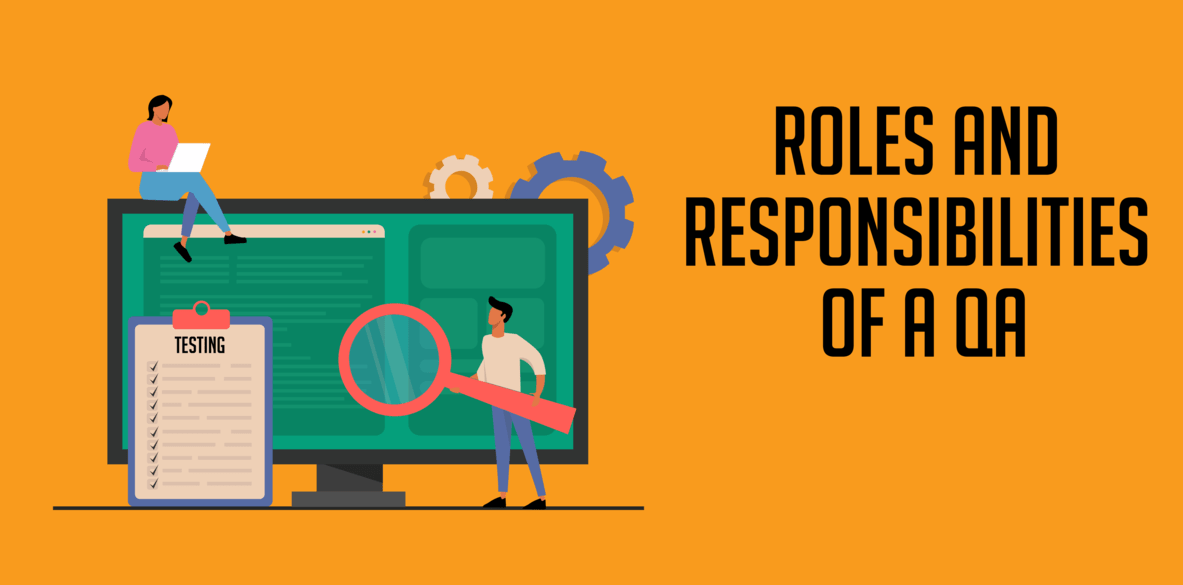
**QUALITY RISK ASSESSMENT & MITIGATION PLAN**

**FAILURE MODE EFFECT ANALYSIS FORTHE ROLE & RESPONSIBILITY OF QA**

**[DISPENSING TO COATING (D2C)]**

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1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk in reducing extra activities of QA personnel from Dispensing to Coating.
2. **SCOPE:** The scope of this document is limited to QA responsibilities in Dispensing, Granulation, Compression & Coating section at ……………... facility.
3. **RESPONSIBILITY:**

|  |  |
| --- | --- |
| **Department** | **Responsibility** |
| Quality Assurance | * Preparation, Review, and Compilation of FMEA * Post Approval of FMEA |

1. **REASON FOR RISK ANALYSIS:**

To mitigate & monitor the risk associated with the removal of extra job responsibilities of QA in Dispensing, Granulation, Compression & Coating areas.

1. **SITE OF STUDY:**
2. **RISK COMMUNICATION & TRAINING:**

* The Risk analysis team shall be authorized by the Head-QA or his/her designee.
* Quality Risk Management team shall be cross functional team comprised of expert from different areas.
* Training shall be imparted to the concerned team.

1. **INTRODUCTION:**

**Role & Responsibilities of QA:** “Quality Assurance” in pharma is responsible for implementing Good Manufacturing Practices& Good Laboratory practices. QA role starts from Dispensing and it remains until dispatch.

**Quality Assurance ensures:**

* To impart cGMP, GLP, Behavioral, Motivational and other kinds of Training ensuring compliance of the specified procedure/guidance’s.
* Handling of Quality Management System, Including Change Controls, Deviations, Incidents, Control of Non-Conforming Materials/Products, OOS, OOT, CAPA, etc.
* Co-ordination with various Departments to implement cGMP in Plant.
* Destruction, Review, Approval and Rejection of Documents.
* In-Process Control.
* Handling of Rework.
* Handling and investigation of Yield Variations.
* Monitoring and Control of Manufacturing Environment.
* Designing and Monitoring the Storage conditions for Materials and Products.
* Monitoring of Utilities like Heating Ventilation and Air Conditioning, Water System, Compressed Air, Nitrogen, Pure Steam Generation etc.
* Employee Training.
* Documentation & Data Control.
* Handling of Qualification and Validation Activities.
* Vendor Qualification Approval, Vendor audit and updating approved vendor list.
* Preparation, Handling and ensuring compliance of various Regulatory Agencies & Customer Audits.
* Investigation and Collection of Samples.
* Annual Product Review.
* Handling of Market Complaints.
* Batch Release / Rejection and Sale Authorization
* Product Recall.
* Handling of Return Goods.
* Stability Studies of Products.
* Management of Control Sample.
* Preparation, Approval of SOP’s, BMR, BPR and Protocols.
* Preparation of Calibration Policy and Implementation.
* Internal audit/ Self inspection.
* Qualification of control testing in lab.

**TYPES OF ROLES & RESPONSIBILITIES OF QA:**

* **Primary Roles & Responsibilities:** The Roles & Responsibilities of QA which directly impact the product quality.
* **Secondary Roles& Responsibilities:** The Roles& Responsibilities of QA which does not have direct impact but plays important role in different process.
* **Tertiary Roles& Responsibilities:** The Roles & Responsibilities of QA which are additional & removal of them does not have any impact.

| **PRIMARY ROLES&**  **RESPONSIBILITIES** | **SECONDARY ROLES& RESPONSBILITIES** | **TERTIARY ROLES& RESPONSIBILITIES** |
| --- | --- | --- |
| **WAREHOUSE** | | |
| No any activity which have direct impact on product quality. | * Verification of Expired or Rejected Material * Redressing of torned bags or ruptured containers. * Nitrogen purging log book verification. * Line Clearance of Sampling & Dispensing areas & Equipments. * Material Verification * Verification of API calculation. * Investigations. * Movement of cold storage materials. * Rejected material verification. * Raw material issue slip verification. * Cold Chamber Alarm Verification. | * Role of QA in staging area. * Pre-Dispensing containers verification. * Dispensing Log book * Environmental Monitoring Log Book * Balance Verification Log Book. * Cleaning Verification of Dispensing tools. * Pass Box log book verification. * Differential Pressure Verification of Pass Boxes& RLAF. * Cold Chamber Cleaning & Sanitization Verification. * Pressure Gauge Verification of RLAF * Pre & Fine Filter Cleaning Record Verification. * Machine Utilization & Cleaning Log book |
| **GRANULATION** | | |
| * SFM Challenge Test Verification. * Material Verification. * Final BMR review & release. | * Verification of Spillage of Material. * Verification of Sampling tools. * Line Clearance of Area & Equipments * Process Monitoring. * BMR online activities Verification. * Bulk Sampling * Weight Verification * Initiation of Deviations, Incidents & Change Control. * Physical Verification of Intermediates. * Verification of Critical Quality Parameters. * Online filling of BMR. * Ensuring use of Data loggers in low RH area. * Verification of foreign particles during sifting. | * Machine Utilization & Cleaning Record * Verification of Environmental Monitoring log book. * Verification of Sieve/Screen/FBD Bags log book * Verification of Sieve Integrity. * Verification of Destruction of Sieves. * Log books of Inward & Outward of Batches |
| **COMPRESSION** | | |
| * In-process check of all parameter, thickness, hardness, D.T. friability, description of tablets, Uniformity of tablets, Group weight verification of tablets. * Material Verification * Recording & Verification of in-process detail in IPQC Logbook (27) - DT, Friability, Hardness tester & Balance operation & cleaning detail * AQL * Weight (Container) verification of compressed tablet * BMR Review & Release. | * Line Clearance of Area & Equipments. * Metal Detector challenge test verified by QA. * Recoveries stored under supervision of QA. * Rejected Bags destroyed in front of QA. * Dies & Punches Issuance, Inspection, Destruction record verified by QA. | * Log book verification for Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification, In & Out of Batches. |
| **COATING** | | |
| * Material Verification * AQL * Sampling of Coated tablets * Weight Verification of Coated tablets * BMR Review & Release | * Line Clearance of Area & Equipments. * Verification of Critical Quality Parameters. * Silicone tube issuance & destruction record. | * Log Book Verification for Machine Utilization, Environmental Monitoring Disintegration time, Balance Verification & Cleaning. |
| **HARDGEL** | | |
| * Material Verification * AQL * Sampling of Hardgel Capsules * Weight Verification of Filled Capsules. * BMR Review & Release | * Line Clearance of Area & Equipments. * Verification of Critical Quality Parameters. | * Verification of In-process log books, Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification & Polishing. |
| **SOFTGEL** | | |
| * Material Verification. * Sampling of Softgel Capsules * AQL * Weight Verification of Capsules * BMR Review & Release. | * Line Clearance of Area & Equipments. * Verification of Critical Quality Parameters. * Verification of different parameter during medicament, gelatin, drying & Polishing. * In-process log book IPQC | * Verification of In-process log books, Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification & Polishing. * Verification of In& Out of batches. * Log Book of Issuance & retrieval of Change parts. |
| **MISCELLANEOUS** | | |
| * Monthly Calibration (135 Balance) * Review & resolve the problem of Tantrasoft issues * Audit trial of UV and Tantrasoft * SOP revision/updation of Manufacturing floor * BMR Review & Release (Compression & Coating) * Visual Inspection of Soft gel Capsules * Data Logger Print Out * Review of UV analysis data * Review of Tantrasoft data * Review of in-process logbook * Review of area logbook * Random review of process the area * UV Rinse/Swab Sample/ testing * Trend of Hardness comparative data * Online Investigation * Market Complain Investigation * Control Sample Withdrawal Activity * BMR & Record room documentation * In-house Complaint investigation * BMR review for audit * Audit Compliance * Handling of Customer during audit * Review of IPQC activity * OJT Compilation * Procurement of Different IPQC Instruments |  |  |

