

COATING PANS



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Main coating processes



1. film coating

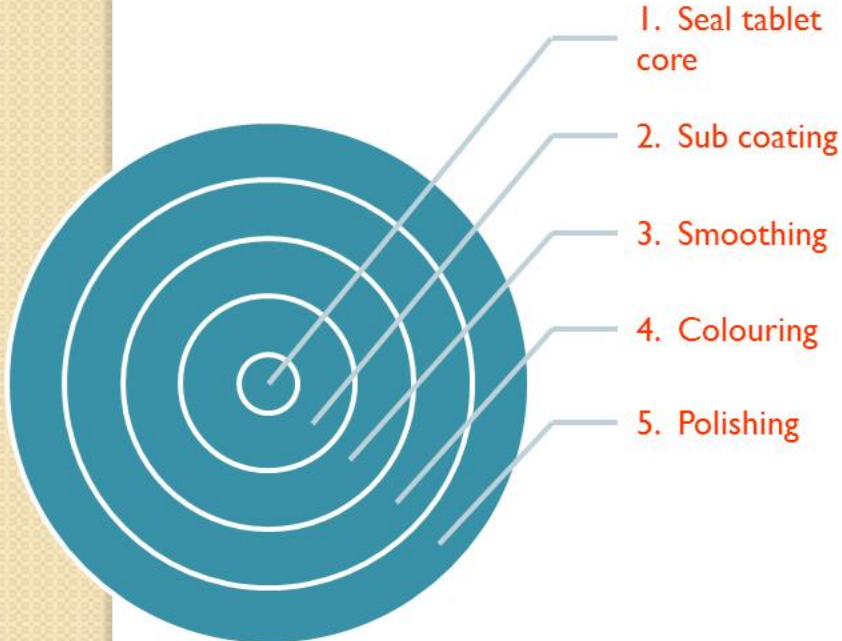


2 .sugar coating



Sugar coating

- Traditionally sugar coatings formed the bulk of coated tablets but today film coatings are the more modern technology in tablet coating.
- **Description of tablets:** Smooth, rounded and polished to a high gloss.
- **Process:** Multistage process involving 6 separate operations.



Example of sugar coated tablets

Brufen® POM

- Available in 200mg and 400mg strength



Premarin® POM

- Conjugated oestrogens 625mcg (maroon) and 1.25mcg (yellow)



Colofac® P

- Mebeverine hydrochloride 100mg Round, white, sugar coated



Kalms® GSL

- 45mg Hops powder, 90mg Gentian powdered extract, and 135mg Valerian powdered extract





FILM COATING

- Modern approach to coating tablets, capsules, or pellets by surrounding them with a thin layer of polymeric material.
- **Process:** Single stage process, which involves spraying a coating solution containing the following;
 1. Polymer
 2. Solvent
 3. Plasticizer
 4. Colourant

The solution is sprayed onto a rotating tablet bed followed by drying, which facilitates the removal of the solvent leaving behind the deposition of thin film of coating materials around each tablet.

Enteric coating

The technique involved in enteric coating is protection of the tablet core from disintegration in the acidic environment of the stomach by employing pH sensitive polymer, which swell or solubilize in response to an increase in pH to release the drug.

Aims of Enteric protection:

- ✓ To mask taste or odour
- ✓ Protection of active ingredients, from the acidic environment of the stomach.
- ✓ Protection from local irritation of the stomach mucosa.
- ✓ Release of active ingredient in specific target area within gastrointestinal tract.

