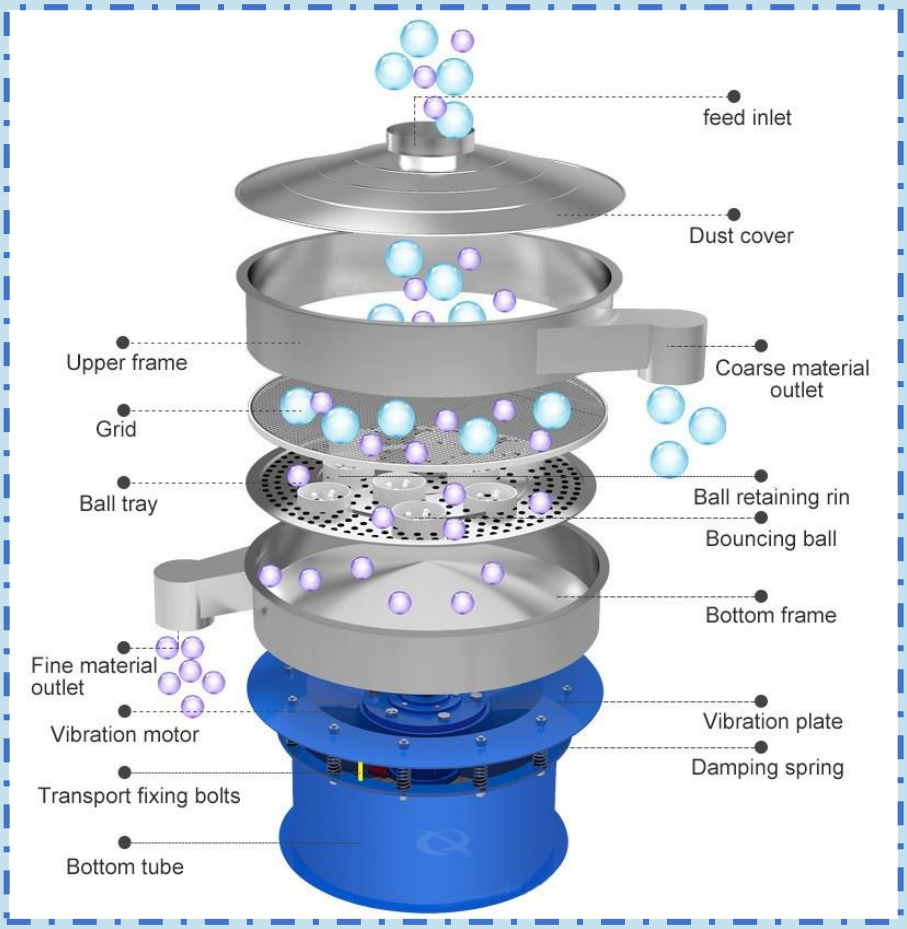
VIBRO SIFTER

The Vibro Sifter machine works on the principle of gyratory vibrations. The material is separated based on its particle size. Once the motor gets energized, vibration is caused in the screen/sieve making the material travel across the sieves according to its particle size.



Qualification Frequency: Once in 2 year

Tests & Checks: Sifting Efficiency

Acceptance Criteria:

