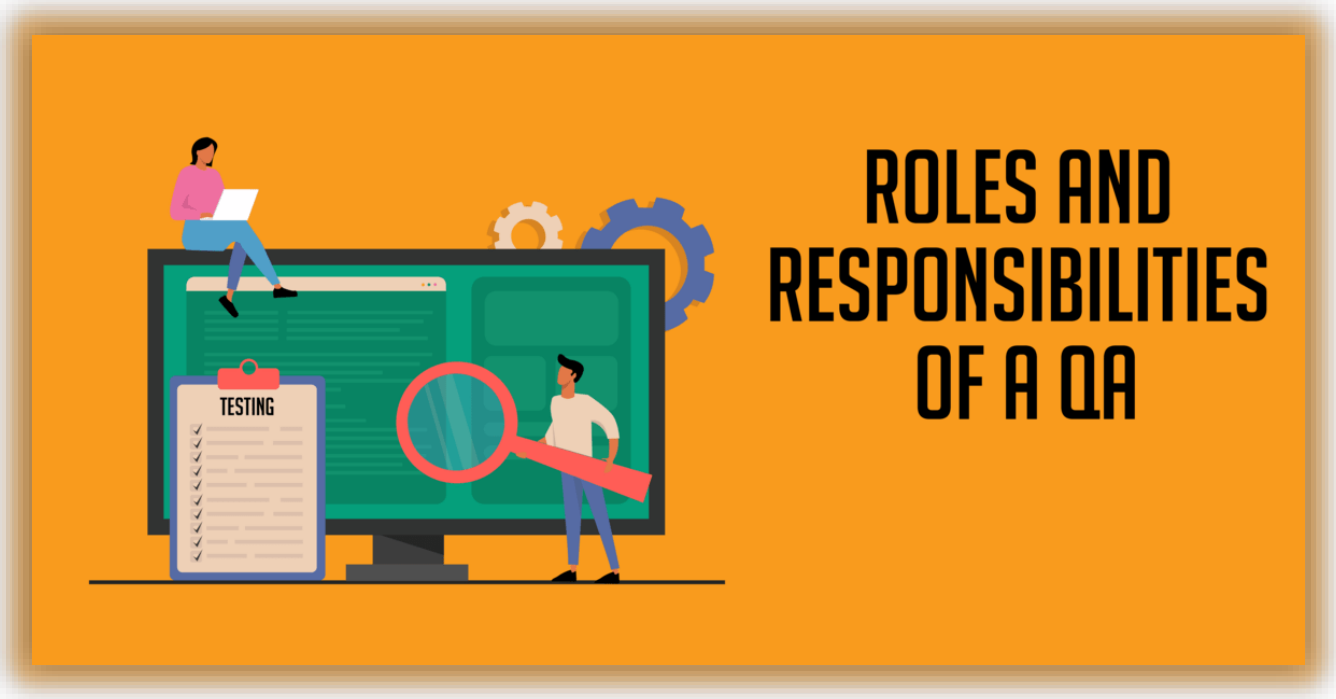
QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]	
Reference Document No.: Role and Responsibility of QA	**Risk Assessment No.:** …….

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FORTHE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]



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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

4. **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.

5. **SITE OF STUDY:**

6. **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.

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7. 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.

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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.	• Machine Utilization & Cleaning Record • Verification of Environmental Monitoring log book. • Verification of Sieve/Screen/FBD Bags log book • Verification of Sieve Integrity.