Examples of enteric coated OTC products

- Enteric coated aspirin E.g. Micropirin®
75mg EC tablets



COATING PANS

TYPES OF COATING PANS

1.CONVENTIONAL COATING PANS

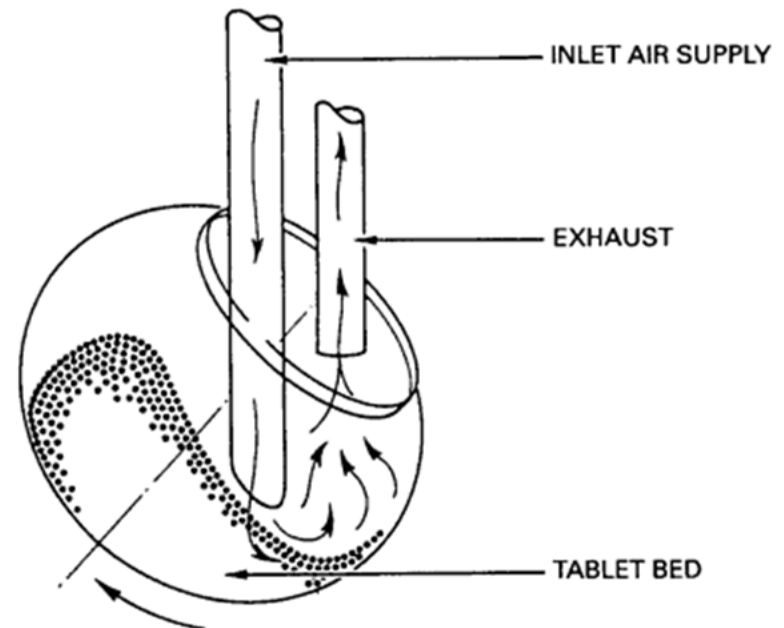
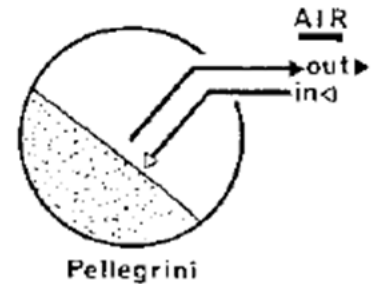
- A)PELLIGRINI PAN
- B)IMMERSION SWORD TYPE PAN
- C)IMMERSION TUBE TYPE PAN

2.PERFORATED COATING PANS

- A)ACCELA COTA PAN
- B)HI-COATER
- C)DRIA COATER
- D)GLATT PAN-COATING EQUIPMENT
- E)HUTTLIN BUTTERFLY PAN
- F)DUMOULIN IDA.X.COATING EQUIPMENT

A) STANDARD COATING PAN

- 1) Circular metal pan mounted at 40 degrees .
- 2) 8-60 inch diameter.
- 3) Rotated on its horizontal axis by a motor.
- 4) heated air is supplied by inlet air supply.
- 5) Exhaust by means of ducts.
- 6) coating soln are applied to tablets by ladling or spraying .
- 7) use of atomizing system to produce even distribution of coatings soln or suspension .



DRAW BACKS OF STANDARD COATING PAN

- 1) Mixing efficiency of tablets was poor.
- 2) Drying efficiency was low because much of drying took place on surface of the tablet bed only.
- 3) Improper balance b/w the introduced & exhausted air increased the chances of health hazards for the operator & risk of explosion when organic solvents were used in coating soln.

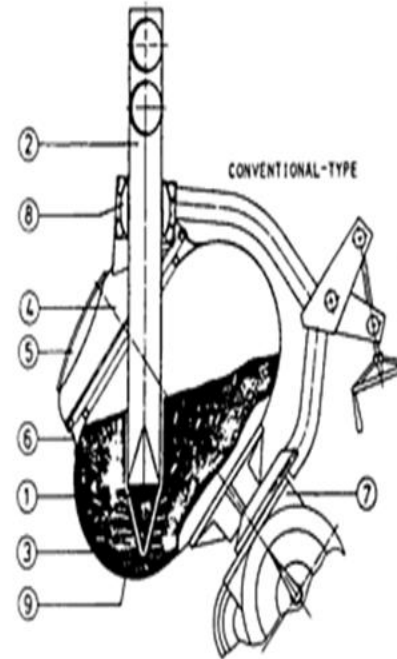
PELLIGRINI COATING PAN

- 1) Available in the range of 10-1000 kg batch.
- 2) Contains baffled pan & diffuser that distributes the drying air uniformly.
- 3) suitable only for sugar coating process but not for film coating due to limitations in drying capabilities.
- 4) Limitations was overcome by installing glatt immersion sword air handling system to improve drying efficiency.

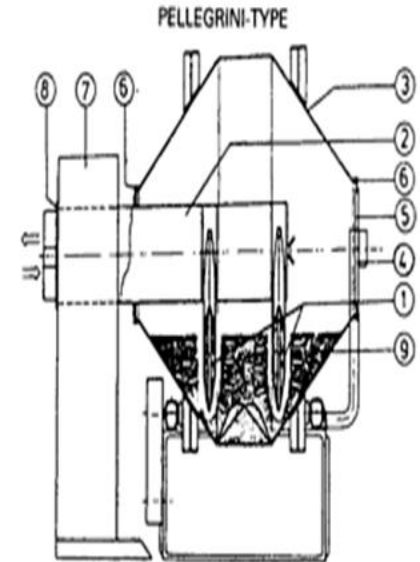
B) GLATT IMMERSION SWORD COATING PAN

1) PLG SYSTEM

Inlet hot air-by a sword.
exhaust air -by a plenum.