**ROLE OF QA IN WAREHOUSE**

* QA ensure that material received from Approved vendor.
* Availability of PO
* Cleanliness of Transporter vehicle
* Integrity of Containers
* Labelling of Containers
* Certificate of Analysis
* Cleaning of Containers
* Shall be received through De-dusting tunnel

**RECEIVING BAY**

* Rejected material shall be stored in presence of QA.
* QA ensures redressing of torned bags or containers

**REJECTED**

**DISPENSING**

**APPROVED**

**QUARANTINE**

**SAMPLING**

* QA ensures to affix seal on each container.
* Seal album shall be under the custody of QA.

**UNDER TEST**

* QA approved the list of stored materials
* Lock & Key of Narcotics/Psychotropic.
* Receiving of Narcotics/Psychotropic in presence of QA
* Verification & Destruction of non-moving material by QA.

**COLD STORAGE**

* Cleaning, Sanitization & Alarm verification shall be done by QA
* QA shall verify the Dispensing tools.
* Operation & Cleaning of Static & Dynamic pass box shall be checked by QA.
* Pressure Differential record of RLAF by QA.
* Line Clearance by QA.

Deviation, Incident & CAPA implementation

**ROLE OF QA IN GRANULATION**

SFM Challenge test

**LINE CLEARANCE**

Line Clearance of Area & Equipment by QA

Verification of Active material calculation

Weight Verification & Label Verification

Intimation regarding material Spillage

**MATERIAL VERIFICATION**

Rinse & Swab Sampling

QA ensure usage of Data logger

Verification of Logbook: Sieve/Screen/FBD bag issuance & retrieval

Verification of Logbook – Machine Utilization, Cleaning, Environmental monitoring, Balance Verification

**LOG BOOK VERIFICATION**

Implementation of Glass Breakdown Policy

Moisture Content Verification

Critical Quality Parameters & Critical Quality Attributes Verification

**IPQA**

Initiation of Deviation & Incident

Verification of Sieve & Screen Integrity along with Destruction record.

Verification of Sampling Tools for Cleanliness

Bulk Sampling

**SAMPLE PREPARATION**

BMR Verification along with Deviation, Incident & CAPA implementation

**BMR REVIEW**

**ROLE OF QA IN COMPRESSION**

Line Clearance of Area & Equipment

Recoveries supervision under QA

**LINE CLEARANCE**

Machine Utilization, Cleaning, Environmental Monitoring & Balance Verification

In & Out of Batches

**LOG BOOK VERIFICATION**

Online Verification of IPQA parameters like Average Weight, Weight Variation, Dimension, Disintegration time, Hardness, Friability.

Tablet defect verification like Foreign particles, Capping, Cracking, Broken, Picking, Non- Uniformity of Color, Sticking, Mottling, Lamination, Chipping, Splitting in layer & Tablet roughness

Punches Inspection, Destruction & Issuance record verification by QA

**IPQA**

Swab & Rinse Sampling & Analysis

Issuance & destruction of FBD bags in presence of QA

**SAMPLE PREPARATION**

Sampling of tablets for IPQA parameters

Online Process Verification of Critical Control Parameters & Critical Quality Attributes, Deviation, Incident & CAPA implementation

**BMR REVIEW**

Metal Detector challenge test verification

**ROLE OF QA IN COATING**

Silicon Tube issuance& Destruction record Verification by QA

Line Clearance of Area & Equipments

**LINE CLEARANCE**

**LOG BOOK VERIFICATION**

Log book for Machine Utilization, Cleaning, Environmental Monitoring, & Balance Verification

In-process logbooks, Disintegration time, Balance Operation & Cleaning Details

Online verification of Process Parameters like Thickness, Disintegration time, Description, Tablet Uniformity, Group weight verification

Online Verification of Different parameters like Pre-Warming, Pan RPM, Spray rate, Peristaltic pump speed, % weight gain, Inlet & Outlet temperature Bed Temperature

**IPQA**

**SAMPLE PREPARATION**

Bulk Sample preparation & Analysis by QC

Swab & Rinse Sampling analysis

**BMR REVIEW**

Online Verification of Critical Quality Parameters & Critical Quality Attributes

**ROLE OF QA IN HARDGEL**

Line Clearance of Area & Equipments

**LINE CLEARANCE**

Verification of Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification & Polishing log books

**LOG BOOK VERIFICATION**

Verification of In-Process Log books

Verification of In & Out Log books

Verification of Capsule defects like, Shell rupturing, Dent Pin hole, Description, Weight verification, Disintegration time

Rinse & Swab Sampling analysis

**IPQA**

**SAMPLE PREPARATION**

Bulk sample preparation

Online Verification of Critical Quality Parameters & Critical Quality Attributes

**BMR REVIEW**

**ROLE OF QA IN SOFTGEL**

Line Clearance of Area & Equipments

**LINE CLEARANCE**

* In process log book verification
* In & Out batches verification

**LOG BOOK VERIFICATION**

Log Book Verification for Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification, Waste Water verification & Drying Verification

Verification of IPQA parameters like Medicament preparation, Gelatin preparation, Drying & Polishing