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	• 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.	• 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		

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PRIMARY ROLES& RESPONSIBILITIES	SECONDARY ROLES& RESPONSBILITIES	TERTIARY ROLES& RESPONSIBILITIES
• 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		

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PRIMARY ROLES& RESPONSIBILITIES	SECONDARY ROLES& RESPONSBILITIES	TERTIARY ROLES& RESPONSIBILITIES
• 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		

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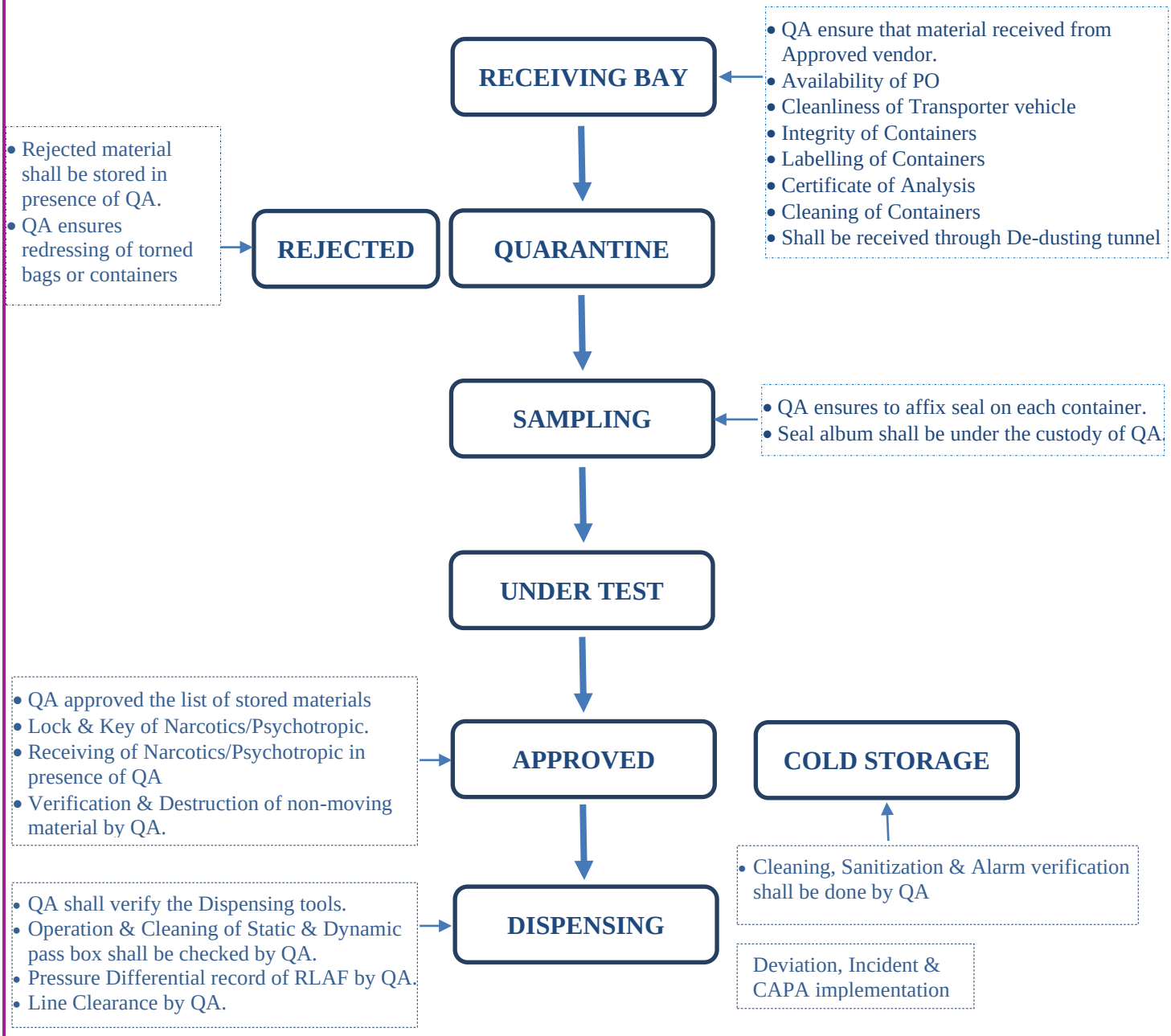
ROLE OF QA IN WAREHOUSE



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ROLE OF QA IN GRANULATION

LINE CLEARANCE

- SFM Challenge test
- Line Clearance of Area & Equipment by QA

MATERIAL VERIFICATION

- Verification of Active material calculation
- Weight Verification & Label Verification
- Intimation regarding material Spillage
- Rinse & Swab Sampling