(a)



(b)

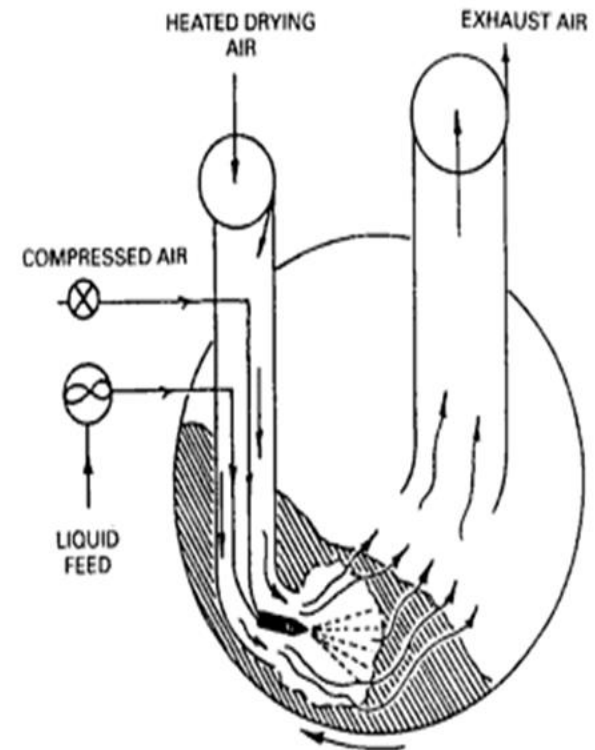
- Key: 1. Immersion Sword
2. Coaxial conduit
3. Coating pan
4. Pan cover
5. Clear control cover
6. Silicone seal
7. Stand
8. Coaxial conduit adjustment
9. Coating bed
10. Base unit fitted with Rollers

2) GS SYSTEM

Inlet hot air-by inlet
plenum.
exhaust air -by two perforated swords.

C) IMMERSION TUBE COATING PAN

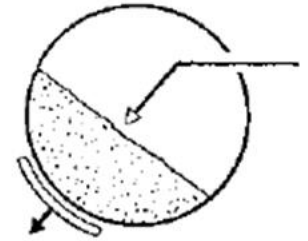
- 1) consists of long tube with a spray nozzle at its tip.
- 2) hot air gets delivered through this tube into tablet bed.
- 3) the drying air flows upward & exhausted by a conventional duct.
- 4) Relatively rapid processing times have been reported for both film & sugar coatings with this system.



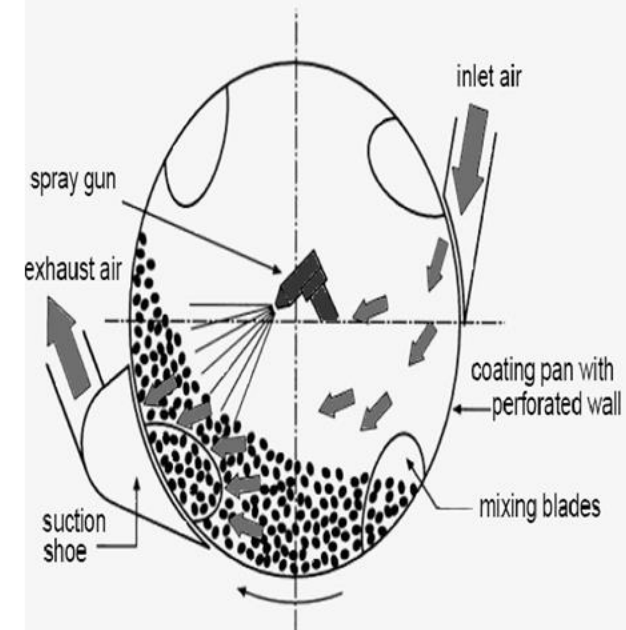
2) PERFORATED COATING PANS

A) ACCELA-COTA PAN

- 1) pan is fully perforated.
- 2) contains mixing blades.
- 3) inlet air is by a plenum in contact with the top of the pan.
- 4) air is exhausted by a plenum located below the pan.

