



MICRO LABS LIMITED,

RISK IDENTIFICATION AND EVALUATION RECORD

Risk Assessment No.:	
Area / Activity / Operation:	

1.0 Risk Identification and Evaluation considering Current Control Measures:

2.0 Conclusion

P: Probability, S: Severity, D: Detectability, RPN: Risk Priority Number

1. # For risk evaluation at the initial stage (raw risk), detectability is low or very low (depending on the risk being evaluated). Therefore, this score should be 4 or 5
 2. \$The Severity remains the same for risk evaluation, therefore should be taken from risk analysis section for calculating RPN.
 3. * Write the name and location of the manufacturing site.
 4. @ For RPN above 20 additional control measures are mandatory. For RPN less than 20, the additional control measures might be suggested to reduce the RPN further.
 5. While execution the form can be split into two if required for ease of execution.

QAP/MLCM/0043/FMT/0001-012

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MICRO LABS LIMITED, _____*

RISK IDENTIFICATION AND EVALUATION RECORD

3.0 Compilation and Review :

Signatories	Compiled By (Originating Department)	Risk Assessment Team					
		My signature below implies that, I have evaluated the risks, its analysis, control measures and confirm that they are in agreement with the brain storming discussion. These are deemed to reduce the risk with in the acceptable limit.					
Name							
Title							
Sign / Date							

4.0 Review comments and approval by Unit head

Name:	
Title:	
Sign / Date:	

5.0 Review comments and approval by Head QA

Name:	
Title:	
Sign / Date:	

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MICRO LABS LIMITED, _____*

QUALITY RISK ASSESSMENT REGISTER

Sl. No.	Date	Risk Assessment No.	Originating Dept.	Brief Description of the Risk System / Operation / Area	Type of Risk Assessment Proactive/ Reactive/As per Annual planner/ Periodic review	Sign / Date (QA / CQA)	Closure Date		Defined periodic review frequency	Sign / Date (QA/ CQA)
							Initial Risk Assessment	Final Closure		

* Write the name and location of the manufacturing site.

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MICRO LABS LIMITED, _____*

ANNUAL RISK ASSESSMENT PLANNER

Planner No.:	Addendum No.: (Where applicable)
Effective Date:	Superseded No.: Dated:

Sl.No.	Area of Risk Assessment	Responsibility (Name of the Department)	Tentative Month	Risk Assessment Number	Closure Date		Sign / Date (QA)
					Initial Risk Assessment	Final Closure	

	Prepared By: QA	Approved By: Head of Site QA
Name:		
Title:		
Sign / Date:		

* Write the name and location of the manufacturing site.

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QUALITY RISK ASSESSMENT INITIATION FORM

From Originating Department:	To:	Quality Assurance
Area / Activity / Operation:	Date:	
Type of Risk assessment	Proactive / Reactive / Periodic / Annual Risk Assessment Planner	
Reference Document No. (If any):		

1.0 Brief Description of the Risk Area / Activity / Operation:

2.0 Purpose:

3.0 Scope:

Originator:	Sign:	Date:
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* Write the name and location of the manufacturing site.



QUALITY RISK ASSESSMENT INITIATION FORM

4.0 Documents to be Considered During Risk Assessment:	
Sl. No.	Document Title

Document Title

Dept. Head:

Sign/Date:

Approval Status:

Approved / Not approved

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Risk Assessmen

/ Date)

* Write the name and location of the manufacturing site

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MICRO LABS LIMITED, _____*

RE EVALUATION OF RISK AFTER IMPLEMENTING THE ADDITIONAL RISK CONTROL MEASURES

Risk Assessment No.:		Date of Initiation:	
Area / Activity / Operation:			

Sl. No	Process Step	Failure/ Risk/ Hazard	Additional Control Measures	QMS Document Reference No. (if any)	Date of Implementation	Re-Evaluation of the Risk					Risk Acceptable? (Yes / No)	Evaluation Done by (Originating Department Head / Designee)	Approved by (Head QA)	
						Probability of the occurrence	Probability Score (P)	Severity (S) #	Detectability (D)	Detectability Score (D)	RPN (PxSxD)			

P: Probability, S: Severity, D: Detectability, RPN: Risk Priority Number

* Write the name and location of the manufacturing site.

Take severity score from the risk analysis section in the initial risk assessment.

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BRAIN STORMING SESSION/ MEETING SCHEDULE

3.0 Comments by Risk Assessment Team:

3.0 Comments by Risk Assessment Team:	
Risk related to	Risk Identified
<input type="checkbox"/> Production	
<input type="checkbox"/> Packing	Sign/Date:
<input type="checkbox"/> QA	Sign/Date:
<input type="checkbox"/> Stores	Sign/Date:
	Sign/Date: <i>Un Controlled Copy</i>

* Write the name and location of the manufacturing site

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BRAIN STORMING SESSION/ MEETING SCHEDULE

3.0 Comments by Risk Assessment Team (Continued...)

Risk related to	Risk Identified
<input type="checkbox"/> Engineering	
	Sign/Date:
<input type="checkbox"/> QC	
	Sign/Date:
<input type="checkbox"/> Safety	
	Sign/Date:
<input type="checkbox"/> Human Resource	
	Sign/Date:

* Write the name and location of the manufacturing site

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BRAIN STORMING SESSION/ MEETING SCHEDULE

3.0 Comments by Risk Assessment Team (Continued...)

Risk related to	Risk Identified
<input type="checkbox"/> Technology Transfer	

<input type="checkbox"/> Information Technology	Sign/Date:
<input type="checkbox"/> Others	Sign/Date:

4.0 Actions proposed for reduction/mitigation of risk based on brain storming session (if any)

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Originating Department: Sign/Date: Reviewed By: Site QA/CQA

* Write the name and location of the manufacturing site

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SME CERTIFICATE

It is here by certified that Mr. / Ms. _____ of

_____ Department has appropriate knowledge, skill, experience and training.

Based on the training, Mr. / Ms. _____

is qualified as a Subject

Matter Expert (SME) to perform Quality Risk Assessment.