LOG BOOK VERIFICATION

- QA ensure usage of Data logger
- Verification of Logbook – Machine Utilization, Cleaning, Environmental monitoring, Balance Verification
- Verification of Logbook: Sieve/Screen/FBD bag issuance & retrieval
- Implementation of Glass Breakdown Policy

IPQA

- Moisture Content Verification
- Critical Quality Parameters & Critical Quality Attributes Verification

SAMPLE PREPARATION

- Initiation of Deviation & Incident
- Verification of Sieve & Screen Integrity along with Destruction record.
- Bulk Sampling
- Verification of Sampling Tools for Cleanliness

BMR REVIEW

- BMR Verification along with Deviation, Incident & CAPA implementation

ROLE OF QA IN COMPRESSION

LINE CLEARANCE

- Recoveries supervision under QA
- Line Clearance of Area & Equipment

LOG BOOK VERIFICATION

- In & Out of Batches
- Machine Utilization, Cleaning, Environmental Monitoring & Balance Verification

IPQA

- Tablet defect verification like Foreign particles, Capping, Cracking, Broken, Picking, Non-Uniformity of Color, Sticking, Mottling, Lamination, Chipping, Splitting in layer & Tablet roughness
- Online Verification of IPQA parameters like Average Weight, Weight Variation, Dimension, Disintegration time, Hardness, Friability.
- Punches Inspection, Destruction & Issuance record verification by QA

SAMPLE PREPARATION

- Swab & Rinse Sampling & Analysis
- Sampling of tablets for IPQA parameters
- Issuance & destruction of FBD bags in presence of QA

BMR REVIEW

- Metal Detector challenge test verification
- Online Process Verification of Critical Control Parameters & Critical Quality Attributes, Deviation, Incident & CAPA implementation

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ROLE OF QA IN COATING

Silicon Tube issuance& Destruction record Verification by QA	**LINE CLEARANCE**	Line Clearance of Area & Equipments
Log book for Machine Utilization, Cleaning, Environmental Monitoring, & Balance Verification	**LOG BOOK 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	**IPQA**	Online Verification of Different parameters like Pre-Warming, Pan RPM, Spray rate, Peristaltic pump speed, % weight gain, Inlet & Outlet temperature Bed Temperature
Swab & Rinse Sampling analysis	**SAMPLE PREPARATION**	Bulk Sample preparation & Analysis by QC
	BMR REVIEW	Online Verification of Critical Quality Parameters & Critical Quality Attributes

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ROLE OF QA IN HARDGEL

LINE CLEARANCE

Line Clearance of Area & Equipments

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

Rinse & Swab Sampling analysis

IPQA

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

SAMPLE PREPARATION

Bulk sample preparation

Online Verification of Critical Quality Parameters & Critical Quality Attributes

BMR REVIEW

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ROLE OF QA IN SOFTGEL

LINE CLEARANCE

Line Clearance of Area & Equipments

- 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 Parameters during Encapsulation

IPQA

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

Rinse & Swab Sample Analysis

SAMPLE PREPARATION

Bulk Sample Preparation

BMR REVIEW

Online Verification of Critical Control Parameters & Critical Quality Attributes

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8. 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.	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.	As per SOP No.: HWH/001 Material containers received with non-compliances are kept in awaiting GRN area. 
• In any case if the material received with any non-compliance, then the same shall be kept in "awaiting GRN" area.	Rejected Materials if not kept in lock & key may got intermixed with the good material.	Awaiting GRN materials are kept in color coded area (Blue Color Lining) and surrounded by rope.
• **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.	High value materials, Narcotic/Psychotropic are kept under the supervision of IPQA personnel, lock & key is provided to avoid any misuse.	For rejected material, the area is dedicated with lock & key with the Red color flooring. 
• 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.		The custody of lock & key is along with QA.
• Whenever any Narcotic material is received from the supplier, the consignment shall be		

