the device facilitating optimum accessibility for cleaning fluid and, especially, allowing a good view for the facility operator are required.

Non-accessible zones, non-visible areas and complex surfaces are to be avoided.

The aspects of washing-in-place also influenced the design and the construction of the INNOJET Centrifugal Coater and the DIOSNA Vertical Centrifugal Coater fairly early on.

We are proud to tell our customers that this technology, unlike all others, is characterised by the fact that washing-in-place is facilitated in an optimum fashion.

The internationally introduced terms of “cleaning-in-place” or “washing-in-place”, in this order, specify the two quality levels of cleaning on site.

The objective is always to achieve the optimum i.e. “cleaning-in-place”.

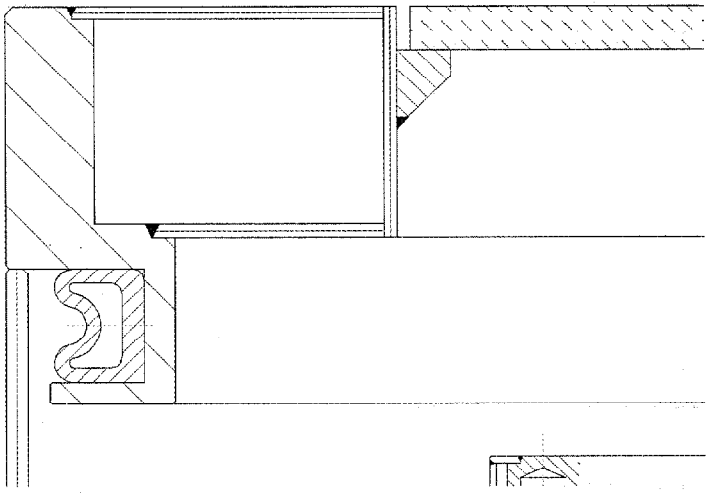
This level of cleanness requires that - after the conclusion of cleaning - no more than a defined and low number of particles of the product treated may be found at any point of the area having come into contact with the product.

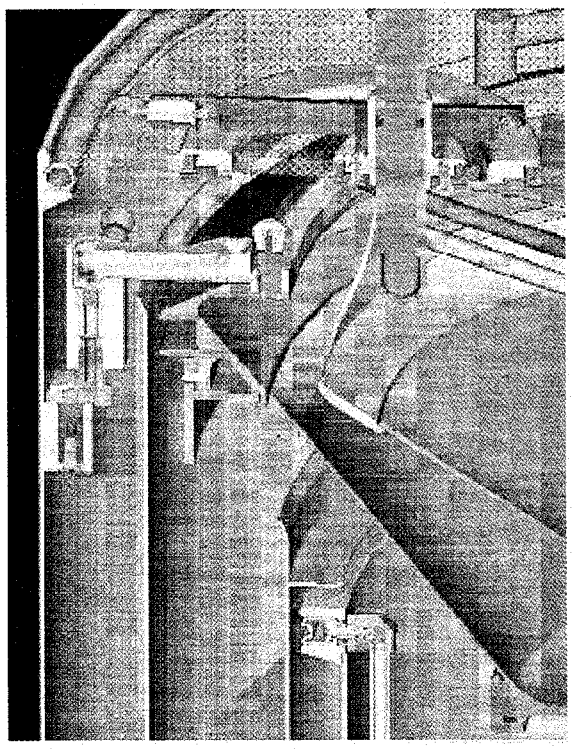
Specifications of this requirement are stipulated in the GMP guidelines.

Washing-in-place is a little more simple. It only requires that facilities may be considered practically clean after washing.

Cleaning-in-place quality can only be achieved if no static or pneumatic seals are present within a system of devices.