Verification of Parameters during Encapsulation

**IPQA**

**SAMPLE PREPARATION**

Bulk Sample Preparation

Rinse & Swab Sample Analysis

Online Verification of Critical Control Parameters & Critical Quality Attributes

**BMR REVIEW**

1. **RISK IDENTIFICATION, EVALUATION & MITIGATION:**

| **RISK IDENTIFICATION** | **RISK EVALUATION** | **RISK MITIGATION** |
| --- | --- | --- |
| * **Warehouse:** QA personnel assures that the containers received should be from approved vendor, confirms the availability of PO. Ensures the cleanliness of transporter vehicle. QA also ensures the integrity & labelling of the received bags and containers. QA also ensures the Certificate of analysis of the received material. Finally, at receiving bay, QA will ensure that the containers & bags shall be cleaned & received through De-dusting tunnel. * In any case if the material received with any non-compliance, then the same shall be kept in “awaiting GRN” area. * **Quarantine area:** In the presence of QA personnel, rejected materials shall be stored in dedicated area. QA also ensures the redressing of torned bags or ruptured containers along with the label. * QA also approved the list & storage condition of raw material. QA shall update the list once in a six month or whenever required. * Lock & key of high value materials, Narcotic/Psychotropic shall be in custody of IPQA personnel. * Whenever any Narcotic material is received from the supplier, the consignment shall be properly checked and weighed & such material shall be stored in lock & key and labelled in presence of only authorized persons of QA/IPQA/QC/ stores & production for sampling, analysis, dispensing and manufacturing operation area of Narcotic and Psychotropic Drugs. * **Sampling:** After sampling, QA ensures to affix seal on each containers & record of the same shall be maintained. The storage of the seals shall be done under lock and key and the same is to be issued as per the requirement by QA. * **Non-moving material:** After receiving list of non-moving material from warehouse, Head QA will give the comment & QA officer will verify the materials and based on decision shall transfer the material to the rejected area with proper status labelling. * **Handling of Dispensing tools:** All Existing usage utensils like as scoops, spatula, spoons, barrel pump, and ladle etc. shall review & verified by warehouse & QA every six month or when required. * **Static Pass Box & Dynamic Pass Box:** Operation & Cleaning of Static & Dynamic Pass Box shall be checked by QA. * **Cold Chamber:** Cold Chamber Cleaning & Sanitization along with alarm shall be verified by QA as per schedule. * **Reverse Laminar Air Flow:** Pressure Differential record shall be verified by QA as per schedule**.** * **Destruction of Rejected/Expired /Non-Moving/Spillage Materials:** Destroy the raw materials in presence of Warehouse & QA Personnel. * **Line Clearance:** Warehouse personintimate to QA for the Line Clearance, further QA personnel will assure that no any contamination or cross contamination shall be forwarded to next dispensed material. | QA plays important role at the time of Receiving of material, in case of any failure during receiving, the same may impact integrity of received material along with Contamination, Cross Contamination & mix ups.  Rejected Materials if not kept in lock & key may got intermixed with the good material.  High value materials, Narcotic/Psychotropic are kept under the supervision of IPQA personnel, lock & key is provided to avoid any misuse.  Chance of intermixing is there in- case seal is not maintained within lock & key.  Non-moving materials may have got expired if not verified and the there may be space constraint or over loading.  There may be the chance that the dispensing tools are not handled properly or of no use over a period of time.  Dirty pass box may result into Contamination & Cross Contamination.  Dirty Cold Chamber can lead to Contamination & Cross Contamination and further regular Alarm verification shall be there to review the temperature fluctuations. Regular temperature fluctuations may result into product failure of those materials which are highly temperature sensitive.  Fluctuation of Pressure Differential may result into contamination, cross contamination & area failure.  Destruction & Spillage of material verification is done in presence of QA.  Improper line clearance can lead to Contamination, Cross Contamination & Mix ups. | As per SOP No.: HWH/001 Material containers received with non-compliances are kept in awaiting GRN area.  cid:773059893470281917243280  Awaiting GRN materials are kept in color coded area (Blue Color Lining) and surrounded by rope.  For rejected material, the area is dedicated with lock & key with the Red color flooring.  **REJECTED MATERIAL**  The custody of lock & key is along with QA.  Seals are kept under lock & key under the custody of QA.  Periodically review process is in place under the supervision of QA.  Periodic Verification is done by QA.  Every time before Operation, the pass boxes are verified by QA for its cleanliness.  Regular monitoring schedule is in place for verification of Cleaning, Sanitization & Alarm related to temperature fluctuation.  Pressure Differential monitoring is in place as per frequency.  QA role is specified in case of Destruction & Spillage of material.  QA role of Line Clearance is there as per BMR. |
| **Granulation:**   * Operating Production intimate to QA for physical verification of intermediate product after completion of process. * Rinse or Swab samples shall be send on daily basis as per the requirement. * Line Clearance of Granulation area is to be doneby QA, Line Clearance shall be done as per the BMR checklist. * Manufacturing chemist weighs each and every ingredient in presence of QA personnel before taking it for manufacturing and shall be recorded in relevant document. * Verification of logbook (176 Nos.)-Machine utilization &Cleaning, Environmental Monitoring, Balance Verification. * SFM Challenge test verification * Online verification of Critical Control parameters & Critical Quality Attributes. * Online filling of BMR. * Sampling of Bulk Samples. * Moisture Content Verification. * Weight Verification of Blended Granules. * Log book entries FBD Bag/Screen Issuance & Retrieval. * Material Spillage verification by QA. * Online Incidents & Deviations. * QA shall ensure use of data logger in low RH area and to attach necessary print of same in BPCR. * Intermediate Product Receipt Check List Prepared/Transferred by QA. * Operating production person shall check the integrity of the Sieve/Screen and verify by QA before and after use & record in respective BMR * Sieve/Screen Destruction Note, Verified by QA * Record any foreign particles observed during sifting of individual raw material, in the BMR, also communicate the same to the vendor through QA/purchase team for necessary CAPA from Vendor. * Under the supervision of QA, all the recoveries shall be stored at recommended storage conditions with complete labeling details i.e. Product name, Batch No., Mfg. Date, Exp. Date, Qty. and SFG Material Code. Executive/Officer QA shall review the appearance of recovery and if there is any change in appearance, destroy the recovery. After approval of QA, Executive/ Officer Production shall crush the recovery in Multi Mill/Comminuting Mill and sift the granules (use the required sieves). * Production shall intimate QA to collect the swab sample of filter bag. Operating production person shall issue the dedicated bag in presence of QA personnel. Reject the bag in the presence of Production and QA. | Mix ups may take place, if not properly verified.  Contamination & Cross Contamination can take place.  Contamination, Cross Contamination & Mix ups may take place if not properly verified.  Deviation in quantity may takes place if not properly verified.  Online Verification of several activities like manufacturing start time, end time, Equipment Cleaning start time, end time, Temperature/RH monitoring & Balance Verification, if not verified online, then there may be the chance of data integrity.  Leakage during rupturing of FBD bag may not be noticed.  Deviation may take place in case CCP & CQA not verified online.  Online data may not be filled resulting into Data Integrity.  Timely bulk sampling not done, may result into delay of batch release for further processing activity.  Will impact the Critical Quality Attributes of the Compressed Tablets.  Any loss in granules quantity will not be tracked, if not noted.  Ruptured FBD bags used for Drying may result into loss of dried granules.  Spilled granules may be used for manufacturing activity.  Online Incident or Deviation may not be initiated or recorded.  Temperature fluctuation may not be recorded.  Mix ups may take place in case of improper verification.  Ruptured sieve & Screen may be used resulting into metallic fiber contamination or wrong mesh size sieve may be used resulting into wrong particle size distribution.  Foreign particles observation not recorded and neither communicated to vendor for the same resulting into repetition of same observation.  Recoveries may be mix up with other granules, resulting into product failure.  Contamination and Cross Contamination may take place in case of dirty filter bags, rejected filter bags may be used. | Verification process of Intermediates is in place.  Rinse & Swab samples are sent at the end of each shift.  Line Clearance is done as per BMR checklist.  Weight verification process is in place.  As per SOP, verification of all processing activities shall be done online by QA personnel.  Solid Flow Meter challenge test is being performed on daily basis before the start of the activity.  As per the BMR, all process parameters & attributes are verified online by QA.  Provision of online filling of data is in place by QA.  Sampling process is in place.  Verification BY QA is the part of BMR.  Verification by QA is the part of BMR.  FBD bag verification by QA is the part of SOP.  SOP of Spilled material is in place.  SOP is in place for recording of online Incident s & deviations.  Temperature verification is the part of BMR.  Verification of Intermediates is a part of SOP.  Verification of Sieve & Screen size by QA is a part of SOP.  SOP is in place for the recording of any incident or deviation observed during sifting.  As per SOP, Verification of recoveries shall be done by QA, in case of failure the same recovery shall be destroyed in presence of QA.  SOP is in place for the Issuance &rejection of Filter bags. |
| **Compression:**   * In-Process Checks for Instrument/Equipment Utilization and Cleaning Log   Verified by QA.   * In-Process Weight Record of 20 Tablets (**Frequency:** Once in a 4 hrs./higher batch size & beginning & end for small b. size), Verified by QA. * Punches Inspection. Destruction of Punches and Dies, Status label& Dies & Punches Set Issuance Record Verified by IPQA. * Challenge Sheet for Metal Detector and Offline Tablets/Capsules pass through Metal Detector shall be Verified by QA. | Online Verification of several activities like Compression start time, end time, Equipment Cleaning start time, end time, Temperature/RH monitoring & Balance Verification, if not verified online, then there may be the chance of data integrity.  Deviations may not be recorded incase verification not done by QA.  Wrong punches or dies may be issued resulting into wrong tablet Compression.  Challenge test not performed or tablet not passed through Metal Detector may result into metal contamination. | As per SOP, verification of all processing activities shall be done online by QA personnel.  Online Verification is a part of QA.  Verification process of Issued Dies & Punches is in place.  Verification of Challenge test & Offline verification is the part of SOP & BMR. |
| **Coating:**   * Line Clearance of Coating area is to be done by QA, Line Clearance shall be done as per the BMR checklist. * Rinse or Swab samples shall be send on daily basis as per the requirement. * Verification of different parameter during coating examples: Pre warming, Pan RPM, Spray rate, peristaltic pump speed, % of Weight gain, inlet and out let temperature, Bed temperature. * Verification of In-process parameter after coating thickness, D.T., Description of tablets, Uniformity of tablets, Group weight verification of tablets. * Coating logbook (87 Nos.) - Machine Utilization &Cleaning, Environmental Monitoring, Balance Verification. Logbook (12 Nos.) - In & out of batches& Balance Verification. * Issuance, Rejection & Destruction of Silicone tubes in presence of QA. | Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.  Residue of previous batch transferred to the next batch.  Deviation in Critical Quality Parameters may result into deviation in Critical Quality Attributes.  Deviation in Critical Quality Attributes may result into product failure and Market Complaint.  Online Verification of several activities like Coating start time, end time, Equipment Cleaning start time, end time, Temperature/RH monitoring & Balance Verification, if not verified online, there may be the chance of data integrity.  Contamination & Cross Contamination through Silicone tubes may takes place. | Line Clearance is a part of SOP & BMR.  Rinse & Swab Sampling is a part of SOP & BMR.  Online process verification is a part of BMR.  Online verification of Critical Quality Attributes by IPQA.  As per SOP, verification of all processing activities shall be done online by QA personnel.  SOP is in place for Issuance, Rejection & Destruction of Silicone tubes in presence of QA. |
| **HARDGEL** | | |
| * Line Clearance of Area & equipment * Checking of different parameter during Capsule filling * Logbook (21 Nos.) - Machine utilization & cleaning, Environmental monitoring, Balance verification, Polishing, Metal detector * Logbook (01 No.) - In & out of batches * Logbook (01 No.) - Issuance &Retrieval of change part * Rinse & Swab Verification. | Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.  Deviation in Critical Quality Parameters & Critical Quality Attributes may result into product failure.  Online Verification of several activities like Coating start time, end time, Equipment Cleaning start time, end time, Temperature/RH monitoring & Balance Verification, if not verified online, there may be the chance of data integrity.  There may be the chance of batches mix ups, if not traceable for in & out entry.  Change part mix ups may take place resulting into wrong filling.  Contamination of previous product residue. | Line Clearance is a part of SOP & BMR.  Online Verification is a part of BMR.  As per SOP, verification of all processing activities shall be done online by QA personnel.  In & Out of batches verification is a part of SOP.  Verification of Change parts by QA is in place.  Rinse & Swab Verification is a part of SOP & BMR. |
| **SOFTGEL** | | |
| * Line Clearance of Area &Equipment * Verification of different parameter during medicament, gelatin, drying, Encapsulation& Polishing * Logbook (35 Nos.) - Machine Utilization & cleaning, Environmental monitoring, Balance verification, waste water, Drying * Logbook (01 No.) - In & out of batches * Logbook (01 No.) - Issuance & retrieval of change part. * Drying Period of Product, Verified by QA. * Rinse & Swab verification. | Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.  Deviation in Critical Quality Parameters & Critical Quality Attributes may result into product failure.  Online Verification of several activities like Encapsulation & Filling start time, end time, Equipment Cleaning start time, end time, Temperature/RH monitoring & Balance Verification, if not verified online, there may be the chance of data integrity.  There may be the chance of batches mix ups, if not traceable for in & out entry.  Change part mix ups may take place resulting into wrong filling.  Improper Drying may result into Capsule leakage.  Contamination of previous product residue. | Line Clearance is a part of SOP & BMR.  Online Verification is a part of BMR.  As per SOP, verification of all processing activities shall be done online by QA personnel.  In & Out of batches verification is a part of SOP.  Verification of Change parts by QA is in place.  Verification of Drying is the part of BMR.  Rinse & Swab Verification is a part of SOP & BMR. |