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
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.	Chance of intermixing is there in-case seal is not maintained within lock & key.	
• **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 materials may have got expired if not verified and the there may be space constraint or over loading.	Seals are kept under lock & key under the custody of 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.	There may be the chance that the dispensing tools are not handled properly or of no use over a period of time.	Periodically review process is in place under the supervision of QA.
• **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.	Dirty pass box may result into Contamination & Cross Contamination.	Periodic Verification is done by QA.
• **Static Pass Box & Dynamic Pass Box:** Operation & Cleaning of Static & Dynamic Pass Box shall be checked by QA.	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.	Every time before Operation, the pass boxes are verified by QA for its cleanliness.
• **Cold Chamber:** Cold Chamber Cleaning & Sanitization along	Fluctuation of Pressure Differential may result into contamination, cross contamination & area failure.	Regular monitoring schedule is in place for verification of Cleaning, Sanitization & Alarm related to temperature fluctuation.
	Destruction & Spillage of material verification is done in presence of	

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
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. Improper line clearance can lead to Contamination, Cross Contamination & Mix ups.	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.	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	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.

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
• Manufacturing chemist weighs each and every ingredient in presence of QA personnel before taking it for manufacturing and shall be recorded in relevant document.	place if not properly verified.	
• Verification of logbook (176 Nos.)-Machine utilization &Cleaning, Environmental Monitoring, Balance Verification.	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.	As per SOP, verification of all processing activities shall be done online by QA personnel.
• SFM Challenge test verification	Leakage during rupturing of FBD bag may not be noticed.	Solid Flow Meter challenge test is being performed on daily basis before the start of the activity.
• Online verification of Critical Control parameters & Critical Quality Attributes.	Deviation may take place in case CCP & CQA not verified online.	As per the BMR, all process parameters & attributes are verified online by QA.
• Online filling of BMR.	Online data may not be filled resulting into Data Integrity.	Provision of online filling of data is in place by QA.
• Sampling of Bulk Samples.	Timely bulk sampling not done, may result into delay of batch release for further processing activity.	Sampling process is in place.
• Moisture Content Verification.	Will impact the Critical Quality Attributes of the Compressed Tablets.	Verification BY QA is the part of BMR.
• Weight Verification of Blended Granules.	Any loss in granules quantity will not be tracked, if not noted.	Verification by QA is the part of BMR.
• Log book entries FBD Bag/Screen Issuance & Retrieval.	Ruptured FBD bags used for Drying may result into loss of dried granules.	FBD bag verification by QA is the part of SOP.
• Material Spillage verification by QA.	Spilled granules may be used for manufacturing activity.	SOP of Spilled material is in place.
	Online Incident or Deviation may not be initiated or recorded.	SOP is in place for recording of online Incident s & deviations.
	Temperature fluctuation may not be recorded.	Temperature verification is the part of BMR.

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• Online Incidents & Deviations.	Mix ups may take place in case of improper verification.	Verification of Intermediates is a part of SOP.
• 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.	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.	Verification of Sieve & Screen size by QA is a part of SOP.
• Operating production person shall check the integrity of the Sieve/Screen and verify by QA before and after use & record in respective BMR	Foreign particles observation not recorded and neither communicated to vendor for the same resulting into repetition of same observation.	SOP is in place for the recording of any incident or deviation observed during sifting.
• 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.	Recoveries may be mix up with other granules, resulting into product failure.	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.
• 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	Contamination and Cross Contamination may take place in case of dirty filter bags, rejected filter bags may be used.	SOP is in place for the Issuance &rejection of Filter bags.

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
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.		
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	Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.	Line Clearance is a part of SOP & BMR.