Date of Training: _____

Certified By: (Head of QA / CQA[#])

Name :

Title:

Sign/Date

- Strike-off whichever is not applicable

* Write the name and location of the Manufacturing Site.

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Risk Assessment No.:	Date of Initiation:
Type of Risk Assessment:	As per Annual Risk Assessment Planner / Reactive/Proactive / Periodic Review
Area / Activity / Operation:	

Originating Department:**1.0 Brief Description of the Risk Area / Activity / Operation:**

2.0 Details of risk / risks identified			
Total No of risks identified	No of risks with RPN 0-20	No of risks with RPN 21-60	No of risks with RPN 61-125

3.0 All identified additional control measures implemented? Yes/ No / No actions Recommended**Final date of implementation:** _____**4.0 After implementation of additional control measures, have the identified risks mitigated? Yes / No / NA****If No. additional risk assessment No. _____****5.0 Periodic review assessment**

Is periodic review required for any risk: Yes / No

If yes,

Review frequency:

If No,

Justification:



MICRO LABS LIMITED, _____ *

RISK ASSESSMENT SUMMARY

6.0 Conclusive comments (Originating Department Head) :#

Name:	Title:	Sign / Date:
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7.0 Approval Comments (Head QA):#

Name:	Title:	Sign / Date:
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Before providing the conclusive comments and approval the respective signatories should review the implementation of control measures

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LIST OF IDENTIFIED SME'S FOR RISK ASSESSMENT

MICRO LABS LIMITED,

Document No.: LISME: YYY	Addendum No.: (Where Applicable)
Effective Date:	Superseded No.: Dated

* Write the name and location of the manufacturing site

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PERIODIC REVIEW OF RISK ASSESSMENT

MICRO LABS LIMITED, _____ *						
Review frequency:						
Periodic Risk assessment number:						
1.0 Brief Description of the Risk Area / Activity / Operation:						
2.0 Periodic assessment						
2.1 Evaluation of Existing risks and control measures						
Verification of control measures for effectiveness						
Failure Mode/ Risk / Hazard	Control Measures	Name of the document / Document number	Section No.	Verification Details	Any non- conformanc es reported	Additional measures recommended (if any)
2.2 Evaluation of additional risks introduced during the review period						
Risk Identification						
Process Step	Failure/ Risk/ Hazard	Potential Cause(s) of failure				

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PERIODIC REVIEW OF RISK ASSESSMENT

3.0 Summary of assessment :

Signatories	Originating Department	Periodic Assessment Team
Name		
Title		
Sign / Date		

4.0 Conclusive comments (Originating Department Head) :

- A. The current control measures continue to be effective: Yes / No
- B. Any new risk identified: Yes / No
- C. If the answer to A is 'No' and/or B is 'Yes', addendum risk assessment No.: _____

My signature below implies that, I have evaluated the current control measures, their effectiveness and assessment of new risks identified by verifying all relevant documentation.

Name:	Title:	Sign / Date:

5.0 Approval Comments (Head QA) :

My signature below implies that, I have verified the evaluation of the current control measures, their effectiveness & assessment of new risks and approves the periodic evaluation.

Name:	Title:	Sign / Date:

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ACTION PLAN FOR THE RISK WITH RPN 60 AND ABOVE *

MICRO LABS LIMITED,	
Risk Assessment No.:	
Originating department :	
Date of risk identified :	
Process Step No. :	
Annexure No.:	
1.0 Brief Description of the identified risk / Hazard/failure	
2.0 RPN -	
3.0 Impact on Product Quality	
4.0 Details of Immediate actions implemented	
Originating department Head Signature / Date	
Site QA Head Signature / Date	
Review & Approval by	
Unit Head Signature / Date	Site QA Head Signature / Date



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

- **Quality System:** Review of procedures with respect to current GMP, change management, Training, Master Documents, Batch Records, Validation / Validation review, QA system, QA release, Document storage / Retrieval / Destruction.
 - **Facility and Equipment System:** Review of procedures with respect to General, Calibration, Equipment, Lubrication / Gasket / Seals, AHU, Water System, Compressed Air System, Steam System, Planned Preventive Maintenance, Building Maintenance, Pest Control, Contamination Control and Waste Control.
 - **Production System:** Review of procedures with respect to Cleaning and Disinfection, Processing area, Washing Area, Equipments, Line Clearance, Product Processing, Documentation, Tablets, Capsules, Liquid orals, ophthalmic and liquid Injections, Health and Hygiene.
 - **Laboratory Controls System:** Review of procedures with respect to General, Sampling, Calibration, Chemicals, Raw material / Packing Material / Finished product analysis, instrumentation, Out of Specification and Stability studies.
 - **Microbiology Section:** General, Water Analysis, Environmental Monitoring, Validations, retention of Samples, Destruction of samples and Laboratory safety.
 - **Materials System:** Review of procedures with respect to Procurement, Receipt, Storage of quarantine / Approved Materials in stores, retesting, handling and storage of Printed Packing materials, handling of rejects, Material Dispensing and handling of excess returns of packing materials.
 - **Packaging and Labeling:** Review of procedures with respect to Stereo Control and Coding.
- The above list is further simplified to individual operations or activities and check points in terms of questions are indicated below. These checkpoints are not exhaustive and help only to initiate the risk assessment process. The risk management team shall consider further checkpoints during review of each operation or activity based on experience, non-conformities observed and audit / inspection reports.
- During each checkpoint the potential consequences and likelihood should be assessed.