Picture 27a sealings in the VCC 150 and the VCC 5



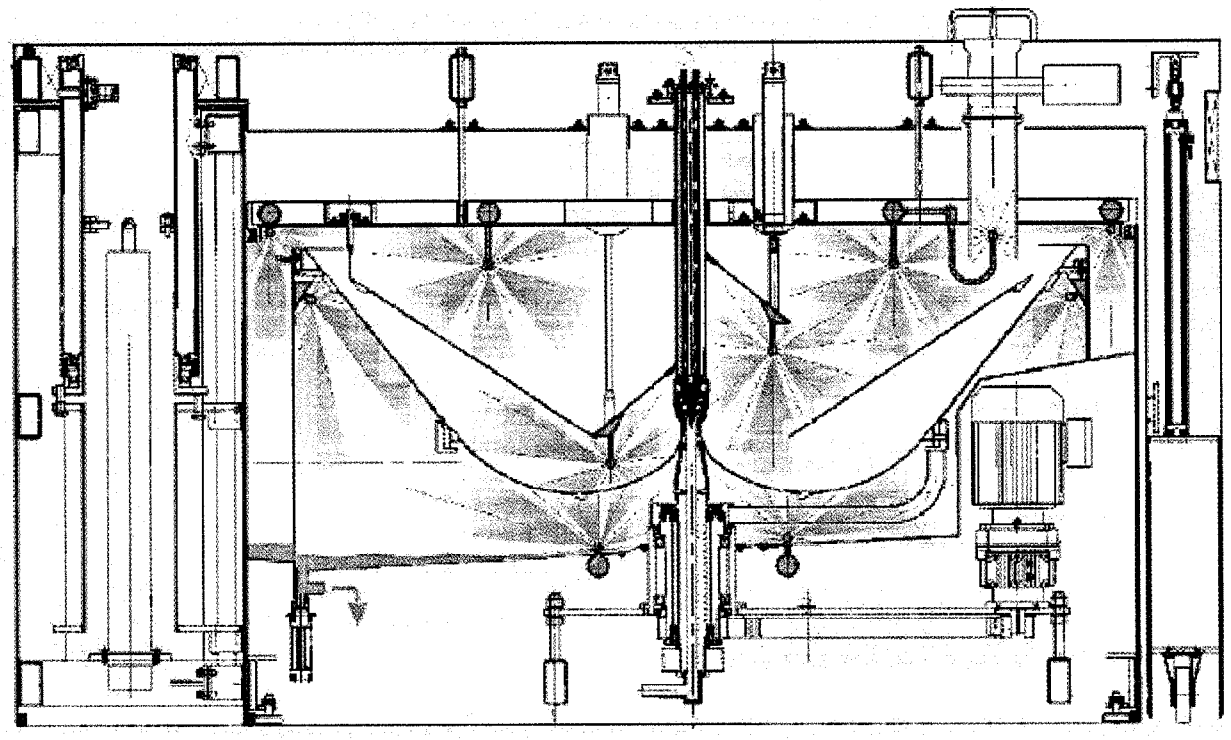


Unfortunately, however, it is impossible to seal the different points of contact in a closed system without flexible sealings in a reasonable manner. Thus pneumatic and static seals must be inserted into a grove and cleaned separately when removed.

These groves must also be cleaned in a special fashion before re-inserting the seals.

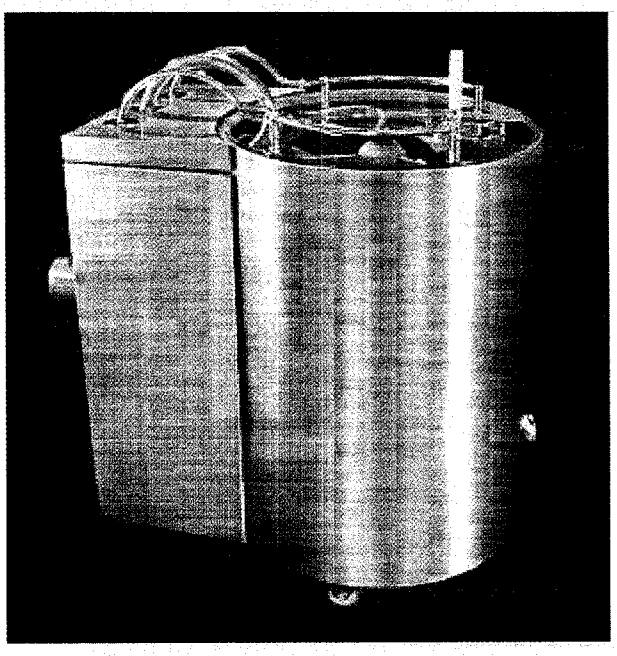
The realisation of washing-in-place for all internal surfaces is largely ensured either by flooding of machines for lot sizes up to 50 kg or by an integrated spraying system for larger facilities.