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
the BMR checklist.	Residue of previous batch transferred to the next batch.	Rinse & Swab Sampling is a part of SOP & BMR.
• Rinse or Swab samples shall be send on daily basis as per the requirement.	Deviation in Critical Quality Parameters may result into deviation in Critical Quality Attributes.	Online process verification is a part of BMR.
• 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.	Deviation in Critical Quality Attributes may result into product failure and Market Complaint.	Online verification of Critical Quality Attributes by IPQA.
• Verification of In-process parameter after coating thickness, D.T., Description of tablets, Uniformity of tablets, Group weight verification of tablets.	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.	As per SOP, verification of all processing activities shall be done online by QA personnel.
• Coating logbook (87 Nos.) - Machine Utilization &Cleaning, Environmental Monitoring, Balance Verification. Logbook (12 Nos.) - In & out of batches& Balance Verification.	Contamination & Cross Contamination through Silicone tubes may takes place.	SOP is in place for Issuance, Rejection & Destruction of Silicone tubes in presence of QA.
• Issuance, Rejection & Destruction of Silicone tubes in presence of QA.		
HARDGEL		
• Line Clearance of Area & equipment	Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.	Line Clearance is a part of SOP & BMR.
• Checking of different parameter during Capsule filling	Deviation in Critical Quality Parameters & Critical Quality Attributes may result into product failure.	Online Verification is a part of BMR.
• Logbook (21 Nos.) - Machine utilization & cleaning, Environmental monitoring,	Online Verification of several activities like Coating start time, end time, Equipment Cleaning start time, end time, Temperature/RH	As per SOP, verification of all processing activities shall be done online by QA personnel.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:** …….

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Balance verification, Polishing, Metal detector • Logbook (01 No.) - In & out of batches • Logbook (01 No.) - Issuance &Retrieval of change part • Rinse & Swab Verification.	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.	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		

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:** …….

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
• Line Clearance of Area &Equipment	Contamination, Cross Contamination & Mix ups may take place in case of improper line clearance.	Line Clearance is a part of SOP & BMR.
• Verification of different parameter during medicament, gelatin, drying, Encapsulation& Polishing	Deviation in Critical Quality Parameters & Critical Quality Attributes may result into product failure.	Online Verification is a part of BMR.
• Logbook (35 Nos.) - Machine Utilization & cleaning, Environmental monitoring, Balance verification, waste water, Drying	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.	As per SOP, verification of all processing activities shall be done online by QA personnel.
• Logbook (01 No.) - In & out of batches	There may be the chance of batches mix ups, if not traceable for in & out entry.	In & Out of batches verification is a part of SOP.
• Logbook (01 No.) - Issuance & retrieval of change part.	Change part mix ups may take place resulting into wrong filling.	Verification of Change parts by QA is in place.
• Drying Period of Product, Verified by QA.	Improper Drying may result into Capsule leakage.	Verification of Drying is the part of BMR.
• Rinse & Swab verification.	Contamination of previous product residue.	Rinse & Swab Verification is a part of SOP & BMR.

QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]	
Reference Document No.: Role and Responsibility of QA	**Risk Assessment No.:** …….

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.

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
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	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	3	1	1	3 **Severity:** Severity is high in case of Line Clearance failure **Occurrence:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
			dispensed or product mix up.			Clearance in Oral Solid Dosage, External Preparation and Oral Liquid"				Chance of Occurrence is less as Line Clearance procedure is in place **Detectability:** Can be detected easily					
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	SOP No.: "Calculation of Active	3	2	1	6 **Severity:** Wrong	NA	NA	NA	NA	NA