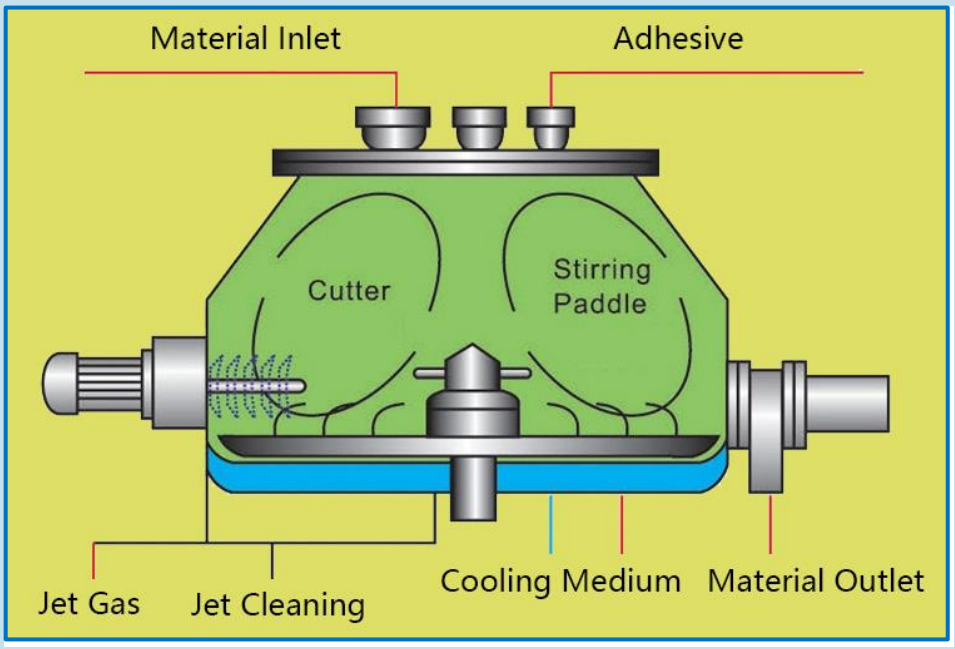
- ✧ Integrity of Sieve should be intact before and after the operation.
- ✧ Required process time should be relevant to the standard.

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

RAPID MIXER GRANULATOR

Rapid mixture granulator works on agitation and tumbling. The impeller is responsible for uniformly mixing wet granules, and the chopper helps in breaking or reducing particle size. At the starting process or during binder addition, the impeller and chopper generally operate at low speed.



Qualification Frequency: Once in 2 year

Test Parameters: Impeller at Slow Speed
Impeller at High Speed
Chopper at Slow Speed
Chopper at High Speed

Tests & Checks: Blend Uniformity Analysis
RPM

Acceptance Criteria:

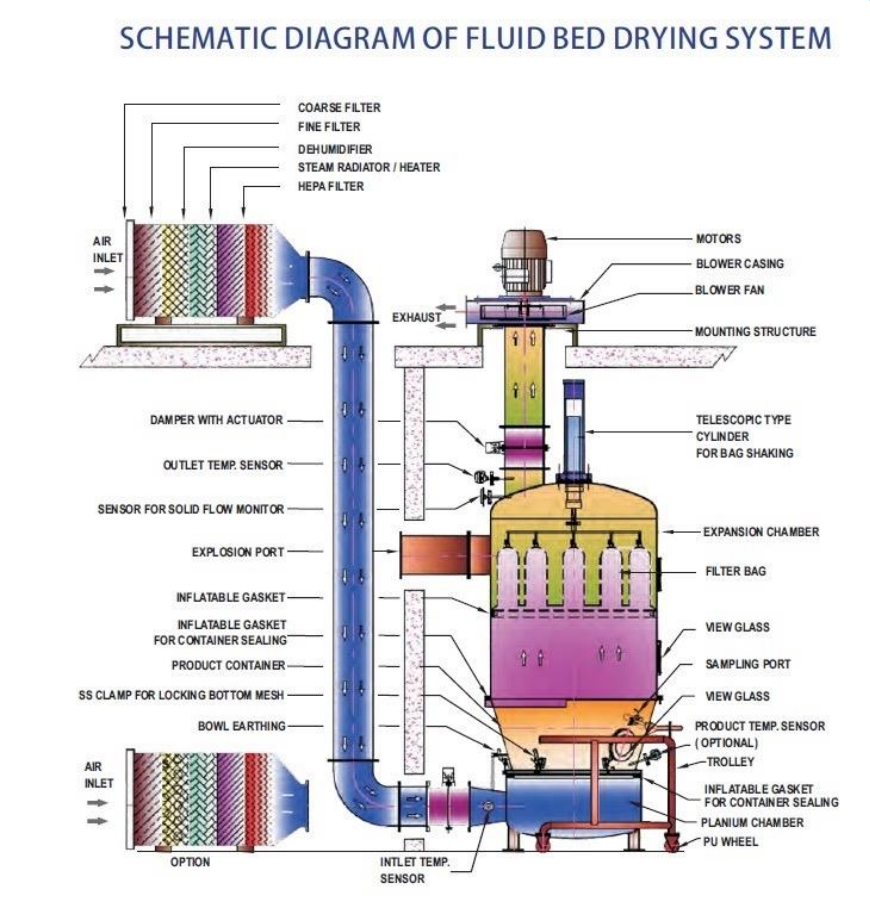
- RSD NMT 5%

Reference:

- Validation Master Plan.
- Schedule M.
- WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

FLUID BED DRYER

Fluid bed dryers work on the principle of fluidization, a process where a material is converted from a static solid-like state to a dynamic fluid-like state. In this process, hot gas or air is introduced through a perforated distribution plate into the area holding the material.



Qualification Frequency: Once in 2 year

Tests & Checks: HEPA filter integrity
Loss on Drying

Acceptance Criteria:

- ✧ PAO leakage shall be NMT 0.01%
- ✧ 2.5-3.5% w/w

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

MULTIMILL

Multi mill is designed to utilize the principle of variable force swing beaters having both knife and impact edges rotating within a selected screen to control the particle reduction, material fed in to the processing chamber moves to the periphery and passes through the screen radially and tangentially.

Qualification Frequency: One in every two year

Tests & Checks: Particle Size of the dispensed/milled powder for the granulation process.

Acceptance Criteria:

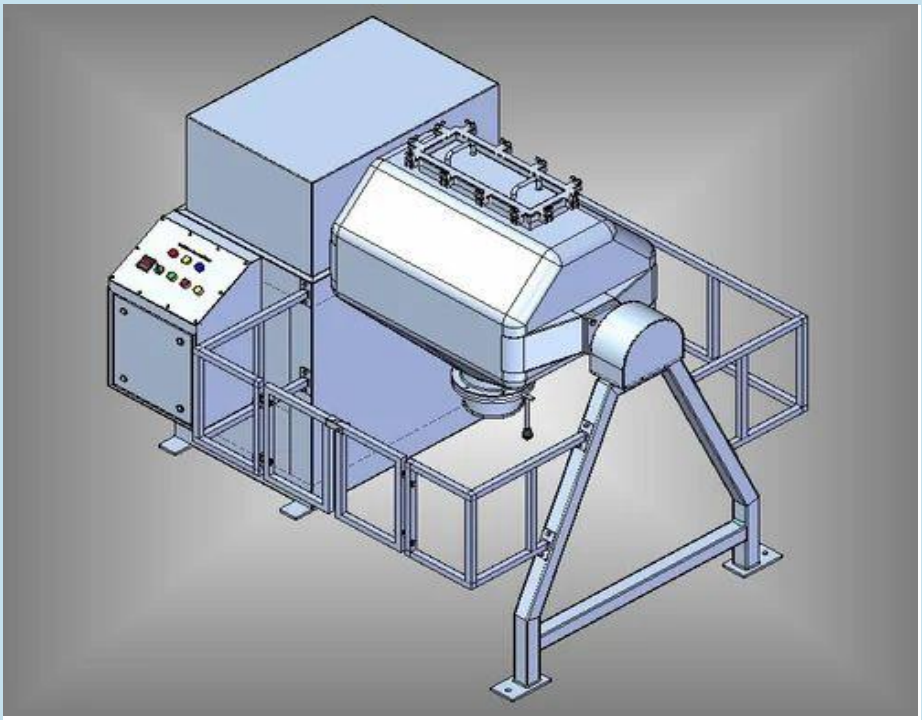
- ✧ Granules of the respective size are passes through the respective mesh.
- ✧ % Retain Granule: NMT 5%
- ✧ Black Particle: Should be Absent
- ✧ Integrity of Screen: Integrated

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

OCTAGONAL BLENDER

The Octagonal Blender operates on a simple yet effective principle. Its unique octagonal shape, combined with an agitator, ensures efficient and homogeneous mixing of ingredients. This results in consistent and high-quality blends, meeting the stringent requirements of pharmaceutical production.



Qualification Frequency: Once in a two year

Tests & Checks:

- ✧ Blend Uniformity Analysis for Assay
- ✧ Blend Uniformity Anlysis for Physical Parameters

Acceptance Criteria:

- ✧ Result of Assay for each sampling location should meet the acceptance criteria given for each product.
- ✧ RSD of individual values of Assay of all sampling location should not be more than 5%.
- ✧ Results of Physical Parameters for all sampling location should not have a significant difference.