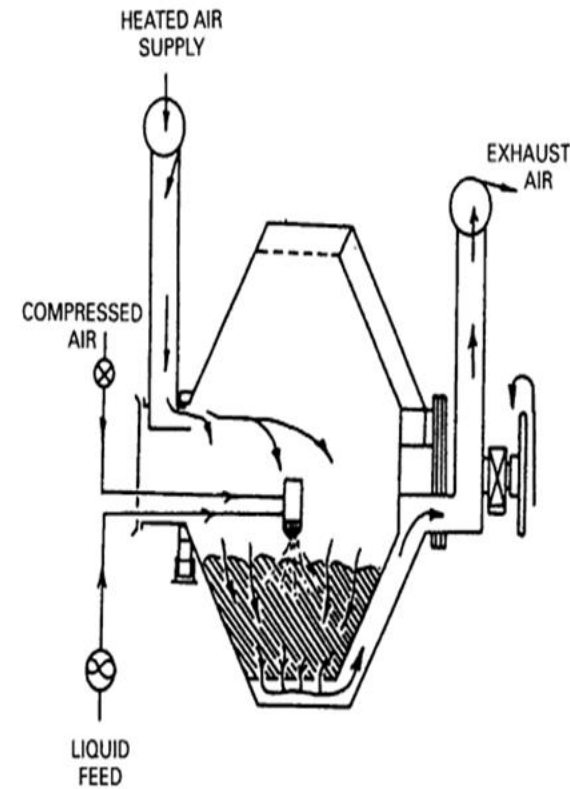
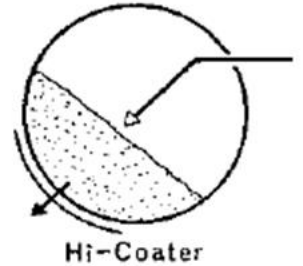


Accela-Cota



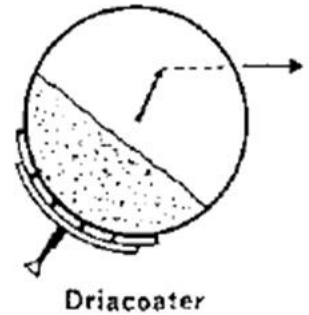
B) HI-COATER PAN

- 1) consists of four perforated segments which are perpendicular to each other.
- 2) each of these perforations acts as an opening for air outlet which is fixed to the exterior of the pan surface.
- 3) drying air is introduced into pan through an opening located on inside periphery of top of the pan.



C) DRIA COATER

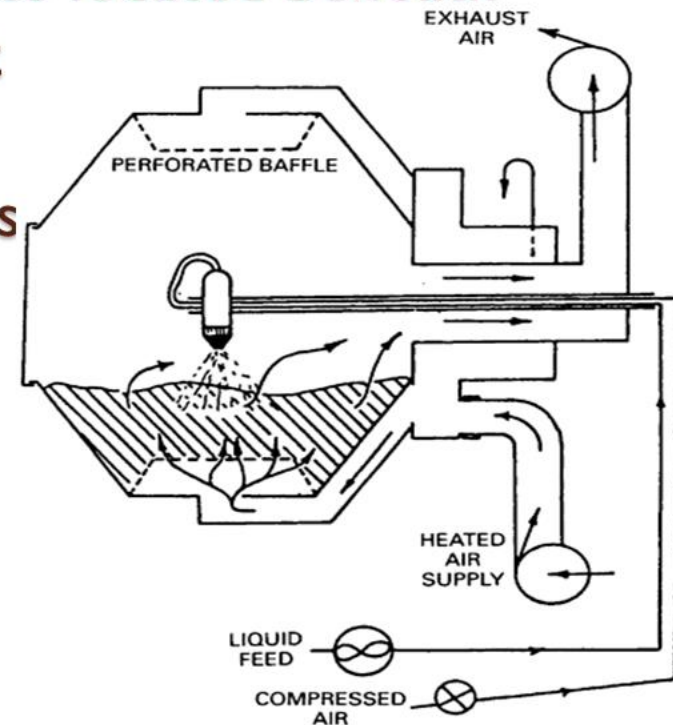
- 1) introduces drying air through hollow perforated baffles located on inside periphery of drum.
- 2) exhaust is from back of the pan.
- 3) different air flows



a) direct flow: air in at the top (through perforated baffles) and exhausted through baffles located beneath tablet bed.