**RISK ASSESSMENT TOOL:**

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

|  |  |
| --- | --- |
| **Column 1** | Serial number of Risk Analysis item. |
| **Column 2** | Item/Function: Identify the process step or component associated with the risk. |
| **Column 3** | Potential Failure Mode: Identify the type of risk associated with the process or component. |
| **Column 4** | Effect of Potential Failure/Cause: Verify that whether risk have GMP impact. |
| **Column 5** | Potential Cause |
| **Column 6** | Risk Mitigation as a Current Control: Write the risk mitigation strategy as considered in design. |
| **Column 7** | References |
| **Column 8/9/10/11** | Severity/Occurrence/Detection/Risk level/Risk Acceptance: Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration. |
| **Column 12** | Recommended action: Recommended actions should be given for controlling failure occurrence. |
| **Column13/14/15/16** | Severity/Occurrence/Detection/Risk level/Risk Acceptance: After recommendation implementations, Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration. |

**Table 1:** Instruction for each column given above.

|  |  |
| --- | --- |
| **Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation:** QA Role & Responsibility from Dispensing to Coating | **Quality Risk Assessment Date:** |

| **S.No.** | **Item/Function** | **Potential**  **Failure Mode** | **Potential Effect of Failure** | **Potential Cause/Mechanism**  **of failure** | **Current Control** | **Reference**  **Document No.** | **S** | **O** | **D** | **RPN**  **(SxOxD)** | **Recommended**  **Actions**  **(if any)** | **Post Risk Evaluation** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S** | **O** | **D** | **RPN**  **(SxOxD)** |
| **WAREHOUSE** | | | | | | | | | | | | | | | |
| 1. | Raw Material Receipt check list verified by QA | COA not available  Ruptured bags  or containers | Wrong material received  Contamination & Cross Contamination | Wrong material received from vendor  Vendor not qualified | Procedure of material receiving in place | SOP No.: “Receipt of Raw Materials in Warehouse” | 3 | 1 | 2 | 6  **Severity:** Severity is high as wrong material received or cross contamination can lead to serious issues.  **Occurrence:**Chance of Occurrence is less as verification process is in place.  **Detectability:**Might Detect failure | NA | NA | NA | NA | NA |
| 2. | QA Line Clearance of Sampling area | Sampling not done | Contamination & Cross Contamination  Wrong material sampled | Pressure Differential not maintained | Procedure of Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid | SOP No.: “Operation and Cleaning of Reverse Laminar Air Flow Unit”  SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place  **Detectability:** Can be detected easily | NA | NA | NA | NA | NA |
| 3. | QA Line Clearance of Dispensing booth | Container not cleaned  Improper labelling  Calculation error | Contamination & Cross Contamination  Wrong material Dispensed  Wrong quantity of material dispensed or product mix up. | Pressure Differential not maintained  Calculation not verified | Procedure of Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid | SOP No.: “Operation and Cleaning of Reverse Laminar Air Flow Unit”  SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place  **Detectability:**Can be detected easily | NA | NA | NA | NA | NA |
| 4. | Material Verification (API & Excipient) by QA | Improper labelling | Wrong material Dispensed | Labelling not verified | Procedure of material receiving in place | SOP No.: “Receipt of Raw Materials in Warehouse” | 3 | 2 | 1 | 6  **Severity:** Improper labelling can lead to mix ups  **Occurrence:** Chance of failure is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 5. | API Calculation Verification (100%) by QA | Calculation error | Wrong quantity of material dispensed | Calculation not Verified | Procedure of QA Verification of Calculation of Active Ingredient for Material Issuance of Batches is in place | SOP No.: “Calculation of Active Ingredient for Material Issuance of Batches” | 3 | 2 | 1 | 6  **Severity:** Wrong calculation can lead to wrong quantity dispensing  **Occurrence:** Chance of wrong calculation is possible  **Detectability:**Can be easily detected during verification. | NA | NA | NA | NA | NA |
| 6. | Pre-Dispensing container Verification by QA | Previous product residue carryover | Contamination & Cross Contamination | Improper Verification | HGR-020-06 Cleaning of HDPE Containers | HGR/020 “Cleaning of HDPE Containers” | 3 | 2 | 1 | 6  **Severity:** Contamination can be severe  **Occurrence:**Chance of Occurrence is possible if not verified properly  **Detectability:**Can be easily detected during verification visually | NA | NA | NA | NA | NA |
| 7. | Review of logbook (97 Nos.) Dispensing detail, Environmental monitoring, Balance verification by QA | Temperature out of limit  Inappropriate material quantity | Material degraded  Assay failure  Market Complaint | Temperature sensitive material  Material quantity not sufficient | Procedure of Verification of log books by QA (Dispensing, EM, Balance Verification) is in place. | SOP No.: “Dispensing of Raw Materials to Production” | 3 | 2 | 1 | 6  **Severity:** Wrong entry can lead to data integrity.  **Occurrence:** Chance of wrong entry is possible  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| 8. | Expired, Rejected Material Verification & Destruction by QA | Expired material used  Rejected material used | Material not rejected & not destroyed | Procedure for Destruction of Rejected/Expired/Non Moving/ Spillage Materials | SOP No.: Destruction of Rejected/Expired/Non Moving / Spillage Materials | 3 | 1 | 1 | 3  **Severity:** Severity of expired material or rejected material is always high.   **Occurrence:**Chance of Occurrence is not possible as verification process is in place  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 9. | During Incident investigation & sample collection by QA | Root cause not identified | CAPA not appropriate | Inappropriate investigation | Procedure of Initiation of Incident & Deviation is in place | SOP No.: “Handling of Incident”  SOP No.: “Handling of Deviation” is in place | 3 | 2 | 1 | 6  **Severity:** Lack  of proper investigation can lead to severity  **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 10. | Nitrogen Gas Leak Test & Purging Log Book verification done by QA | Nitrogen purging not done | Material degradation | Microbial count increases | Procedure of Nitrogen purging &Verification by QA is in place | SOP No.: “Handling &Storage of Raw Materials” | 3 | 2 | 1 | 6  **Severity:** Improper purging can lead to increase in microbial count   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Purging can be easily detected through log book entry | NA | NA | NA | NA | NA |
| 11. | Redressing Container/Bag Label Checked by QA | Contamination to the next material during dispensing | Contamination & Cross Contamination | Ruptured containers & bags | Procedure of Redressing is in place | SOP No.: “Handling & Storage of Raw Materials” | 3 | 2 | 1 | 12  **Severity:** Severity of ruptured container is high, can lead to contamination   **Occurrence:** Chance of Occurrence is possible  **Detectability:**  Can be easily detected | NA | NA | NA | NA | NA |
| 12. | Movement of Cold Storage materials (2ºC to 8ºC) Verified by QA | Material not stored in cold storage | Material degraded | Storage condition inappropriate | Procedure of Movement of material to Cold Storage Chamber in place | (SOP No.: “Handling & Storage of Raw Materials”) | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of temperature fluctuations  **Occurrence:**Chance of temperature fluctuation is possible  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| 13. | Reconciliation of Material Seal, issued by QA & Rejected by QA | Reconciliation of Material Seal not maintained | Mix up may takes place | Record not maintained | Procedure for maintaining of reconciliation of seal available | SOP No.: “Procedure for Maintaining Manufacturer Seal Album & Resealing of API” | 3 | 2 | 1 | 6  **Severity:** Mix ups may lead to severity  **Occurrence:** Chance of failure is possible  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| 14. | Officer/Executive Warehouse and Officer/Executive QA shall identify the materials based on the merits of decision and transfer the materials which are to be destroyed to “Rejected Area” with proper status label. | Non-moving materials remain kept in area | Expired material may be used | Material may got expired if not noticed | Procedure of Handling of Non-Moving material is in place. | SOP No.: “Handling of Non Moving Raw Materials, Packing Materials and Finished Products” | 3 | 1 | 1 | 3  **Severity:** Severityis high as expired materials may be used for manufacturing.  **Occurrence:**Chance of Occurrence is less as verification process is in place  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| 15. | Operating Person QA shall calculate the quantity of active ingredient based on assay and water/LOD of active ingredient using the formula given in BMR (Wherever applicable).  After Approval from QA, Operating Person shall give the Process Order No. to the Operating Person Warehouse to issue the “Raw Material Issue Slip”. | Quantity of API not compensated as per the LOD | Assay failure | Loss on Drying not compensated | Procedure of QA Verification of Calculation of Active Ingredient for Material Issuance of Batches is in place | SOP No.: “Calculation of Active Ingredient for Material Issuance of Batches” | 3 | 2 | 1 | 6  **Severity:** Severity is high, quantity not compensated can lead to assay failure.  **Occurrence:**Chance of Occurrence is possible  **Detectability:** Can be easily detected**.** | NA | NA | NA | NA | NA |