MICRO LABS LIMITED, BANGALORE

No.: QAP/MLCM/0043/ANX/001-007

LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
Quality System:	
Management	
1.	Is current version of Organogram available and is it reviewed annually?
2.	Is responsibility of all key personnel in the site defined and reviewed annually?
3.	Is Quality Policy of the site displayed and communicated to all employees?
4.	Is Continuous Quality Improvement plan for year available with action plan and responsibility?
Training	
5.	Is there a training procedure with schedule and list of trainers? Is the schedule followed religiously?
6.	Whether training needs for the year prepared and available for all employees?
7.	Whether training is provided to employees as per training needs and schedule?
8.	Whether employees are given induction training at the time of joining and reports available?
9.	Whether employees are given Specific on Job training and reports available? Is procedural training where revisions occur imparted to relevant personnel?
10.	Whether Job description for all categories of employees prepared and available and is Job description reviewed annually for all category of employees?
11.	Whether current Job description provided to all the employees?
12.	Whether employees are given routine refresher training like cGMP as per frequency and reported?
13.	Whether employees are trained after a change in job and documented?
14.	Whether the employees are assessed for awareness and competency?
15.	Whether external training like HR/ Safety training provided to all the employees and documented?
SOPs	
16.	Is SOP for SOP available and followed?
17.	Is approved current master SOP index available?
18.	Is copy of SOP distribution controlled by QA?
19.	Is obsolete SOP retrieval carried out promptly by QA and are obsolete master copies maintained and stored properly?
20.	Are SOPs reviewed before review date (is any SOP found displayed after review date)?

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LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
Master Documents	
21.	Is approved license available to manufacture the product with validity?
Sl. No.	Parameters to be Checked
22.	Is Approved site master plan available and updated?
23.	Is Approved Master validation plan available and updated?
24.	Is current Approved Site Quality Plan available and followed?
25.	Is current version of Approved product master formula record available for all products and followed?
Batch Records	
26.	Are all batch records prepared with reference to MFR's and MFR reference No. mentioned in all batch records?
27.	Are all batch records issue controlled by QA?
28.	Are all issue of batch sterels approved and controlled by QA?
29.	Are master formula record and site batch record (BMR / BPR) similar / identical when it is cross checked and verified?
Validation / Validation Review	
30.	Is Site facility construction / area qualification carriedout and protocol / reports available?
31.	Is product process validation carried out for all products and are compiled reports available?
32.	Cleaning validation carriedout for cleaning procedure (Dosage form wise)?
33.	Is RO life of the product bulk / blend storage period validated and reports available?
34.	Is facility validation review carried out and reported?
35.	Is product process validation review carried out for all products and reported?
36.	Is Cleaning validation review carried out and reported?
37.	Is Equipment validation review carried out and reported?
QA System	
38.	Is QA in-process control in place for checks on all critical quality parameters of all products?
39.	Is in-process control parameters trended and reviewed (Any action taken based on trend analysis for any product)?
40.	Is change control system followed for all change in process / facility / equipment and documents and are reports available?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
41.	Is change control register maintained and any change control raised in documentation reflected in Batch Record?
42.	Is deviation control system followed for deviations in product processing and are they investigated / CAPA taken / and same documented?
43.	Are all type of deviations trended and reviewed (Any CAPA taken based on trend analysis for any product)?
44.	Are product complaint compliance reports prepared, communicated to the client in time and the same reports available?
45.	Is product complaints communicated to the concerned in-house departmental personnel, investigated and CAPA taken to prevent the re-occurrence and is the same documented?
46.	Is Periodic Product review schedule prepared and available for all products?
47.	Is PPR carried out as per schedule and reports available as on date?
48.	Is current version of approved PQRA protocol available?
49.	Is PQRA carried out for all dosage forms and reported with risk score and CAPA raised with responsibility / target date?
QA Release	
50.	Is finished product release procedure followed? Are batch records / QC reports reviewed and review points compiled before product release (At any time observed that any product dispatched before QA release)?
Document Storage / Retrieval / Destruction	
51.	Is record room arranged with documents product wise, batch no. wise and year wise in an orderly manner? And are documents easily traceable (Check for traceability time required for one batch record manufactured in previous year)?
52.	Is record room for retention of documents provided with lock and key system with authorised entry and also pest control monitoring and free from fire hazards?
53.	Is documents retention period maintained for batch records, SOPs, audit schedules, specification and validation documents?
54.	Is expired documents destroyed after retention time and is the same documented?
Facilities and Equipment Systems:	
General	
55.	Is Approved site layout drawing for all the floors (men and material movement separately) available and updated? Is there an approved drawing with equipment locations?
56.	Are the engineering drawings version numbered / dated and controlled?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
57.	Is there proper lightening system for all sections and with adequate lux levels?
58.	Are doors of all critical operations in working condition and door discipline maintained?
59.	Is job order system with work permit for running (or) breakdown (or) preventive maintenance in place and is it followed and documented?
60.	Are there lists of critical spare parts for all equipments? Is the required stock of critical spare parts maintained ?
Calibration	
61.	Are master equipments / instruments list for calibration available?
62.	Is calibration carried out in-house or by an approved outside agency?
63.	Are calibration certificates available for calibrated equipments / instruments as on date with validity? Are the calibration standards traceable to national standards?
64.	Are adjustments done during calibration recorded? Are there procedures to handle out of calibration equipments?
Equipment	
65.	Are Equipments master list available for all departments?
66.	Are Equipments contacts parts are tested for SS316?
67.	Are equipments / instruments routinely calibrated as per schedule and reports available?
68.	Are equipments qualified for Design, Installation, Operation and Performance (DQ, IQ, OQ and PQ)?
69.	Is change control system in place for change in critical equipment (or) change in location of processing (or) change in the preventive maintenance schedule etc.?
70.	Is critical spare parts list available for critical equipments and is it stored and labeled properly (equipment wise)?
71.	Is break down maintenance for critical equipments trended and reviewed annually and is it reported with CAPA?
72.	Is validated status of equipments maintained?
73.	Are equipments free from noise and noise level is within the noise control limits?
Lubricants / Gaskets / Seals	
74.	Is approved specification for food grade lubricants available and is it purchased as per approved specification and controlled on receipt? Is MSDS available for food grade lubricants?
75.	Is food-grade lubricant only used for servicing product contact parts of critical equipments?