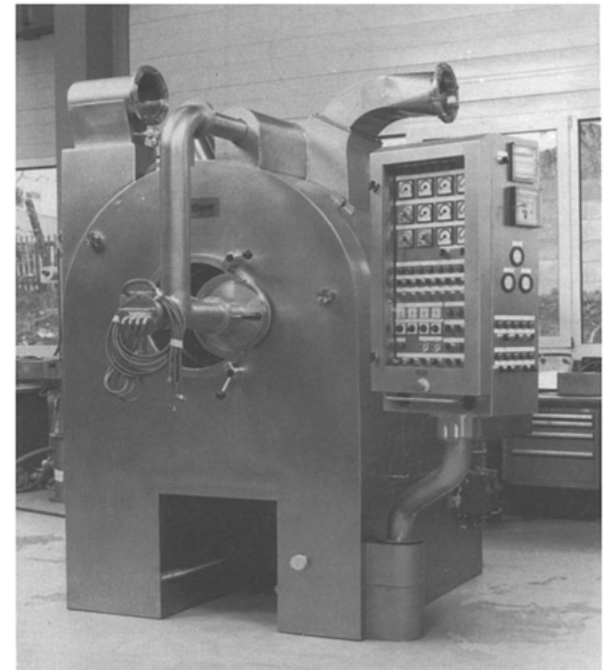
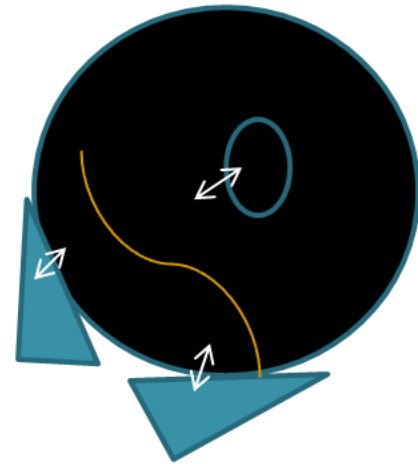
b) reverse flow A: air in through baffles located beneath tablet bed and exhausted via baffles at top of pan.

c) reverse flow B: air in through baffles located beneath tablet bed, and exhausted via plenum connected to opening at back of pan.



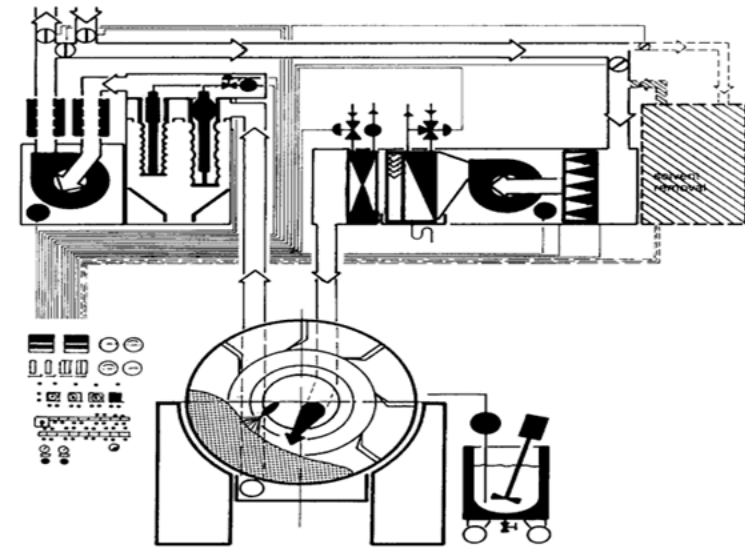
D) GLATT PAN-COATING EQUIPMENT

- 1) similar to that of accelacota.
- 2) a divided air plenum located beneath the moving tablet bed enables air to be blown into or exhausted from the pan through either or both of the two sections.
- 3) in addition , another air plenum , connected to an opening above the door (similar to that in a hicoater) also allows air to be blown into or exhausted from the pan.
- 4) quite expensive.