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

COMPRESSION MACHINE

The basic principle behind the tablet compression machine is hydraulic pressure. This pressure is transmitted unreduced through the static fluid. Any externally applied pressure is transmitted via static fluid to all the directions in the same proportion.

Qualification Frequency: Once in Two Year

Tests & Checks:

- ✧ Description
- ✧ Weight of 20 tablets
- ✧ Average Weight
- ✧ Uniformity of Weight
- ✧ Thickness
- ✧ Hardness
- ✧ Disintegration Time
- ✧ Friability

Acceptance Criteria

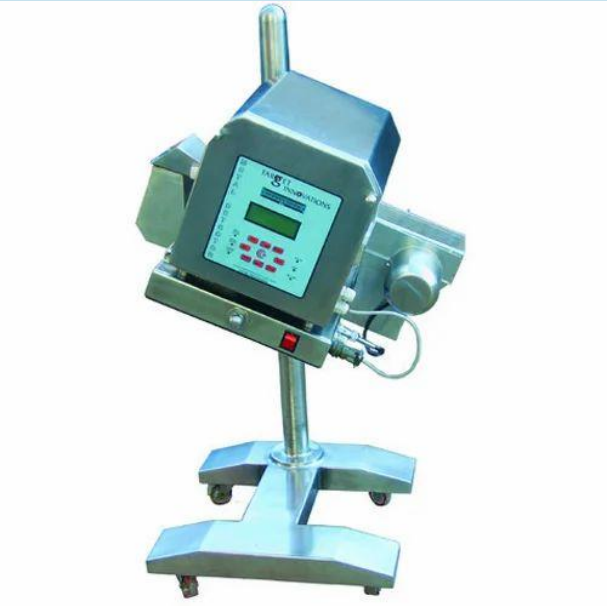
Product specific

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

METAL DETECTOR

Metal detectors contain one or more inductor coils that are used to interact with metallic elements on the food or pharmaceutical products. Metallic contaminant in the product creates high frequency magnetic field within the detector coil, which in turn activates a reject flap by means of a solenoid.



Qualification Frequency: Once in Two Year

Tests & Checks:

- For Reject Timer (On delay)
- For Reject Timer (Off delay)
- For Sensitivity Level
- For Phase Level

Acceptance Criteria:

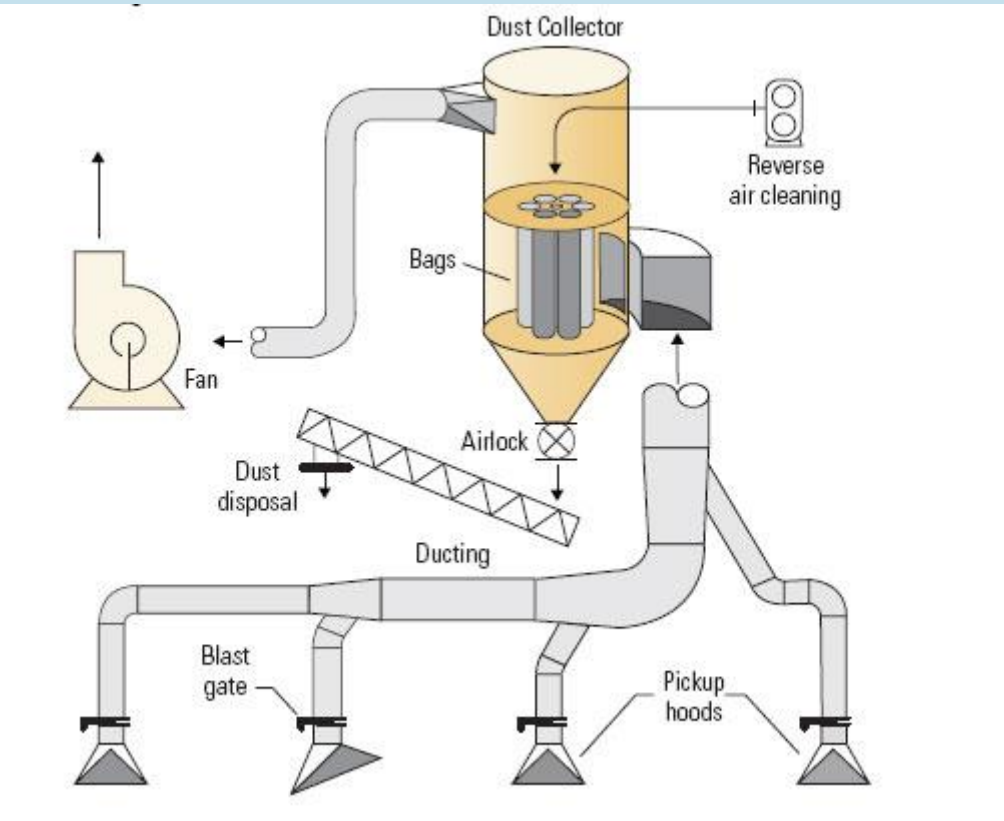
- All the product samples should be passed through the aperture.
- Ferrous, Non Ferrous and Stainless Steel metal samples should be reject when they pass through the aperture of Metal Detector.
- The Metal Detector Flap should not operate if onlly the product is passed through the aperture.