Picture 28 Section ICC-150 integr. spraying system for washing



Unfortunately, reliable data is not yet available due to lack of time. This will result from practical applications performed during future tests in our laboratory.

We will surely keep you informed on the results so that you can pass the information on to your customers.



Picture 29 Photo ICC-5 full portrait

The closed system

As opposed to any other tablet coating facility according to prior art, this new technology represents a consistently closed system.

In any other facility, the rotating throats of the outlet of the pan and the static part of the housing must be sealed.

This causes undesired friction and material wear, and, above all, does not create any reliable internal and external sealing of the product chamber.

In our case, the lid of the machine rests on the static opening of the housing. The point of connection is sealed by means of a hollow tube, for smaller machines, and a pneumatic seal for larger machines.

The central bearing of the vertical drive shaft at the lower end of the product container is also waterproof and gasproof.

Washing a facility of this size requires, in any case, the corresponding equipment for liquid processing and disposal e.g. by Kärcher, Tuchenhagen or Gibli/Schweiz.

Customer demands and their willingness to invest determines the convenience of such equipment.

This part of the washing system is usually bought "off the shelf" and installed by all facility suppliers of fluidised bed technology, air flow bed technology and coating technology.

And now for the operator control

The new "Centrifugal Coater" technology permits the installation of an operator control entirely geared to customer wishes.

Usually, the distinction in respect of convenience and equipment is made between a mere laboratory machine, a pilot facility or a production facility.

It goes without saying that the degree of automation in a laboratory facility is usually lower than in a pilot or production facility. Exceptions not excluded.

The common feature of all sizes is, however, that the coating processes may be reliably controlled, regulated, measured and certified according to the following parameters:

Control - parameters

1. Pan revolutions
2. Process air quantity
3. Inlet air temperature
4. Outlet air temperature
5. Spraying output in g/min.
6. Spraying time in min.
7. Time for pre-heating of the machine
8. Pre-heating temperature
9. Vacuum in the process container
10. Total resistance of the process device
11. Total process time in min.
    Interval time for washing in min.

Picture 30 test report

Date: 11.08.01 Ch.-B:
Trial N: 1 Sheet No.
Customer:
Visitor:

TEST REPORT
ICC 5

INNOJET TECHNOLOGIES

Raw material:	tablets	Type of process:	aqueous X / organic
Diameter:	10 mm		
Raw weight:	5000 g	Operator:	
Quantity of coating %:	3 %		
Coating components:	Opadry II	Type of spray nozzle:	SO 12 1 nozzle
Quantity of solids %:	12 %		
Quantity of solids g:	150 g	Quality of air press.:	6 bar oil free unheated
Solvent:	Wasser		
Quantity of solvent is:	1100 ml	Type of pump:	peristaltic pump
Total quantity of coating:	1250 g	Tube - Ø:	6/4 mm

Trial of target:

not OK

time (min)	pan speed rpm	temp. (actual value) inlet air (°C)	outlet air (°C)	product (°C)	qty.of air (actual value) inlet air m3/h	outlet air m3/h	spray system spray press. (bar)	supp. air press (bar)	pump Feed (Hz)	spray rate g/min	system resistance product (Pa)	instrument (Pa)	remarks
0	115	40.5	34.2		34.7		2.00	0.80	35	24			
10	115	40.3	30.9		29.8		2.00	0.80	35	24			
15	115	40.0	30.9		29.8		2.00	0.80	35	24			
25	115	42.0	29.9		28.8		2.00	0.80	40	28			
46	110	44.2	29.7		28.1		2.00	0.80	40	28			
62	110	46.1	29.7		28.9		2.00	0.80	40	28			
73	110	47.6	29.9		30.0		2.00	0.80	45	30			
110	110	47.6	29.9		30.0		2.00	0.80	45	30			

result:	color- homogenity:			homogenity of layer - thickness:			edge			side		
				Calotte								
	poor	good	very good	poor	good	very good	poor	good	very good	poor	good	very good

total impression:

It essentially depends on the type of usage whether a coating facility must comply with normal electrical protection regulations or special Ex-regulations.

Aqueous coating procedures do not require any Ex-protection.

Another remark concerning Ex-protection:

If excessive solvent concentration is – even partially - expected in the system or the outlet air of coating processes (using organic solvents) DIOSNA is the only company in the world capable of supplying a Centrifugal Coater designed with a defined pressure shock resistance.