| 16. | Cleaning Record of Dispensing tools, verified by QA | Dispensing done by Dirty tools. | Contamination & Cross Contamination | Verification not done by QA  Cleaning not done as per SOP. | Procedure for Handling & Cleaning of Dispensing Tools is in place. | SOP No.: “Handling and Cleaning of Dispensing Tools” & Checklist of Storage Tools, Verified by QA”. | 3 | 2 | 1 | 6  **Severity:** Contamination can lead to dispensing failure   **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected, if verified properly | NA | NA | NA | NA | NA |
| 17. | Pass box log, Checked by QA | Dirty Pass box Contaminate the containers | Contamination & Cross Contamination | Verification not done by QA  Cleaning not done as per SOP. | Procedure for Verification of Cleaning of Pass box is in place. | SOP No.: “Operation and Cleaning of Static Pass Box” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of Contamination  **Occurrence:** Chance of failure is possible  **Detectability:**Can be easily detected visually | NA | NA | NA | NA | NA |
| 18. | Differential Pressure Record (Dynamic Pass Box) Checked by QA  **Frequency:** Before and after Operation | Calibration not done or malfunctioning of Pressure Gauge | Classified area of Dispensing got disturbed | Verification not done by QA | Procedure of Verification of Differential Pressure is in place  Calibration available | SOP No.: “Operation and Cleaning of Dynamic Pass Boxes” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of Pressure Differential failure  **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 19. | Cold Chamber Cleaning and Sanitization Log, verified by QA  **Frequency:** Floor cleaning: Weekly  **Frequency:** Wall & Ceiling sanitization: Monthly  Cold Chamber Alarm Challenge Test Record, Verified by QA Operating Person | Dirty & Contaminated Cold Chamber  Temperature fluctuation not noted. | Contamination & Cross Contamination  Continuous Temperature fluctuations may result into temperature sensitive material degradation | Cleaning not done as per frequency  Malfunctioning of Alarms | Procedure for Verification of Cleaning & Sanitization is in place  Procedure for Verification of Alarm is in place  Temperature Mapping is in place | SOP No.: “Operation, Cleaning and Sanitization of Cold Chamber”  **Frequency:** Fortnightly | 3 | 1 | 1 | 3  **Severity:** Contamination  can lead to severe issues  **Occurrence:** Chance of occurrence is not possible, as procedure of cleaning & sanitization is in place  **Detectability:**Can be easily detected as log books are filled for tracking. | NA | NA | NA | NA | NA |
| 20. | Pressure differential record of RLAF for Dispensing Booth No.11 to 15 & Sampling Booth No. 05 to 06, Verified by (QA) | Pressure Differential across filters not achieved | Contamination & Cross Contamination | Calibration of Pressure Gauge not done  Pre-filter, Fine filter & HEPA filter got ruptured or choked | Procedure for Verification of Pressure Differential is in place  Calibration is in place | SOP No.: “Operation and Cleaning of Reverse Laminar Air Flow Unit” | 3 | 1 | 1 | 3  **Severity:** Failure in Pressure Differential can lead to Contamination  & Cross Contamination  **Occurrence:**Chance of Occurrence is not possible as verification process in log book is in place.  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 21. | Rejected material log, Verified by QA Sign & Date. | Reject material dispensed | Product failure  Market Complaint | Reject material kept in Quarantine area | Procedure for Verification of rejected material log is in place | SOP No.: “Handling of rejected raw material and packing material” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of wrong entry.  **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 22. | Nitrogen Purging Log Book, Verified by QA Sign & Date | Nitrogen purging not done | Microbial growth  Product failure | Unaware of nitrogen purging | Procedure for Verification of Nitrogen Purging is in place | SOP No.: “Dispensing  of Non-Sterile  Raw Material” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Nitrogen purging not done.  **Occurrence:** Chance of Occurrence is less  **Detectability:**Can be easily detected through log book | NA | NA | NA | NA | NA |
| 23. | Cold Chamber Temperature Monitoring Record, Verified by QA  **Frequency:** Every 2 Hrs. | Temperature monitoring not done | Temperature sensitive material degraded | Too much of temperature fluctuation | Procedure for Monitoring done after every 02 hours is in place | SOP No.: “Operation, Cleaning and Sanitization of Cold Chamber” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of temperature fluctuation  **Occurrence:**Chance of Occurrence is possible in case of temperature fluctuation.  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 24. | Cleaning of the Weighing Balance, Pressure Gauge of RLAF, Pre-filter, Fine filter, Dynamic/Static pass box shall be verified by warehouse and IPQA personnel. | Weighing Balance not calibrated  Pressure Gauges are malfunctioned  Pre-filter, Fine filter are contaminated  Dynamic & Static Pass Box are dirty | Wrong material weighment verification  Wrong Pressure Differential monitoring  Contamination & Cross Contamination | Verification procedure by QA not in place | Procedure for Verification by QA is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity can be high in case of Verification not done online for Balance, Pressure Gauge, RLAF Filters, Pass Boxes   **Occurrence:** Chance of Occurrence is less as verification process is in place  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| **GRANULATION** | | | | | | | | | | | | | | | |
| 25. | Line Clearance of area & Equipments | Line Clearance not done by QA | Contamination & Cross Contamination  Product mix ups | Residue of previous product | Procedure of Line Clearance is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure  **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place  **Detectability:**Can be detected easily | NA | NA | NA | NA | NA |
| 26. | Verification of logbook (176 Nos.) - Machine Utilization &Cleaning, Environmental monitoring, Balance verification, SFM challenge test | Verification not done | Excursions observed in temperature & RH  Wrong quantity of material weighed  Material got exhausted from ruptured FBD bags | Temperature & RH monitoring not done  Balance not calibrated  Balance not verified  Challenge test not performed for Solid flow monitor | Procedure of Verification of Machine Utilization, Cleaning, Environmental Monitoring, Balance Verification & SFM challenge test is in place | Dedicated BMR & Related log books | 3 | 2 | 1 | 6  **Severity:** Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 27. | Process monitoring | Critical Control parameters & Critical Quality Attributes not verified | Product failure  Market Complaint | Monitoring not done by QA | Instructions in BMR in place | Dedicated BMR | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 28. | BMR Activity Verification |
| 29. | Sampling of bulk | Sampling not done | Any failure in Compression will not be traced | Sampling not done |
| 30. | Weight Verification of theblend granules by QA | Weight verification not done | Wrong quantity transferred to Quarantine | Weight Verification not done by QA |
| 31. | Verification of SFM Challenge test of FBD (Fortnightly) | Verification not done | Material got passed through filter bag | Verification not a part of QA | Procedure for Verification of Solid Flow Monitor Sensor challenge test is in place | SOP No.: “Operation and Cleaning of Solid Flow Monitor Sensor” | 3 | 2 | 1 | 6  **Severity:** SFM Challenge test failure may result into outflow of material   **Occurrence:**Chance of failure is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 32. | Logbook (20 Nos.) - Inward &Outward of batches | FIFO not followed | Granules hold time failure | Log book not maintained | Procedure of Inward & Outward of batches is in place. | SOP No.: “Receipt Storage Issuance of Materials in Staging Area Quarantine Area” | 3 | 1 | 1 | 3  **Severity:** Severity is high if granules hold for more than the hold time   **Occurrence:** Chance of Occurrence is less as Hold time of Granules is Validated  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 33. | Logbook (66 Nos.) Sieve/Screen/FBD bag issuance & retrieval  Detail.  Operating Person Production shall check the integrity of the Sieve/Screen and verify by QA before and after use & record in respective BMR.  Sieve/Screen  Destruction note Verified by QA | Record not maintained  Ruptured Sieve/Screen issued for sifting  Ruptured Sieves & Screens used for manufacturing | Contamination & Cross Contamination | Ruptured Sieves/Screens of FBD Bags may result into contamination & Cross Contamination | Procedure of Verification of Sieve & Screen is in place | SOP No.: “Handling of Sieves and Screens” | 3 | 2 | 1 | 6  **Severity:** Improper Verificationof Sieve, Screen & FBD bags can lead to Contamination & Cross Contamination  **Occurrence:** Chance of Occurrence is possible  **Detectability:**Might detect failure | NA | NA | NA | NA | NA |
| 34. | If any material spill on the floor, it shall be immediately cleaned with the help of vacuum cleaner and intimate to QA | QA not intimated for spillage | Spilled material reused | Intimation to QA is not a part of SOP | Procedure of Verification of Spillage by QA is in place | SOP No.: “Production Discipline” | 3 | 2 | 1 | 6  **Severity:** Spillage may contaminate the surrounding  **Occurrence:** Chance of Spillage is possible  **Detectability:** Can be easily detectable | NA | NA | NA | NA | NA |