MICRO LABS LIMITED, BANGALORE

No.: QAP/MLCM/0043/ANX/001-007

LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
76.	Are critical equipments Checked for any leakage of lubricants during processing and recorded?
77.	Is approved specification for food grade seals, gaskets, filters available for product contact parts and is it purchased from approved specification and controlled on receipt?
78.	Is usage of seals, gaskets and filters on product contact parts of the equipments controlled and documented?
79.	Are like to like replacements done for maintenance of equipments? Are all changes other than like to like handled through change control procedures?
AHU	
80.	Is AHU air intake area protected from pest, dust and any other contamination?
81.	Are all the Air Handling Units / Ventilation systems in service floor identified with Code no., Supplied to details and is master AHU list available?
82.	Are all AHUs and Ventilation systems validated and reported?
83.	Is AHU monitored for pressure differential of each department and adjusted as per limits if required on daily basis?
84.	Is magnehaulic gauge used for reading pressure differential calibrated and updated?
85.	Are AHU duct lines clean and free from any leakage?
86.	Are pre-filters of AHU units cleaned as per schedule and reports available and documented?
87.	Are return filters cleaned during product to product changeover and documented?
88.	Is point exhaust system available for product dust generating equipments and is the same dust collected in dust collectors?
89.	Are the filters of dust collector cleaned routinely and documented?
90.	Are the AHUs / Ventilation systems routinely validated? Does the schedule in line with current ISO guidelines?
Water System	
91.	Is main water storage tank supplying feed water to Purified water plant cleaned as per schedule and documented (is any physical / microbial contamination observed)?
92.	Are conductivity reading instruments used in Purified Water plant calibrated and due date is within the validity period?
93.	Is the purified water line identified with label and indicated with flow directions?
94.	Is Purified water system validated and documented?
95.	Are Water pipe lines and valves leak proof ?
96.	Is Purified water Plant / loop line system sanitized as per schedule and documented?