Reference:

- Validation Master Plan.
- Schedule M.
- WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

DUST COLLECTOR

The filter housing is the mechanical assembly in which filters are installed. The intake air passes through filters in the filter housing to remove the powder particles. Commonly, a Cartridge filter is used in a pharmaceutical dust collector. Cartridge filters have high efficiency than other types, such as baghouse.



Qualification Frequency: Once in two Year

Tests & Checks:

- ✧ Mesured Velocity
- ✧ Air Volume
- ✧ Dust Collector pipe internal diameter
- ✧ Back flow of Dust Exraction unit

Acceptance Criteria:

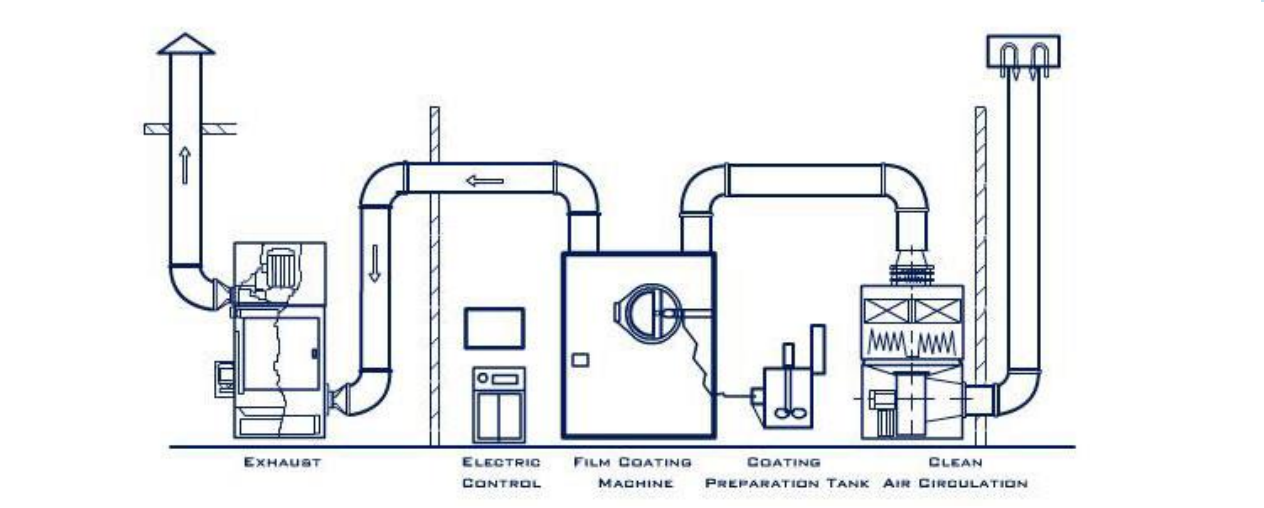
- ✧ Calculated Air Volume should not be less than 180 CFM

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

AUTO COATER

The hot air penetrates through the tablets core layers and is discharged from the bottom of the layers, so that the coating medium sprayed on the surface of the tablet cores will dry rapidly and evenly, thus forming a solid and smooth surface film on tablet.