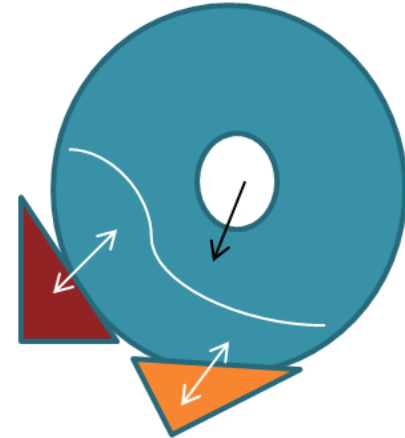
E) HUTTLIN BUTTERFLY PAN

- 1) It has a series of large ,angled ,slotted openings in the pan wall at the junction of the cylindrical portion with each of the front or back panels.
- 2) these openings permit air to be exhausted from the pan.
- 3) drying air is applied to the surface of the bed of the product being coated by means of a slotted tube.
- 4) front and back of the pan can be disconnected from the cylindrical ,central section and hinged down.



F) DUMOULIN IDA.X.

- 1) Fully perforated cylindrical central section.
- 2) the two air plenums that function as both inlet or exhaust air systems are located in contact with the outside of the pan.
- 3) a third plenum, connected to a slotted tube located inside the pan and above the cascading product bed allows inlet air only to be directed onto the surface of product being coated.
- 4) air flows.
 - a) single flow
 - b) reversed single flow
 - c) double flow
 - d) direct double flow





VALIDATION OF COATING PAN

VALIDATION PROTOCOL

The 3 major elements of a validation protocol for a tablet coating pan include

1. Installation qualification (IQ)
2. Operational qualification (OQ)
3. Performance qualification (PQ)

Installation qualification (IQ)

- An IQ establishes confidence that the equipment is properly installed.
- The installation must meet the manufacturer's specified guidelines along with design challenges at installation.
- Also, the supporting electrical utilities must meet all electrical codes.

The information required for an IQ evaluation is

- Equipment identification,
- Required documentation,
- Equipment utility requirements,
- Major component specifications,
- Component material,
- Lubricants and
- Equipment safety features

Equipment identification

Record the equip Id num in a table along with the following information:

- Equipment manufacturer's,
- Purchase order no:
- Model number
- Serial num
- Company assigned equipment num,
- The location of the equipment

Required documentation

- Record the equipment and manufacturer's operation and maintenance manual and drawings in the below table.

| Number | Description | Date |
|---------------|---|-------------|
| - | Tablet coating pan instruction, operation, maintenance manual | - |
| A47-042 | Electrical diagram drawing | - |

- Record the SOP's that cover the setup, operation and cleaning of the tablet coating pan in following table

| Number | Description | Release date |
|---------------|--|---------------------|
| COAO59 | Setup and operation of a tablet coating pan | 9/08/94 |
| COAO60 | Coating dept- equipment cleaning procedure | 3/22/96 |

Equipment utility requirement

- Compare the manufacture's specified volts (v), amps (A) and compressed air pressure required to their as found conditions at the time of qualification testing and record the results in the below table :

| Utility | specifications | Measured results | Acceptable (yes or no) |
|-----------------|--|------------------|-------------------------|
| Volts | Spray systems-115 Coating pan- 460 | | |
| Amps | Coating pan motor = 4.8 Supply blower= 4.8 Exhaust blower= 4.8 | | |
| Compre-ssed air | 90 +/- 10% psig | | |

- Also record the location of the power supply source.
- Record the instruments used to measure the volts, amps and compressed air in below table

| Test instrument | Id num | Calibration date |
|---------------------------|---------------|-------------------------|
| Multi meter | ME-025 | 04/19/09 |
| Air pressure guage | P-102 | 02/19/09 |

Major components specifications

- The major components include:
 - ❑ Coating pan motor
 - ❑ Supply blower motor
 - ❑ Exhaust blower motor
 - ❑ Spray systems
- The manufacturer, model num, serial num and other utilities required should be specified.
- The material of construction of different component should be specified as follows

| Component | Material |
|---------------------|------------------------|
| Coating pan | 304SS |
| Spray system | Stainless steel |

- ***LUBRICANTS :***

Record the lubricant used to operate coating pan and indicate if they make contact with the product.

- ***EQUIPMENT SAFETY FEATURES:***

record the safety features of the equipment.

OPERATIONAL QUALIFICATION

- An OQ evaluation should establish that the equipment can operate within specified tolerances and limits.
- The coating pan will be validated for its operating ability.
- Information required for the OQ evaluation is calibration of the instruments used to control the pan, equipment control functions (switches and push buttons) and equipment operation (tablet coating pan rotation, pan speed, pan supply temperature, spray system operation)



- **CALIBRATION REQUIREMENTS:**

Verify that all critical instruments on the equipment have been logged into the calibration systems, have calibration procedures in place, and are in calibration at the time of qualification testing.