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LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
97.	Are water filters used in Purified Water plant cleaned / replaced as per schedule and documented?
98.	Are vent filters used in Purified water plant storage tank replaced as per schedule and documented?
99.	Is approved specification available for water / vent filters and is it purchased as per specification and controlled on receipt?
100.	Is integrity certification from supplier available for water / vent filters and verified on receipt?
101.	Is U.V Lamp unit used for disinfection of Purified Water supply replaced as per schedule / running hours and documented?
102.	Is Purified Water Plant regenerated regularly and documented?
103.	Is Preventive maintenance schedule available for Purified Water Plant and done / documented?
104.	Is conductivity and pH of the output Purified water monitored regularly and recorded?
Compressed Air System	
105.	Is the compressed air line color coded with identification label and indicated with flow directions?
106.	Is approved specification available for compressed air filters and is it purchased as per specification and controlled on receipt?
107.	Are filters available for filtration of compressed air moisture and oil contamination and filters replaced as per schedule and documented?
108.	Is integrity testing certificate from suppliers available for compressed air filters?
109.	For Sterile dosage forms, is compressed air or other gasses used filtered through 0.22 micron filter at point of use?
Steam System	
110.	Are any chemicals added to boiler infeed water?
111.	Is steam supplied to production area, Dry and filtered?
112.	Are Steam filters cleaned as per schedule and documented?
113.	Is boiler serviced as per preventive maintenance schedule and reports available?
114.	Is there a effective removal of condensate from steam distribution system to drain out the condensate online?
115.	Is steam condensate tested for microbial contamination and documented?
116.	In case of sterile dosage forms does the steam condensate meet WFI requirements? Is there a pure steam generator in place at site?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Planned Preventive Maintenance	
Sl. No.	Parameters to be Checked
117.	Is equipment's planned preventive maintenance calendar with schedule for the year available and followed?
118.	Is preventive maintenance carried out for all critical equipments and reports available?
119.	Are equipments given Annual Maintenance Schedule and are those equipments listed out?
120.	Is frequency of the preventive maintenance for equipments reviewed based on break downs frequency / continuous performance and changed through the change control system?
121.	Is preventive maintenance carried out for all equipments as per schedule (Is any equipment found not undergone preventive maintenance and running continuously)?
Building Maintenance	
122.	Is there a procedure for building maintenance? Has an assessment for the same done?
123.	Is building maintenance work carried out as per schedule and documented?
124.	Is <u>Non-routine work</u> to <u>return to routine work</u> procedure followed during building maintenance work and reported?
Pest Control	
125.	Is pest control site location map is available for pest control activities and pest control activity is done as per map?
126.	Is pest control programme schedule available and is pest control (Rodent control and disinfection) carried out as per the schedule and reported?
127.	Is pest control carried out outside the premises and away from critical operations? Are there agreements for pest control activities with the vendor?
128.	Is MSDS available for pest control chemicals and safety precautions taken during pest control activity?
129.	Is insecticidator (Pest-o-Flash light) located at men entry / material entry clean and working condition satisfactory and is record for the same maintained?
Contamination Control	
130.	Is facility design in line with current requirements of Schedule M and International regulatory requirements? Has an assessment been done for contamination threats from facility design?
131.	Are air supplies to manufacturing and packaging areas meet current requirements of ISO / EU Classification? Are there sufficient numbers of Air handling units for supply of required Quality of air?
132.	Is there any possibility of cross contamination with respect to Air handling system (For Ex. Contamination to adjacent area operations due to Usage of common AHUs and common corridors without air locks for manufacturing of different potent drugs)?
133.	Are there point exhaust systems for critical equipments?
134.	Is temperature and humidity controlled / monitored and reported for all critical manufacturing operations?
135.	Is pressure differential for critical manufacturing operations controlled / monitored and reported?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
136.	Is door discipline maintained and door closure system maintained for all areas?
137.	Has an assessment for possibilities of cross contamination from utilities like water, steam systems, compressed gasses carried out?
138.	Has an assessment for possibilities of cross contamination from men and material movement carried out?
139.	Are Canteen and toilet facilities cleaned and disinfected as per schedule and is there any possibility of contamination from these areas?
Waste Control	
140.	Are product waste and general waste identified, segregated and handled separately?
141.	Are product / general waste collected in polybags with status label?
142.	Is there a control over movements / handling of waste during transfer from processing area to disposal area?
143.	Is product waste stored under safe storage before disposal with status label?
144.	Is product waste disposed safely and documented?
145.	Is ETP handled safely and documented?
146.	Is hazardous waste from ETP collected, labeled and stored safely before disposal?
147.	Is hazardous waste disposed off promptly and is the same documented?
148.	Is microbial waste from QC Lab disposed off safely?
Building Security Measures	
149.	Is system in place to ensure that only authorized personnel enters into stores, manufacturing / packing, utility and laboratory areas?
150.	Is Security measures provided for doors and windows?
151.	Is Lockable security system in place for equipments locked after set-up and start up checks have been completed?
152.	Are the Keys of the critical areas controlled by the designated responsible supervisor on line during operation and stored in the security department when not in use?
153.	Are all the Computer systems and computerized equipments secured with password protection to prevent unauthorized use?
154.	Is there system to avoid the carrying of Cameras and cellular phones with picture-taking capabilities to manufacturing areas?
General Safety Measures	
155.	Is safety policy of the company displayed and followed?
156.	Are fire extinguishers available for all areas? Are all fire extinguishers coded and labeled?
157.	Are the fire extinguishers serviced and service tags available with due date for service?
158.	Are fire alarm systems available and working conditions satisfactory?
159.	Are emergency exit doors available for all the departments along with moving directions?
160.	Is emergency evacuation plan available with escape route directions?
161.	Is First Aid facility available for all the departments? Are first boxes available with required medicines.