Qualification Frequency: Once in two year
After any major breakdown
After change of location

Tests & Checks: Coating Pan RPM
Coating Time
Description
Dimension
Average Weight
% Weight Gain
Individual Weight Variation

Acceptance Criteria:

- ✧ As per Specification

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

BLISTER PACKING MACHINE

The working principle of the flat blister packaging machine: the formed film is heated and softened by the flat heating device, and the softened film is blown into a blister by using compressed air in the flat forming device, and the filling device fills the package into the blister.

Qualification Frequency: Once in every 5 year time
After any major breakdown of after major modification.
After Change of Location

Tests & Checks:	**Acceptance Criteria**
Knurling Uniformity	Should be Uniform
Sealing Temperatur:	Should be within the range specified in BPR
Perforation:	Should be uniform
Leak Test:	No Pocket of Blister pack should show sign of leakage in the test
Wrinkles:	Should be absent
Pin Holes:	Should be bsent
Coding Imprints	Should be Clear & Legible
Cutting Edges:	Should be Uniform

Localized Overheating: Should be absent

Discoloration of Blister Packs: Should be absent

Defective Tablets and Blister detection by Camera: Machine should effectively identify the defective tablet and blister packs

Rejection mechanism for defective blister packs: Machine should effectively reject th defective tablet and blisster packs

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

STRIP PACKING MACHINE

The product is fed through hopper and feeding device flows to the heat sealing roller cavities, the desired laminated foil from the two rollers is drawn on the sealing rollers which packs and seals the products continously. The sealed strip passes through the vertical and horizontal cutters to get desired strip sizes.

Qualification Frequency: Once in every 5 year time
After any major breakdown of after major modification.
After Change of Location

Tests & Checks:	**Acceptance Criteria**
Knurling Uniformity	Shoud be uniform
Sealing Temperature	Should be within the range specified in BPR
Leak Test	No pocket of Strip pack should show sign leakage in the test
Wrinkles	Should be absent
Pin Holes	Should be absent
Coding Imprints	Should be clear & legible
Cutting Edges	Should be Uniform
Localized ocerhealting	Should be Absent
Discolouration of Stipcs	Should be Absent

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.

✧ FDA/ISPE Baseline Pharmaceutical Engineering Guideline Volume 5:-Commissioning and Qualification Guide, First Edition/March 2001.
✧ EU Guide to Good Manufacturing Practice, Part 4, 1997.
✧ European Commission's working party on control of medicines and inspection document, Validation Master Plan, Design Qualification, Installation & Operation Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

ALU-ALU BLISTER PACKING MACHINE

Blisters get continuously formed and the web is taken to the sealing station by using a guide track. There is also a suitable automatic filling system provided in the machine. Aluminum foil is also fetched from a different reel and it is fed to the sealing station.

Qualification Frequency:

- ✧ Once in every 5 year time
- ✧ After any major breakdown of after major modification.
- ✧ After Change of Location

Tests & Checks:	**Acceptance Criteria**
✓ Knurling Uniformity	Should be Uniform
✓ Sealing Temperature	Should be within the range specified in BPR
✓ Perforation	Should be Uniform
✓ Leak Test	No pocket of Blister pack should show sign of leak test
✓ Wrinkles	Should be Absent
✓ Pin Holes	Should be Absent
✓ Coding Imprint	Should be clear & legible
✓ Cutting Edges	Should be uniform
✓ Localized Overheating	Should be absent
✓ Discoloration of Blister Packs	Should be absent
Defective tablets and blister detection by Camera	Machine should effectivley identify the defective tablet and blister packs
✓ Rejection mechanism for blister packs	Machine should effectivley reject the defective defective tablet and blister packs

defective blister packs

Reference:

- ✧ Validation Master Plan.
- ✧ Schedule M.
- ✧ WHO essential drugs & medicine policy, QA of Pharmaceutical Vol-2 Good Manufacturing Practices & Inspection.