Thank you for your attention. I trust you will be successful with this new and interesting technology.

INNOJET® TECHNOLOGIES

- moving solutions -

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HYGIENE - PRODUKTION - AUSRÜSTUNG

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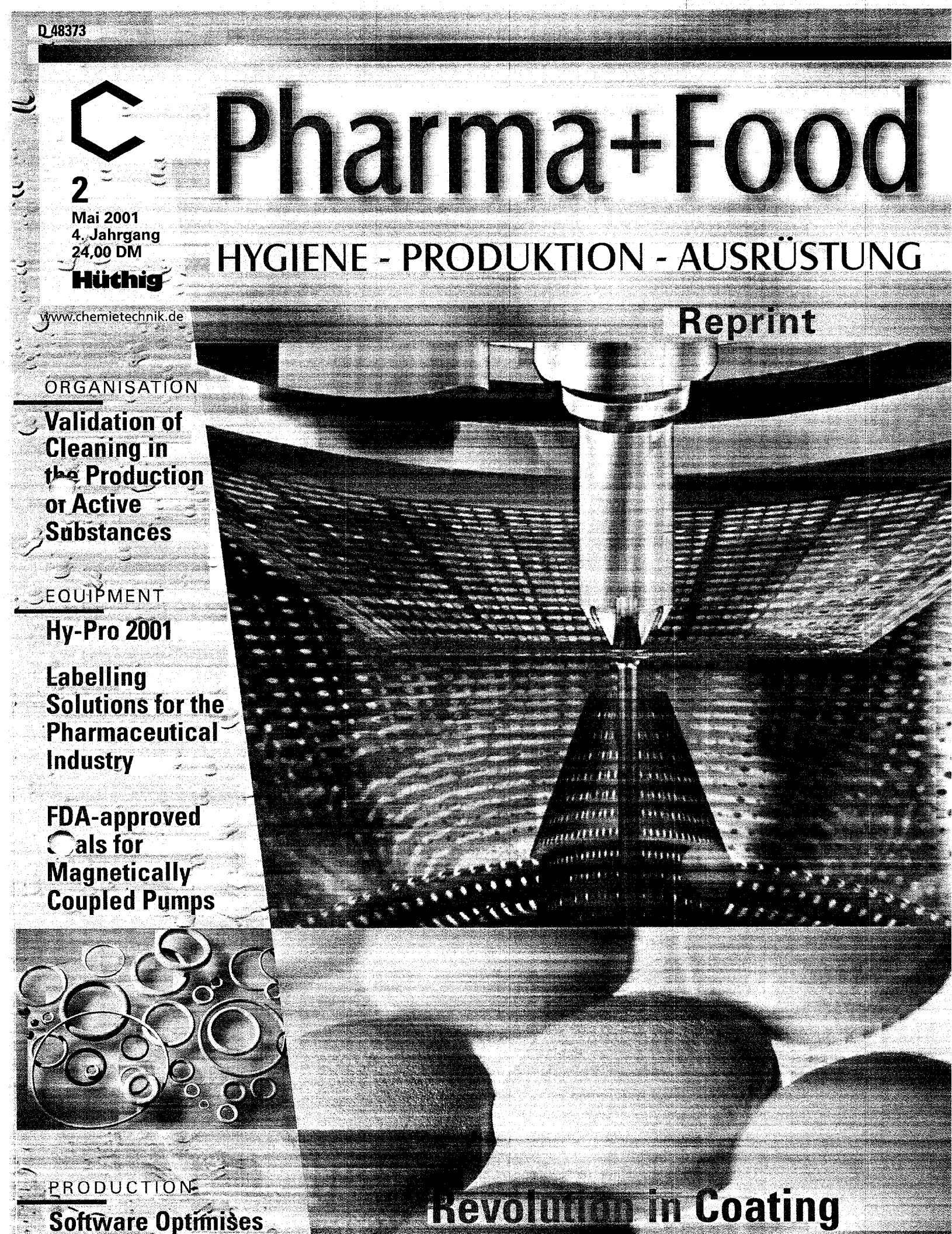

ORGANISATION

Validation of Cleaning in the Production of Active Substances

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Hy-Pro 2001

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FDA-approved Seals for Magnetically Coupled Pumps