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
162.	Are Safety procedures available for accidents and reporting?
163.	Are MSDS available for hazardous chemicals and followed?
164.	Are QC hazardous chemicals, toxic chemicals and hazardous gases handled and disposed safely.
Production System:	
Cleaning and Disinfection	
165.	Are current specifications available for cleaning agents and disinfectants?
166.	Are disinfectants controlled on receipt and checked against approved specification and Supplier COA verified before use?
167.	Is cleaning and disinfection schedule available for all critical operations?
168.	Is cleaning and disinfection carried out for all sections as per schedule? Is there a system of rotation of disinfectants? Has disinfectant validation done to assess the effectiveness?
169.	Are drains of manufacturing areas and purified water plant routinely disinfected and documented?
Processing Area (Production / Packing)	
170.	Is processing area maintained in line with current regulatory and GMP requirements?
171.	Are material / men movements procedure followed? Is it a unidirectional flow?
172.	Is working area restricted to authorize working personnel designated by supervisor?
173.	Are SOP's displayed for all operations at work place?
174.	Are temperature, humidity and pressure differential are monitored and recorded?
175.	Are the floor, area, sealing, light fixtures, doors and glass panels of each section of the department cleaned and maintained?
Washing Area	
176.	Is washing area of the department clean and supplied with required utility lines?
177.	Are utility lines like Raw water / DM water line, compressed air and steam line colour coded and labeled for identification?
178.	Are the equipments 'cleaned' and 'To be cleaned' segregated, labeled and stored properly?
179.	Is steam filter used for sanitation of equipments cleaned as per schedule and labelled?
180.	Are product waste and general waste bins provided and waste stored accordingly?
181.	Is washing area provided with input classified air equivalent to that of processing area?
Equipments	
182.	Are all Equipments coded? Is a master list of equipments with code numbers maintained?
183.	Are Equipments supplied with safety features? Are all Equipments earthed?
184.	Are Equipments of GMP model with product contact parts made up of SS 316?
185.	Are the electrical lines / wirings of all Equipments concealed and safe for operation?
186.	Are Equipments provided with safety doors (or) machine guards, emergency off switch etc.,?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
187.	Are all moving equipment parts guarded?
188.	Are the equipments operated and cleaned as per SOPs / Schedule?
189.	Are Equipments subjected to cleaning verification during product to product changeover?
190.	Are all Equipments in use labeled with the adequate status label? Are SOP's displayed for all equipment operations and cleaning at work place?
191.	Are all equipments maintained and used as per manufacturer's specifications?
192.	Are all equipments, indicators, gauzes assessed for requirement of calibration?
Line Clearance	
193.	Are line clearance procedures followed, checked and documented for product to product and batch to batch changeover?
194.	Is line clearance process challenged (Is line clearance challenge test carried out for all chemists section wise) and documented?
195.	Is the line clearance process reviewed when there is a change in new product / new equipment / new facility and any modification on the same etc.,?
196.	Is any engineering work or any other atypical occurrence recorded in the area / line clearance sheet of batch record?
197.	Is there any possibility of cross contamination for any section once after the line is certified by QA?
198.	Are line clearance activities entered, certified and documented in batch records?
Product Processing	
199.	Are all the operators working in the area follow personnel hygiene and hygienic operations by wearing personal protective apparels (any working personnel observed without hand gloves/ mask / proper uniform)?
200.	Are weighing balances used are calibrated and zero error checks done (any balance observed with out of calibration status (or) expired calibration due date)?
201.	Are status labels affixed for line status, equipment status, and material status and is it appropriate with signature and date?
202.	Is product processing carried out as per the Product Batch Record instructions and SOP's?
203.	Are in-process instruments calibrated and its working condition found satisfactory?
204.	Are in-process checks carried out as per schedule and readings are appropriate and within the specified limits?
205.	Whether the tamper proof system is available in manufacturing / packing of products to avoid any misuse (or) mischief?
206.	Any process deviations observed against batch record instructions / SOPs? Are they investigated and recorded ?
Documentation	
207.	Are batch record entries legible & factual?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
208.	Are logs of temperature, humidity, and pressure differential, and equipment, area recorded and updated?
209.	Are all maintenance and preventive maintenance logs entered and updated?
Tablets (Specific to Tablet Manufacturing Only)	
210.	Are sieves clean and integrity checks satisfactory?
211.	Are sieves labeled and stored properly?
212.	Are sieves inspection records entered and updated?
213.	Are FBD bags used are dedicated and clean?
214.	Are FBD bags labeled and stored properly?
215.	Are FBD bags cleaning record entered and updated?
216.	Are punches and dies clean and lubricated?
217.	Are punches and dies labeled and stored securely?
218.	Are punches and dies inspected regularly to check whether the mentioned quantity available, damaged if any and lubrication status etc? Are numbers of punches and dies mentioned in label / log matching physically when it is counted for all products?
219.	Are punches and dies history / inspection records entered and updated?
220.	Are product in-process containers labeled with relevant details and stored properly in the in-process room?
221.	Are product rejects for disposal segregated and labeled with relevant details?
222.	Are the product rejects for recovery if any segregated / labeled with relevant details and stored properly?
Capsules (Specific to Capsules Manufacturing Only)	
223.	Is humidity found within specified limits and recorded?
224.	Are sieves clean and integrity is satisfactory?
225.	Are sieves labeled and stored properly?
226.	Are sieves inspection records entered and updated?
227.	Are product in-process containers labeled with relevant details and stored properly in the in-process room?
228.	Are product rejects for disposal segregated and labeled with relevant details?
229.	Are the product rejects for recovery segregated / labeled with relevant details and stored properly?
Liquid Orals (Specific to Liquid Orals Manufacturing Only)	
230.	Is temperature of DM water used for washing of bottles maintained as specified in SOP?
231.	Are dedicated filter pads used for product filtration?
232.	Are filter press filters cleaned / labeled and stored properly?
233.	Are dedicated filter cartridges (1 ^u) used for product filtration?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
234.	Are filter cartridges cleaned / labelled and stored properly?