| 35. | Manufacturing chemist weighs each and every ingredient in presence of QA personnel before taking it for manufacturing and shall be recorded in relevant document.  In case of any deviation from BPCR, manufacturing chemist inform to production In-charge and QA for necessary action. | Not weighed in presence of QA  Deviation not recorded | Improper quantity of material weighed  Product manufactured with deviation & no further CAPA initiated | Verification is not a part of BMR or SOP | Procedure of Verification by QA is in place. | “Production Process and Control” | 3 | 2 | 1 | 6  **Severity:** Severity is always high if weight not verified  **Occurrence:**Chance of failure of weight verification is possible  **Detectability:**Can be easily detected. | NA | NA | NA | NA | NA |
| 36. | After calculation of active ingredient it is to be verified by QA and then prepare raw material issue slip as per SOP “Receipt of Raw material in Production Area” | Calculation not verified by QA | Wrong quantity material dispensed | Verification of Calculation is not a part of SOP | Procedure of Verification by QA is in place | SOP No.: “Calculation of Active Ingredient for Material Issuance of Batches” | 3 | 2 | 1 | 6  **Severity:**Severity is high, quantity not compensated can lead to assay failure.  **Occurrence:**Chance of Occurrence is possible  **Detectability:** Can be easily detected**.** | NA | NA | NA | NA | NA |
| 37. | Operating Productionperson shall intimate to QA for physical verification of intermediate product after completion of process i.e. granulation, as per Annexure- III Titled as “Intimation for Physical Verification of Intermediate Product Before Packing” and attached in BPCR.  Before starting any process i.e. sifting, mixing, drying, compression, filling, coating. Operating Person Production shall check the area and equipment/machine as per line clearance checklist attached in BPCR.  Operating Person Production shall fill the details in checklist & line clearance format and inform to Operating Person QA to release for processing.  Operating Person QA shall check all the relevant documents like rinse water or swab test report. If any deviation found by QA, then it shall be informed to Operating Person Production for corrective action.  After corrective action, Operating Person Production shall again inform to Officer/ Executive QA to verify the corrective action. After release by QA start the processing. | Physical Verification of Granules not done by QA  Release of intermediate stage not done by QA  Deviation not identified by QA person. | Mix ups may take place, if not verified by QA | Improper labelling  Corrective action not initiated in case of deviation or incident | Procedure of Verification by QA is in place | SOP No.: “Line Clearance  SOP No.: “Handling of Deviation” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of intermediate mix ups.  **Occurrence:**Chance of Mix ups of intermediate is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 38. | QA shall ensure use of data logger in low RH area and to attach necessary print of same in BPCR | Low RH product run in normal temperature & RH  Temperature & RH fluctuation not recorded | Temperature & RH product may degraded. | Verification by QA is not the part of SOP or BMR. | Dedicated BMR | SOP No.: “  Good Practices in Low Relative Humidity Area” | 3 | 2 | 1 | 6  **Severity:** Severity is high  **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 39. | Intermediate Product receipt check List  Prepared/Transferred by QA | Intermediate product not verified by QA | Wrong quantity intermediate product got transferred | Product verification by QA is not a part of process | Procedure of Verification by QA is in place | SOP No.: “Intermediate Product Receipt Check List” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of verification of Intermediate  **Occurrence:**Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 40. | Officer/Executive QA shall check the Sampling tools visually for its cleanliness. | Sampling tools not verified by QA | Contamination & Cross Contamination | Improper Cleaning of Sampling tool | Procedure of Verification Sampling tools by QA is in place | SOP No.: “Handling and Cleaning of Sampling Tools” | 3 | 2 | 1 | 6  **Severity:** Severity of Contamination & Cross Contamination is high   **Occurrence:**Chance of failure is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 41. | Cleaning Record of Sampling Tools, Verified by QA | Cleaning record of Sampling tools not maintained | Contamination & Cross Contamination | Verification by QA is not a part of SOP |
| 42. | Check list of movable Equipment/Instrument, Checklist Observation by IPQA | Integrity, Cleanliness, Calibration Status, log book, Preventive maintenance, Qualification Status of the equipment not verified by QA | Product integrity got affected along with Contamination & Cross Contamination | Malfunctioned Equipment used for manufacturing activity | Procedure of Verification by QA is in place | SOP No.: “Handling of Movable Equipment/Instrument” | 3 | 1 | 2 | 6  **Severity:** Severity is high in case equipment is not qualified or calibrated  **Occurrence:**  Severity is high, quantity not compensated can lead to assay failure.  **Detectability:** Can be easily detected**.** | NA | NA | NA | NA | NA |
| 43. | During the Glass Breakage, all open product in immediate area put on Hold, remove from the area and notify Production Supervisor and QA.  Glass Breakage Record, Verified By QA | Products may kept in open condition | Product failure due to Glass contamination | Persons unaware about the policy, no verification process in place. | Procedure of Verification by QA is in place | SOP No.: “Glass Policy” | 3 | 1 | 1 | 3  **Severity:** Severity of Glass contamination is high  **Occurrence:**  Chance of Occurrence is possible  **Detectability:** Can be easily detected | NA | NA | NA | NA | NA |
| 44. | Record any foreign particles observed during sifting of individual raw material, in the BMR, also communicate the same to the vendor through QA/purchase team for necessary CAPA from Vendor. | Foreign particle contamination not addressed to vendor neither any CAPA generated | Contamination & Cross Contamination | QA verification is not the part of BMR or SOP | Procedure of Verification by QA is in place | SOP No.: “Operation and Cleaning of Vibro Sifter” | 3 | 1 | 1 | 3  **Severity:** Severity of foreign particles contamination is high  **Occurrence:**  Chance of Occurrence is less as verification process is in place  **Detectability:**  Can be detected easily | NA | NA | NA | NA | NA |
| **COMPRESSION** | | | | | | | | | | | | | | | |
| 45. | Line Clearance of the area & Equipments | Line Clearance not done by QA | Contamination & Cross Contamination & Product mix ups | Line Clearance is not a part of QA responsibility | Procedure of Verification of Line Clearance by QA is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place  **Detectability:**Can be detected easily | NA |  |  |  |  |
| 46. | Verification of logbook (120 Nos.)- Machine utilization & cleaning, Environmental monitoring, Balance verification | Verification not done | Excursions observed in temperature & RH  Wrong quantity of material weighed | Temperature & RH monitoring not done  Balance not calibrated  Balance not verified | Procedure of Log book verification is in place | Dedicated BMR & Related log books | 3 | 2 | 1 | 6  **Severity:** Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 47. | Logbook (12 Nos.)- In & out of batches | FIFO not followed | Granules hold time failure | Log book not maintained | SOP No.: “Receipt, Storage and Issuance of Materials in Staging Area and in Quarantine Area”. | 3 | 2 | 1 | 6  **Severity:** Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 48. | **Officer/Executive Production & IPQA shall check the following parameters as defined in BMR.**  Average Weight  Weight Variation  Dimension  Length  Diameter  Width  Thickness  Disintegration Time  Hardness  Friability  (Once in a 4 hrs./higher batch size & beginning & end for small b. size)  **Officer/Executive Production & IPQA shall check the following tablet defects physically as per given below:**  Oil/Black Particle  Capping  Cracking of Tablets  Broken Tablets  Picking problem  Non-Uniformity of color if colored granules.  Sticking  Mottling  Lamination  Chipping/Splitting  Edging  Splitting in layered tablet  Surface roughness. | Parameters out of specification  Tablet defects not verified | Out of Specification & Tablet defects may result into Market Complaint | IPQA verification is not a part of process | Dedicated BMR in place | **SOP No.:** “Check List for Bulk Tablet Defects” | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 49. | All the recoveries shall be stored under the supervision of QA with complete labeling details | Recovery can be used with good product | Contamination & Cross Contamination  Product failure | Mix ups of recovery in good product | Procedure of recovery storage under supervision is in place | SOP No.: “Handling and Utilization of Recovery” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of recovery mix ups  **Occurrence:**  Chance of Occurrence is possible  **Detectability:**  Can be easily detected through log book. | NA | NA | NA | NA | NA |
| 50. | Production shall intimate QA to collect the swab sample of filter bag.  Operating Production person shall issue the dedicated bag in presence of QA personnel.  Reject the bag in the presence of Production and QA | Swab sample not collected  Dedicated filter bags bot used  Rejected Filter Bags used | Contamination & Cross Contamination | QA not intimated | Procedure of Verification by QA is in place | SOP No.: “Handling of Filter Bags of FBDFBP and Vent filters of RMG” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of Contamination & Cross Contamination  **Occurrence:** Chance of Occurrence is possible  **Detectability:** Can be easily detected by analysis | NA | NA | NA | NA | NA |