PRODUCTION

Software Optimises

Revolution in Coating

Farewell to Irregularities

New coater assures uniform layer thickness

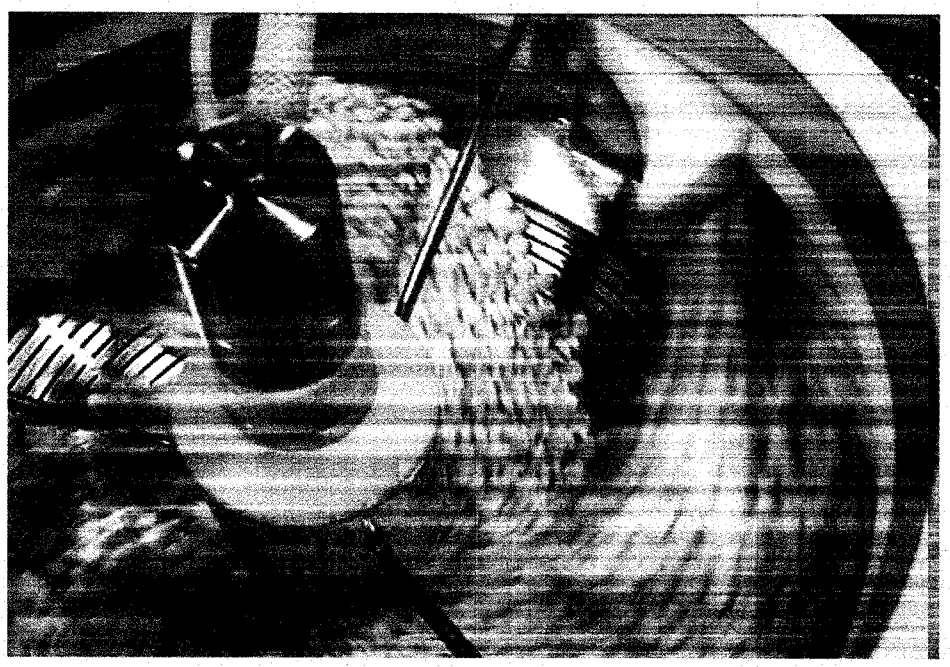


Fig. 1: The vertical centrifugal coater does not suffer from the disadvantages of conventional coaters and assures uniform coating of tablets

Coating of tablets and pellets was formerly a rather ineffective and time-consuming process, and the results generally anything but satisfactory. Moreover, constant supervision was necessary. Now, movement has come into the coating world in the truest sense of the word: the new vertical centrifugal coater eliminates the existing drawbacks and with convincing results.

In the drums of conventional coaters application of the coating medium by the bottom spray process is usually impossible because the spray systems projecting into the product bed are subject to relatively high mechanical stress. Consequently, the top spray process is primarily employed. The disadvantages of the latter process are well known: the fine spray particles are deflected and dried by the strong counterflow before they ever reach the product to be coated. This leads to losses of spray medium and irregular surface coating.

Dead zones in conventional equipment

Another disadvantage of conventional drum coaters is the occurrence of a neutral or dead zone in the moving bed of tablets. The reason lies in the existence of two opposing directions of motion during the movement of the product. On the one hand, there is an upward motion due to rotation of the drum; on the other hand, there is a downward movement on the upper side of the tablet bed. The region tablet bed where these two motions are reversed is characterised by relatively little motion, i.e. a neutral or dead zone occurs. This flow pattern, which is typical of drum coaters, gives rise to two drawbacks:

- Coating of tablets is non-uniform because it cannot be assured that all the tablets spend the same time on the surface of the tablet bed, as would be required for uniform coating by the spray jets.
- Subsequent drying and air exposure of the tablets is also rather ineffective because it cannot be assured that the coated tablets are uniformly exposed to the stream of dry air at the bottom of the drum.

Moreover, the low drying performance of conventional drum dryers is impaired by the high tablet bed. The height of the tablet bed means that essentially only the outermost layer of tables comes into contact with the stream of air.