235.	Are SS pipelines used for transferring of product cleaned status?
236.	Are dedicated transfer tubes for transferring liquids used?
237.	Are product rejected solution for disposal segregated and labeled with relevant details?
238.	Are product waste and general waste bins provided and waste stored accordingly?
239.	Is Vent filter (Used for Nitrogen gas) usage log entered and updated?
240.	Is Product filter (1µ cartridge) cleaning record entered and updated?
241.	Is filter pads cleaning record of filter press entered and updated?
Ophthalmic and Liquid Injectables (Specific to their manufacturing Only)	
242.	Is online monitoring of TOC for WFI is maintained as specified in SOP?
243.	In chemical testing and BET for WFI is performed prior to manufacturing?
244.	Are dedicated filter cartridges used for product filtration?
245.	Are integrity tests of product cartridge filter carried out before and after filtration?
246.	Are load patterns for the sterilization cycle validate?
247.	Are in-process instruments such as pH meter, leak test apparatus and balances calibrated?
248.	Is Hold time for bulk solution established?
249.	Are interventions recorded adequately?
250.	Are the personnel entering aseptic area are trained and authorized?
251.	Is cleaning, sterilization and operation log maintained updated?
252.	Is nitrogen gas used during manufacturing, filling and storage filtered through sterilized 0.2µ filter?
Health:	
253.	Whether employees are subjected to Pre-employment medical checkup before appointment and reports available for all new recruits?
254.	Whether employees are subjected to medical checkup periodically thereafter and reports available for all employees (check for reports of current year)?
255.	Are there procedures in place for preventing personnel suffering from infectious diseases to core manufacturing areas and activities?
256.	Does penicillin sensitivity tests form a part of employee recruitment for sites manufacturing Beta Lactum formulations?
257.	Whether visual inspectors of packing line subjected to eye checkup at routine intervals and reports available (applicable for Injectable manufacturing facilities)?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
258.	Is First Aid facility provided to the working personnel and is they trained?
Hygiene:	
259.	Are there procedures for Personnel Hygiene and has sufficient training imparted?
260.	Is garment regime discipline (primary and secondary uniform) maintained by the working employees as per dosage forms manufactured and also criticality of operations?
261.	Whether the employees are provided with safety apparels like gloves, mask, goggles etc., for their specific job?
262.	Are employees checked and assessed for their work discipline (whether they follow SOP / Batch record instructions)?
263.	Whether the employee-to-employee (designation- wise) reporting procedure is followed?
Laboratory Control System:	
General	
264.	Is QC area (Instrumentation / Chemical / Microbiology) well maintained with cleanliness / proper closure of doors and free from wall / ceiling cracks, floor pits / damage and paint peel-off etc.,?
265.	Are cleaning records entered and updated?
Sampling	
266.	Whether the dedicated QC chemists are available for sampling of raw materials?
267.	Whether sampling spoons are stored with segregation and cleaned status?
268.	Whether the dedicated spoons (with active raw material name engraved) are used for sampling of Active raw materials?
269.	Whether sampling is carried out in sampling booth under required environmental conditions and recorded?
270.	Whether sampling is carried out under calibrated clean balance?
271.	Whether cleaning verification carried out for sampling spoons used for inactive materials?
272.	Are containers which have been sampled identified as such by means of sampled stamp?
273.	Are all containers adequately sealed after sampling?
274.	Does under testing label affixed immediately after sampling of materials?
275.	Are sample after sampling labeled and signed with all relevant details?
276.	Is sampling register for RM / PM entered and updated as on date?
277.	Are all sections / instruments / equipments / working table in QC department clean (is microbiology area / LAF kept clean)?
278.	Reference / Working Standards
279.	Are all Reference standards samples purchased from Govt. approved labs (Eg : CDL) (or) from Clients (Is RF procured from any other place and is it a approved lab) and procurement records maintained?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
280.	Are all Reference standards labeled and stored as per storage specification mentioned?
281.	Are working standards prepared with relevant details and documented?
282.	Is there a system for checking exp. date of WS and replacing it (Is any expired WS found in storage)?
283.	Is stock solution labeled and stored as per SOP?
284.	Is destruction record of WS maintained and updated?
Calibration	
285.	Is daily calibration carried out for weighing balance and records entered and updated?
286.	Are standard weights used for weighing balance calibrated and certificates available?
287.	Is glass wares received calibrated in-house and Is calibrated glass wares used with calibration Reference No.?
288.	Are in-house calibration carried out for instruments and records available as on date?
Chemicals	
289.	Are chemicals list available in QC and all chemicals labelled as per SOP?
290.	Are all chemicals stored in an orderly manner in racks with code No. and other relevant details?
291.	Are all the reagent bottles labeled with the required relevant details as per SOP?
292.	Are any expired reagents found in chemical racks?
293.	Are the chemicals in chemical stock room stored in an orderly manner?
294.	Are corrosive chemicals stored and handled under fumigation cupboard with safety precautions?
295.	Are Volumetric solution records entered and updated?
296.	Are all preparation records for general solutions entered and updated?
Raw Material / Packing Material / Finished Product Analysis	
297.	Are current RM / PM and Water analysis specification for the product available / followed?
298.	Are current Water analysis specification available and is water analysed daily and reports available?
299.	Are current version of intermediate / finished product specifications available and followed?
300.	Is the current version of Artwork, Standard specimen and shade cards copy and printed packing material instructions available for all products?
301.	Are current version of product quality standards (PQS) and method of analysis (MOA) available for all products?
302.	Are PPI, Artwork, specifications of raw / packing materials and finished products regulatory complied?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
303.	Is intermediate / finished products tested by QC and reported / approved before finished products release?
304.	Is Analysis reports of all the products reported on line to QA (Is any documentation error observed on running (or) completed test reports of RM / PM / FP)?
305.	Are PQS / MOA of all products and COA similar / identical when it is cross checked and verified?
Instrumentation:	
306.	Are current SOP's for all instruments (Functions and operational procedure) displayed?
307.	Are all QC Instruments coded, calibrated and labeled with calibration status?
308.	Are instrument logs for all instruments entered and updated?
Out Of Specification:	