| 51. | Punches Inspection Record, Verified by QA  Destruction of Punches and Dies, Verified by QA  Status label, Verified by QA  Dies & Punches Set Issuance format, Verified by IPQA | Verification not done | Wrong punches & Dies issued | Punches & Dies not verified by QA | **SOP No.:** “Handling of Dies and Punches” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of Wrong punch issuance.   **Occurrence:**Chance of Occurrence is possible in case not verified.  **Detectability:**Can be easily detected through issuance log book | NA | NA | NA | NA | NA |
| 52. | Offline Tablets/Capsules pass through Metal Detector, Verified by QA  If metal particles are identified, QA shall inform to customer about the findings and decide mutually about release of batch.  Challenge Sheet for Metal Detector, Verified by QA. | Metal Detector challenge test not performed | Contamination & Cross Contamination | Verified not performed by QA | Procedure of Verification by QA is in place | SOP No.: “Operation and Cleaning of Metal Detector” | 3 | 2 | 1 | 6  **Severity:** Severity is high in case of Contamination & Cross Contamination  **Occurrence:**  Chance of Occurrence is possible  **Detectability:**Can be easily detected in case metal detector not used for Verification. | NA | NA | NA | NA | NA |
| **COATING** | | | | | | | | | | | | | | | |
| 53. | Line Clearance of Area & equipment | Line Clearance not done by QA | Contamination & Cross Contamination & Product mix ups | Line Clearance is not a part of QA responsibility | Procedure of Verification of Line Clearance by QA is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place  **Detectability:**Can be detected easily | NA | NA | NA | NA | NA |
| 54. | Verification of different parameter during coating examples: Pre warming, Pan RPM, Spray rate, peristaltic pump speed, % of Weight gain, inlet and out let temperature, Bed temperature. | Verification of Critical Control Parameters & Critical Quality Attributes not done online | Out of Specification observed | QA not involved in Verification | Procedure of Verification of online process parameters by QA is in place | Dedicated BMR | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 55. | Verification of In-process parameter after coating thickness, D.T., description of tablets, Uniformity of tablets, Group weight verification of tablets. | Verification of In-process parameters not done | Out of Specification  Market Complaint  Excursions not observed | Online IPQA Verification not done | Procedure of Verification of online Critical Quality Attributes by QA is in place | Procedure of Verification of Quality Attributes by QA is in place | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 56. | In-process Logbook IPQC (27 Nos.) - DT & Balance operation & cleaning detail | Log book not verified by QA | Tracking not available in case of any failure | Good Documentation Practices not followed | Procedure of Log book verification is in place | Dedicated BMR & Related log books | 3 | 2 | 1 | 6  **Severity:** Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 57. | Coating Logbook (87 Nos.) - Machine utilization & cleaning, Environmental monitoring, Balance verification |
| 58. | Operating person of Production shall issue the dedicated Silicon Tube Set in presence of QA personnel and enter the detail  Assemble the Silicon Tube on peristaltic pump and spray guns after getting line clearance from QA  Reject the Silicon Tube in the presence of Production, QA & Engineering personnel.  Destruction Record of Silicon Tubes, Verified by QA | Silicon tubes not cleaned properly  Rejected Silicone tubes used | Contamination & Cross Contamination | Residue of previous product transferred to the next product | Verification procedure of Silicon tubes is in place | SOP No.: Handling of Silicon Tubes | 3 | 2 | 1 | 6  **Severity:** Contaminated Silicon tubes may result into failure  **Occurrence:** Chance of Occurrence is there  **Detectability:**Can be easily detected visually | NA | NA | NA | NA | NA |
| **HARDGEL** | | | | | | | | | | | | | | | |
| 59. | Line Clearance of Area & equipment | Line Clearance not done by QA | Contamination & Cross Contamination & Product mix ups | Line Clearance is not a part of QA responsibility | Procedure of Verification of Line Clearance by QA is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:** Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as line clearance procedure is in place  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 60. | Checking of different parameter during Capsule filling | Verification of In-process parameters not done | Out of Specification  Market Complaint  Excursions not observed | Online IPQA verification not done | Procedure of Verification of online Critical Quality Attributes by QA is in place | Procedure of Verification of Quality Attributes by QA is in place | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 61. | In-process Logbook IPQC (04 Nos.) | Log book not verified by QA | Tracking not available in case of any failure | Good Documentation Practices not followed | Procedure of Log book verification is in place | Dedicated BMR & Related log books | 3 | 2 | 1 | 6  **Severity:** Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 62. | Logbook (21 Nos.) - Machine utilization & cleaning, Environmental monitoring, Balance Verification& Polishing | Verification not done | Excursions observed in temperature & RH  Wrong quantity of material weighed | Temperature & RH monitoring not done  Balance not calibrated  Balance not verified |
| 63. | Logbook (01 No.) - In & out of batches | FIFO not followed | Granules hold time failure | Log book not maintained |
| 64. | Rinse & Swab Sampling analysis | Rinse & Swab sampling fails in results | Contamination & Cross Contamination | Dirty equipments | Verification of Rinse & Swab Sampling is in place | SOP No.: “Procedure for Sampling and Testing of Swab/Rinse Water for Chemical and Assignment of A.R. No. to Received Sample” | 3 | 1 | 1 | 3  **Severity:** Dirty equipments can lead to contamination & cross contamination  **Occurrence:**Chance of Occurrence is not possible as cleaning procedures are in place/.  **Detectability:**Can be easily detected through analysis. | NA | NA | NA | NA | NA |
| 65. | Online Verification of IPQA parameters like Description, Dimension, Weight Verification, Disintegration time verification | Verification of In-process parameters not done | Out of Specification  Market Complaint  Excursions not observed | Online IPQA verification not done | Procedure of Verification of online Critical Quality Attributes by QA is in place | Procedure of Verification of Quality Attributes by QA is in place | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| **SOFTGEL** | | | | | | | | | | | | | | | |
| 66. | Line Clearance of Area & equipment | Line Clearance not done by QA | Contamination & Cross Contamination & Product mix ups | Line Clearance is not a part of QA responsibility | Procedure of Verification of Line Clearance by QA is in place | SOP No.: “Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid” | 3 | 1 | 1 | 3  **Severity:**Severity is high in case of Line Clearance failure   **Occurrence:** Chance of Occurrence is less as line clearance procedure is in place  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 67 | Rinse & Swab Sampling analysis | Rinse & Swab sampling fails in results | Contamination & Cross Contamination | Dirty equipments | Verification of Rinse & Swab Sampling is in place | SOP No.: “Procedure for Sampling and Testing of Swab/Rinse Water for Chemical and Assignment of A.R. No. to Received Sample” | 3 | 1 | 1 | 3  **Severity:**Dirty equipments can lead to contamination & cross contamination  **Occurrence:**Chance of Occurrence is not possible as cleaning procedures are in place/.  **Detectability:**Can be easily detected through analysis. | NA | NA | NA | NA | NA |
| 68. | Verification of different parameter during medicament, gelatin, drying & Polishing | Critical Control parameters & Critical Quality Attributes not verified | Product Failure & Market Complaint | Online verification not done by QA | Procedure of Verification of online Critical Quality Attributes by QA is in place | Procedure of Verification of Quality Attributes by QA is in place | 3 | 2 | 1 | 6  **Severity:** Severity is high, if process parameters not verified online.   **Occurrence:** Chance of Occurrence is possible  **Detectability:**Can be easily detected | NA | NA | NA | NA | NA |
| 69. | Checking of different parameter during Encapsulation |
| 70. | In-process Logbook (04 Nos.) | Entry not done & neither verified for the usage | Tracking not available for investigation, incase of any failure | Log Verification | Procedure of Log book verification is in place | Dedicated BMR & Related log books | 3 | 2 | 1 | 6  **Severity:**Severity is high in case log book not filled online   **Occurrence:**Chance of Occurrence is there  **Detectability:**Can be easily detected as log books are filled online | NA | NA | NA | NA | NA |
| 71. | Logbook (35 Nos.) - Machine utilization & cleaning, Environmental monitoring, Balance verification, waste water, Drying | Verification not done | Excursions observed in temperature & RH  Wrong quantity of material weighed | Temperature & RH monitoring not done  Balance not calibrated  Balance not verified |
| 72. | Logbook (01 No.) - In & out of batches | FIFO not followed | Granules hold time failure | Log book not maintained |
| 73. | Logbook (01 No.) - Issuance & retrieval of change part | Wrong Change part issued | Wrong product manufactured with different specification | Verification by QA not done |
| 74. | Drying Period of Product, Verified by QA | Soft capsules generated | Leakage or Soft Capsules | Drying time not achieved | Drying procedure is in place | SOP No.: “Inspection and Storage of Soft Gelatin Capsules” | 3 | 2 | 1 | 6  **Severity:** Improper leakage may leads to leakage or rupture of soft capsules  **Occurrence:**Chance of Occurrence is possible  **Detectability:**  Can be easily detected by inspection | NA | NA | NA | NA | NA |