The new Vertical Centrifugal Coater, VCC, has been jointly developed by the Diosna and Innojet companies. It consists of a perforated, bowl-shaped container which rotates around a vertical axis and a static return flow cone located therein. Centrifugal force is utilised to control the movement of the tablets to be coated. The product to be coated is circulated within the coater. It initially rises up the wall of the rotating bowl. On reaching the top rim of the bowl it is led via guides into the return flow cone and descends along the walls of the cone back to the bottom of the bowl, where the cycle starts all over again.

On leaving the return cone in the direction of the bottom of the bowl the tablets are sprayed with coating material by a radial spray nozzle with a spray angle of 30°.

Exploiting centrifugal force in the coating process

Owing to the centrifugal force arising from the movement of the product, neutral or dead zones can no longer occur in the coater. Instead, all the tablets circulate through the vessel in a uniform manner, i.e. pass the spray nozzle the same number of times and thus acquire a highly uniform coating. The layer thickness of the tablets in the return cone is reproducible and is dependent on the rotational speed of the bowl. The significantly smaller layer thickness in the coater leads to a highly homogeneous, fast, and almost loss-free utilisation of the spray medium.

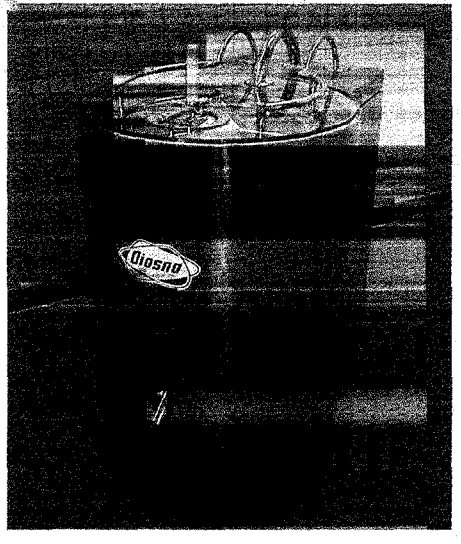


Fig. 2: The height of the VCC assures ease of operation

Since the bowl and the return cone are made of perforated stainless steel, a more uniform and intensive drying is achieved: the drying air is fed into the system from below and removes moisture from the product in two regions – on passage through the bowl and through the return cone – before it travels on to the waste air and aftertreatment system. Another version of the equipment permits further increase of the process air temperature after completion of the first product motion phase. To this end, an electrical resistance heater is installed under the perforated return funnel. Extending the process air temperature range at his point lowers the relative humidity of the process air and increases the capacity for moisture take up correspondingly. Such a device counteracts undesired cross-moistening and saturation effects of the product surface. It ultimately leads to a drastic shortening of the drying and processing times.

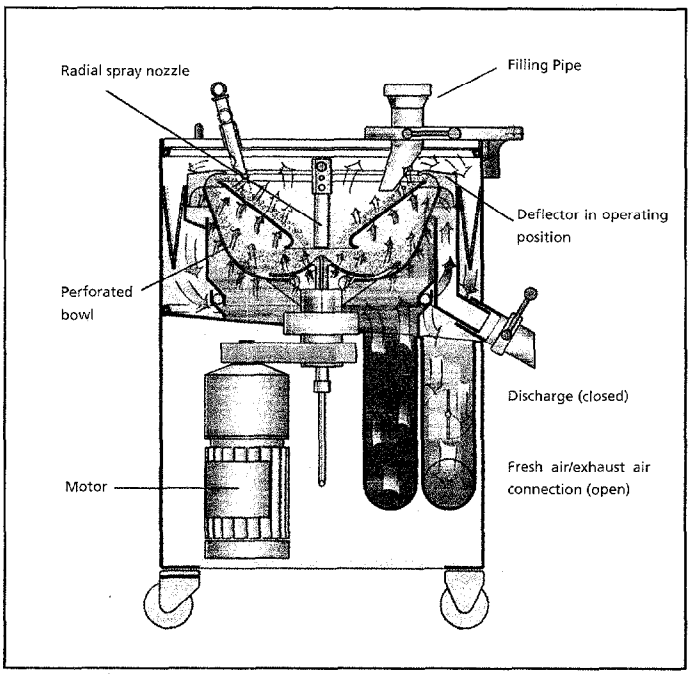


Fig. 3: Schematic of coating process

While the mode of construction of conventional drum coaters precludes their complete emptying, the vertical coater can be charged and discharged completely automatically. Manual emptying is accordingly no longer required – such coaters are automatically discharged right down to the very last tablet. On emptying, the rotating bowl is first lowered so that the guides no longer direct the product into the centre of the bowl. Instead, the tablets fall over the outer rim of the bowl into a lightly vibrating feed channel, along which the tablets are conveyed to a central discharge pipe.