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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)
					of Calculation of Active Ingredient for Material Issuance of Batches is in place	Ingredient for Material Issuance of Batches"				calculation can lead to wrong quantity dispensing **Occurrence:** Chance of wrong calculation is possible **Detectability:** Can be easily detected during verification.					
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	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										Detectability: Can be easily detected during verification visually					
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/	SOP No.: Destruction of Rejected/Expired/Non Moving / Spillage	3	1	1	3 **Severity:** Severity of expired material or rejected material is	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
					Spillage Materials	Materials				always high. **Occurrence:** Chance of Occurrence is not possible as verification process is in place **Detectability:** Can be easily detected					
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:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										an be easily detected					
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	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										to contamination **Occurrence:** Chance of Occurrence is possible **Detectability:** Can be easily detected					
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	Reconciliation of Material	Mix up may takes place	Record not maintained	Procedure for maintaining	SOP No.: "Procedure	3	2	1	6 **Severity:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
	by QA & Rejected by QA	Seal not maintained			of reconciliation of seal available	for Maintaining Manufacturer Seal Album & Resealing of API"				Mix ups may lead to severity **Occurrence:** Chance of failure is possible **Detectability:**C an be easily detected.					
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	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										Detectability: an be easily detected.					
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 o 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	3	2	1	6 **Severity:** Contaminatio n can lead to dispensing failure **Occurrence:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
						Tools, Verified by QA".				Chance of Occurrence is possible **Detectability:**C an be easily detected, if verified properly					
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	Calibration not done or malfunctioni ng of	Classified area of Dispensing got disturbed	Verification not done by QA	Procedure of Verification of Differential	SOP No.: "Operation and Cleaning of Dynamic	3	2	1	6 **Severity:** Severity is high in case	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
	Frequency: Before and after Operation	Pressure Gauge			Pressure is in place Calibration available	Pass Boxes"				of Pressure Differential failure **Occurrence:** Chance of Occurrence is possible **Detectability:** Can be easily detected					
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	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:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
			material degradation							Can be easily detected as log books are filled for tracking.					
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 an Cleaning of Reverse Laminar Air Flow Unit"	3	1	1	3 **Severity:** Failure in Pressure Differential car 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

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
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:** C an 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:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										Can be easily detected through log book					
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	Weighing Balance not calibrated Pressure Gauges are	Wrong material weighment verification Wrong Pressure	Verification procedure by QA not in place	Procedure for Verification by QA is in place	SOP No.: "Line Clearance in Oral Solid Dosage,	3	1	1	3 **Severity:** Severity can be high in case of	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
	pass box shall be verified by warehouse and IPQA personnel.	malfunctioned Pre-filter, Fine filter are contaminated Dynamic & Static Pass Box are dirty	Differential monitoring Contamination & Cross Contamination			External Preparation and Oral Liquid"				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.					
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	3	1	1	3 **Severity:** Severity is high in case of Line Clearance failure	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
						and Oral Liquid"				**Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place **Detectability:** Can be detected easily					
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

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
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	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
										possible **Detectability:** Can be easily detected					
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	Record not maintained	Contamination & Cross	Ruptured Sieves/Screens	Procedure of Verification	SOP No.: "Handling of	3	2	1	6 **Severity:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
	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	Ruptured Sieve/Screen issued for sifting Ruptured Sieves & Screens used for manufacturing	Contamination	of FBD Bags may result into contamination & Cross Contamination	of Sieve & Screen is in place	Sieves and Screens"				Improper Verificationof Sieve, Screen & FBD bags can lead to Contamination & Cross Contamination **Occurrence:** Chance of Occurrence is possible **Detectability:** Might detect failure					
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:**	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										Can be easily detectable					
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:**	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
										Chance of Occurrence is possible **Detectability:** Can be easily detected.					
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	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

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
	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/														

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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)
	Executive QA to verify the corrective action. After release by QA start the processing.														
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 Practice 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	NA	NA	NA	NA	NA

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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)
										Occurrence is possible **Detectability:** Can be easily detected					
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	Product integrity got affected along with Contamination & Cross	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	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
		maintenance, Qualification Status of the equipment not verified by QA	Contamination							or calibrated **Occurrence:** Severity is high, quantity not compensated can lead to assay failure. **Detectability:** Can be easily detected.					
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

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												S	O	D	RPN (SxOxD)
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 particle 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	SOP No.: "Line Clearance in Oral Solid Dosage,	3	1	1	3 **Severity:** Severity is high in case of Line	NA				

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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)
					place	External Preparation and Oral Liquid"				Clearance failure **Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place **Detectability:** Can be detected easily					
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	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
										detected as log books are filled online					
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	Parameters out of specification Tablet defects not	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.	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
	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	verified								**Occurrence:** Chance of Occurrence is possible **Detectability:** an be easily detected					