**Where: S=**Severity**; O=**Occurrence**; D=**Detection

**Assessment of Severity, Occurrence and Detection: Evaluation of RPN:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity Effect** | **Likelihood Occurrence** | **Likelihood of Detection** | **Rating** |  | **RPN Rating** | **Category** |
| No Effect | Unlikely | Always Detected | 1 |  | 12 to 27 | High |
| Moderate Effect | Possible | Might Detect Failure | 2 |  | 7 to 11 | Medium |
| Serious Effect | Almost Certain (Every time) | Lack of Detection Control | 3 |  | Upto 6 | Low |

| **S.No.** | **Recommended Action** | **Responsible Person** | **Target Date of Completion** |
| --- | --- | --- | --- |
| 1. | **Related SOP’s to be revised for QA role & Responsibilities in Warehouse:**   1. HHW/001 “Receipt of Raw Materials in Warehouse” 2. HWH/026 “Operation & Cleaning of RLAF” 3. QAH/012 “Line Clearance in Oral Solid Dosage, External Preparations and Oral Liquid” 4. HGR/003 “Calculation of Active Ingredient for Material Issuance of batches is in place. 5. HGR/020 “Cleaning of HDPE Containers”. 6. HWH/004 “Dispensing of Raw Materials to Production” 7. HWH/030 “Destruction of Rejected/Expired/Non Moving /Spillage Materials. 8. HWH/012 “Handling & Storage of Raw Materials”. 9. HWH/013 “Procedure for Maintaining Manufacture Seal Album & Resealing of API”. 10. HWH/014 “Handling of Non Moving Raw Materials, Packing Materials & Finished Products” 11. HGR/003 “Calculation of Active Ingredient for Material Issuance of Batches” 12. HWH/015 “Handling and Cleaning of Dispensing Tools” 13. HWH/017 “Operation and Cleaning of Static Pass Box” 14. HWH/019 “Operation & Cleaning of Dynamic Pass Boxes” 15. HWH/025 “Operation Cleaning and Sanitization of Cold Chamber” 16. HWH/034 “Handling of Rejected raw material and Packing Material” 17. HWH/049 “Dispensing of Non-Sterile Raw Material” 18. QAH/012 “Line Clearance in Oral Solid Dosage, External Preparation & Oral Liquid” 19. HPT/054 “Operation and Cleaning of Solid Flow Monitor Sensor” 20. HGR/030 “Logbook Inward & Outward of Batches” 21. HGR/022 “Handling of Sieves & Screens” 22. HGR/001 “Production Discipline” 23. HGR/002 “Production Process and Control” 24. HGR/003 “Calculation of Active Ingredient for Material Issuance of Batches” 25. HGR/005 “Line Clearance” 26. HGR/013 “Good Practice in Low RH area” 27. HGR/015 “Intermediate Product Receipt Check List” 28. HGR/024 “Handling and Cleaning of Sampling Tools” 29. HGR/050 “Handling of Movable Equipment/Instrument” 30. HGR/052 “Glass Policy” 31. HPT/001-HPT/084 “Operation & Cleaning of Equipments” 32. HPC/001-HPC/033 “Soft gel & Hard gel SOP’s. |  |  |
| 2. | Training of Personnel for the new job responsibilities |  |  |
| 3. | Job responsibilities to be revised |  |  |
| 4. | Change Control to be initiated |  |  |
| 5. | BMR to be revised for the QA role in Line Clearance |  |  |
| 6. | Log books to be revised. |  |  |

**CAPA (Required/Not Required):**NotRequired

**If required, mention CAPA No.:** …………….

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Quality Risk Management Team** | | | **Reviewed By**  **Head Operations**  **(Sign & Date)** | **Approved By**  **Head QA**  **(Sign & Date)** |
| **Name** | **Department** | **Sign & Date** |
|  |  |
| Mr. Binod | Warehouse |  |
| Mr. JP Mehta | Production |  |
| Mr. Balbir Bhandari | Packing |  |
| Mr. Bhupendra Mehra | Quality Assurance |  |
| Mr. Kartik Sonawane | Quality Assurance |  |
| Mr. Arun Kumar | Quality Assurance |  |

**Verification of Recommended Action:**

**…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………**

**Remarks (if any):**

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|  |  |
| --- | --- |
| **Verified By**  **Operating Person QA**  **(Sign & Date)** | **Approved By**  **Head QA**  **(Sign & Date)** |
|

1. **CONCLUSION:**………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

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1. **REFERENCES:**

* Reference SOP of Risk Assessment (QAH/126).
* Related SOP’s.

1. **DOCUMENTS TO BE ATTACHED:**

* Training Record.

1. **DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:**

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

1. **CHANGE CONTROL, IF ANY:**……………………………………………………………………………………………………………………….………….……………………………………………………………………………………………………………………………..…………………………………………………………………………………………………………………………………………………………………………………………………………..…

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1. **ABBREVIATIONS:**

FMEA : Failure Mode Effect Analysis

RPN : Risk Priority Number

CAPA : Corrective action preventive action

SOP : Standard Operating Procedure

QRM : Quality Risk Management

QA : Quality Assurance

QMS : Quality Management System

RH : Relative Humidity

ID : Identification

1. **FMEAAPPROVAL:**

**PREPARED BY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESIGNATION** | **NAME** | **SIGNATURE** | **DATE** |
| **OPERATING PERSON**  **(QUALITY ASSURANCE)** |  |  |  |

**REVIEWED BY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESIGNATION** | **NAME** | **SIGNATURE** | **DATE** |
| **OPERATING MANAGER**  **(QUALITY ASSURANCE)** |  |  |  |
| **HEAD**  **(PRODUCTION)** |  |  |  |

**APPROVED BY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESIGNATION** | **NAME** | **SIGNATURE** | **DATE** |
| **HEAD**  **(QUALITY ASSURANCE)** |  |  |  |