Record all the information for the calibrated instruments used to control the pan.

Equipment control functions

- The objective of the testing equipment control functions is to verify that the push buttons on the coating pan operate per manufacturer's specifications.
- The pan will be operated with the pan empty.
- Operate each control listed in the below table and verify its proper operation

| Test operation | Expected results | Acceptable (Y/N) |
|------------------------------|--|-------------------------|
| Power start/stop push-button | <p>When the pan start/stop push button is pressed, the pan starts and rotates continuously.</p> <p>When the pan start/stop push button is pressed again, the pan stops rotating.</p> | <p>Yes</p> <p>yes</p> |
| Pan jog push button | <p>When the pan jog button is pressed the pan rotates clockwise, then it stops rotating when the pan jog push button is released.</p> | <p>yes</p> |
| Heater on/off push button | <p>When the heater on, push button is pressed, the heater starts.</p> <p>When the heater off, push button is pressed, the fan heater stops.</p> | <p>Yes</p> <p>Yes</p> |
| Fan on/off push button | <p>When the fan start push button pressed, the fan starts and rotates continuously.</p> <p>When the fan stop push button is pressed the fan stops.</p> | <p>Yes</p> <p>Yes</p> |
| Exhaust plenum clamp switch | <p>When the exhaust plenum clamp switch is rotated counter clockwise, the plenum is clamped into place.</p> | <p>Yes</p> |
| Speed control knob | <p>When the pan speed control knob is rotated counter clockwise, the pan speed increases</p> <p>When the pan speed control knob is rotated clockwise, the pan speed decreased</p> | <p>Yes</p> <p>yes</p> |

TABLET COATING PAN ROTATION DIRECTION TEST

Objective of this test is to verify that the tablet coating pan rotates in the proper direction. The pan will be operated empty.

Press the start push button and observe the direction of rotation of the coating pan as viewed from the front and record the results.

- ***Tablet coating pan speed test:***

Objective is to document the speed of the tablet coating pan with the pan empty. A tachometer will be required for this test.

PROCEDURE- Measure the speed of the coating pan with a calibrated tachometer and record the results in the table.

- Verify that the measured speed is within 10% of the variable speed of 12-36rpm.
- Record the instruments used to measure the speed.

- ***Pan supply temperature control test:***

Objective is to verify that that pan supply temperature controller operates according to the manufacturer's specifications.



- ***Tablet coating pan operation test:***

The operation of the tablet coating pan is tested to document its performance using placebo tablet but with out spray systems placebo will be used for maximum loading conditions.

- Procedure: Fill the pan with placebo tablet to the appropriate level and record the test material used.
- Set the pan speed to 11rpm and run 5 tests for 5 min each after the steady state is achieved. Enter the set points and conduct the tests and record the results.

SPRAY SYSTEM OPERATION TEST:

Tested to verify that it operates according to the manufacturer's specifications. Water will be used as a spray medium. A graduated cylinder and a stop watch will be required.

- Start the spray systems and select a low flow rate. Capture the water from the spray systems with a graduated cylinder for 1min. Repeat this test for medium and high flow rates and record the results.

| Flow rate | Selected delivery flow rate | Measured delivery flow rate | acceptable |
|------------------|------------------------------------|------------------------------------|-------------------|
| Low | 50 | 50 | Yes |
| Medium | 100 | 110 | yes |
| High | 200 | 240 | yes |

- Record the instruments used to measure the volume of the water and operating time

PERFORMANCE QUALIFICATION

- Once it has been established that the equipment is properly installed and functioning within specified operating parameters, it must be shown that the coating pan can operate reliably under routine, minimum and maximum operating conditions.
- **TABLET COATING PAN OPERATION**
- The pan operation is tested to document the performance and speed of the tablet coating pan using placebo tablets and orange opadry coating medium. a tachometer will be required.

Procedure;

- . Fill the pan with placebo tablets and record the placebo and spraying materials used in a table
- . Enter the set points and start spraying the tablets after the steady state is achieved. record the results in a table
- . measure speed of the coating pan with a calibrated and record the results in a table
- . verify that the measured speed is within 10% of the variable speed from 12 to 36 rpm.

Coating pan speed specification = 12 to 36 rpm

. the measured maximum rpm of 12 falls within specifications

. the measured maximum rpm of 35 falls within the specifications

. record the instrument used to measure the speed that is tachometer

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