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												S	O	D	RPN (SxOxD)
	tablet Surface roughness.														
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	Swab sample not collected Dedicated filter bags bot 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:**	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
	personnel. Reject the bag in the presence of Production and QA	Rejected Filter Bags used								Chance of Occurrence is possible **Detectability:** Can be easily detected by analysis					
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	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
										book					
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	3	1	1	3 **Severity:** Severity is high in case of Line Clearance failure	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
						and Oral Liquid"				**Occurrence:** Chance of Occurrence is less as Line Clearance procedure is in place **Detectability:** Can be detected easily					
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	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
										detected					
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:** C an 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:**	NA	NA	NA	NA	NA
57.	Coating Logbook (87 Nos.) - Machine utilization & cleaning, Environmental														

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												S	O	D	RPN (SxOxD)
	monitoring, Balance verification									Chance of Occurrence is there **Detectability:** Can be easily detected as log books are filled online					
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:** C an be easily detected visually	NA	NA	NA	NA	NA

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												S	O	D	RPN (SxOxD)
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:** C an 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.	NA	NA	NA	NA	NA

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
										Occurrence: Chance of Occurrence is possible **Detectability:** C an be easily detected					
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	Contamination & Cross	Dirty equipments	Verification of Rinse &	SOP No.: "Procedure for	3	1	1	3 **Severity:**	NA	NA	NA	NA	NA

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
		sampling fails in results	Contamination		Swab Sampling is in place	Sampling and Testing of Swab/Rinse Water for Chemical and Assignment of A.R. No. to Received Sample"				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.					
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	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.	NA	NA	NA	NA	NA

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
			observed							**Occurrence:** Chance of Occurrence is possible **Detectability:** C an be easily detected					
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

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
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	Product Failure & Market Complaint	Online verification not done by QA	Procedure of Verification of online Critical Quality	Procedure of Verification of Quality Attributes by QA is in place	3	2	1	6 **Severity:** Severity is high, if process	NA	NA	NA	NA	NA

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
69.	Checking of different parameter during Encapsulation	Attributes not verified			Attributes by QA is in place					parameters not verified online. **Occurrence:** Chance of Occurrence is possible **Detectability:** Can be easily detected					
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	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											

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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)
73.	Logbook (01 No.) - Issuance & retrieval of change part	Wrong Change part issued	Wrong product manufactured with different specification	Verification by QA not done						log books are filled online					
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:

Severity Effect	Likelihood Occurrence	Likelihood of Detection	Rating
No Effect	Unlikely	Always Detected	1

Evaluation of RPN:

RPN Rating	Category
12 to 27	High

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Reference Document No.: Role and Responsibility of QA | **Risk Assessment No.:**

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

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA (QAH/001) | **Risk Assessment No.:** QRA/H/23/0003

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.		

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA (QAH/001) | **Risk Assessment No.:** QRA/H/23/0003

S.No.	Recommended Action	Responsible Person	Target Date of Completion
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.		

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA (QAH/001) | **Risk Assessment No.:** QRA/H/23/0003

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			

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Reference Document No.: Role and Responsibility of QA (QAH/001) | **Risk Assessment No.:** QRA/H/23/0003

Verification of Recommended Action:

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Remarks (if any):

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Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

9. CONCLUSION:……………………………………………………………………………………………

10. REFERENCES:

- Reference SOP of Risk Assessment (QAH/126).
- Related SOP's.

11. DOCUMENTS TO BE ATTACHED:

- Training Record.

12. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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13. CHANGE CONTROL, IF ANY:

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14. 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

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FAILURE MODE EFFECT ANALYSIS FOR THE ROLE & RESPONSIBILITY OF QA [DISPENSING TO COATING (D_2C)]

Reference Document No.: Role and Responsibility of QA (QAH/001)	**Risk Assessment No.:** QRA/H/23/0003

15. 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)			