COMPACT

Vertical Centrifugal Coater

The major characteristics of the vertical centrifugal coater are:

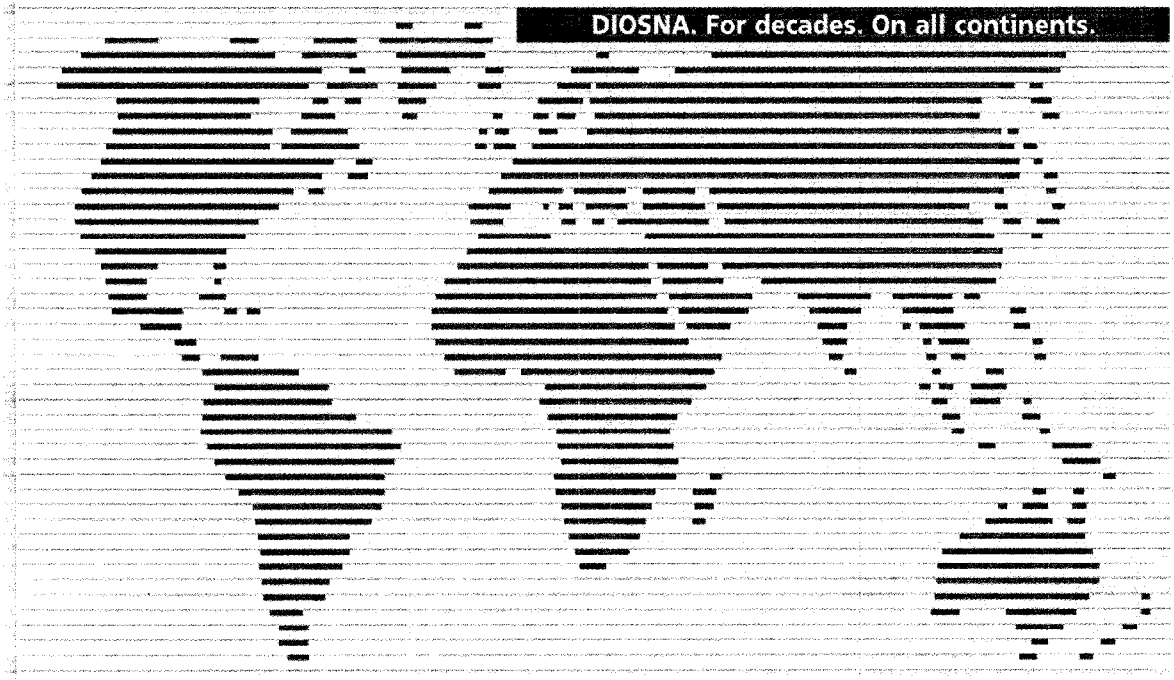
- reduction of processing time by 50% and more by uniform coating and intense air circulation;
- reduced consumption of coating material by uniform coating and very low spray losses;
- reproducible high quality through thickness and uniformity of the coating;
- smaller machines made possible by much shorter processing times;
- complete and automatic discharge
- degrees of filling between 20 and 100% possible.

Predestined for WIP

Washing in place (WIP) makes good sense even for the modest dimensions of a laboratory coater; pilot- and production scale equipment are truly predestined for integral WIP. That part of the centrifugal coater which comes into contact with the product can readily be taken apart without tools. Moreover, the product contacting region can be completely flooded because it is of waterproof design and construction.

According to the design concept even production-scale equipment height should not exceed 1100 mm in height to the top of the hinged glass cover. Thus the user is able to visually check and operate the equipment.

The vertical centrifugal coater is primarily suited for aqueous and organic solvent film coating processes on pharmaceutical tablets of conventional shapes, sizes, densities, and weights. It can also be used for film coating of pellets and granules if the perforation of the product holder and the product return cone is selected accordingly.



Our business experience has prepared us to meet the high demands of the pharmaceutical industry through practical solutions. Technical know-how and deep seated quality consciousness are the frame work for DIOSNA equipment success. All over the world.

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