309.	Are OOS for RM / PM / FP investigated promptly and reported with CAPA and are all OOS reports available for OOS occurred in QC?
310.	Are OOS trended and reviewed annually?
311.	Are destruction records available for rejected Printed Packing Material?
Stability Studies	
312.	Are stability studies carried out for all products as per ICH storage specifications?
313.	Are stability Raw data available for all products as on date?
314.	Is temperature / humidity of stability chambers monitored round the clock and records available?
Microbiology Section	
General	
315.	Is microbiology area facilitated with air lock and change over procedure (Is secondary changeover procedure followed)?
316.	Are aseptic conditions maintained during M/B testing?
317.	Are M/B media used as per label instructions and log maintained / updated?
318.	All incubators functions as per specified temperature?
319.	Are temperature records are entered and updated for incubators?
320.	Is LAF clean and pressure differential is within the limit as specified and logs entered and updated?
321.	Is Autoclave operated as per SOP and are autoclaving records entered and updated?
322.	Are all the materials used for M/B analysis sterilized before disposal?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
Water Analysis	
323.	Is water sampling plan available?
324.	Is water analysed as per schedule and reports available as on date?
325.	Is microbiological monitoring of water carried out on routine basis and are trend results satisfactory?
Environmental Monitoring	
326.	Is Environment monitoring schedule available in place and monitoring tests carried out as per schedule?
327.	Is microbiological monitoring of area (plate exposure) carried out on routine basis and are trend results satisfactory?
328.	Is microbiological monitoring of Room supply air (Air sampling) carried out on routine basis and are trend results satisfactory?
329.	Are alert and action limits evaluated annually based on trends?
330.	Is periodic identification to species level carried out to identify microbiological isolates to establish a baseline of local environmental isolates and reported?
Validations	
331.	Is Method Validation carried for all products manufactured and available?
332.	Is Analyst validation carried for all the chemists working in QC?
333.	Are M/B validation carried for manufacturing equipments and reports available?
334.	Are personnel working in production area validated and reports available?
335.	Is LAF / Autoclave / Incubators and Microbiology working area periodically validated and reports available?
336.	Is effectiveness of the cleaning procedure validated and reported?
337.	Is effectiveness of the disinfectants validated and reported?
338.	Is Due point test carried out for compressed air and documented?
339.	Is compressed air supplied to production areas tested for oil and moisture contamination level by QC and documented?
340.	Is compressed air used for product contact operations validated and reports available (for Ex. RMG / Coating operation)?
341.	Are drains are monitored by M/B analysis and reports available?
342.	Are microbiological method validation carried out and reports available?
343.	Are critical instruments validated and reports available?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
Retention of Samples	
344.	Are all samples of RM and FP retained as per SOP?
345.	Are all samples of RM and FP segregated and stored in a control sample room?
346.	Is temperature of area monitored / entered and updated? Is thermometer calibrated and calibration status is valid as on date?
347.	Is control sample record available for storage of control sample with relevant details and updated as on date?
Destruction of Samples	
348.	Is destruction of samples carried out as per that SOP?
349.	Are any samples found left out, not destroyed as per schedule?
350.	Is destruction record available for destruction of samples and entered / updated?
Laboratory Safety	
351.	Is general safety instruction SOP available for QC activities?
352.	Are poisonous chemicals stored separately with lock and key?
353.	Is fume cupboard available for handling of corrosive chemicals and its operation conditions satisfactory?
354.	Is MSDS (Material safety data sheet) available for corrosive / hazardous chemicals / poisonous chemicals?
Material System:	
Procurement:	
355.	Whether approved vendor list available for all materials and followed?
356.	Is approved vendor list the current version and is within the review period? Is current list available with concerned departments like Purchase, Stores and QC?
357.	Whether materials purchased as per vendor list?
358.	Is there a system of Vendor approval? Are all Vendors audited and approved?
359.	Are supplier audit approvals reviewed periodically (at least actives and printed / Primary packaging materials) as per schedule and reported?
Receipt	
360.	Is material receipt bay monsoon protected? Is the area maintained in hygienic manner?
361.	Material movement – Are materials only be handled in material entry with proper security system?
362.	Is vacuum cleaner available and are materials received de-dusted with vacuum cleaner?
363.	Is there pest control system to avoid entry of pests and rodents at material entry? Are air curtain and pest-o-flash lights in operational condition?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
364.	Are incoming materials checked against receipt checklist for material name, grade, weights and any physical damage etc., and is the same recorded and maintained? Is approved vendor list verified before material acceptance?
365.	Are printed packing materials like printed labels, cartons, foils and leaflets etc., received to secured areas?
366.	Are materials rejected at receipt stage handled properly, controlled, communicated and documented?
367.	Is checklist for receipt of materials filled with relevant details and documented?
368.	Is receipt control book maintained and updated?
Storage of Quarantine / Approved Materials in Stores	
369.	Is there proper segregation of materials as Quarantine / Approved and Rejected? Is there a system of access control to storage areas?
370.	Has sufficient storage space with racking system available for orderly storage and flow of materials? Is storage area maintained in a clean and hygienic way all the times?
371.	Are approved storage specifications for all raw materials available and do all materials stored as per required storage conditions?
372.	Are storage conditions (temperature and humidity) monitored daily and documented / updated?
373.	Is there a proper location identification system with rack number details for each materials stored? Is location board updated with all materials stored in respective racks?
374.	Are materials segregated and stored in pallets or Racks off the floor / off the walls?
375.	Are all materials labeled with relevant details?
376.	Do all QC approved labels contain the company name, material name, grade, code number, quantity, status, mfg date, retest date and expiry date, use before date (for actives) and storage conditions where appropriate?
377.	Are all packing materials labeled with QC approved status? Is expiry dating practice in place for packing materials?
378.	Are there physical partitions between different materials when stored on same pallet?
379.	Are used part quantity approved materials like materials in poly bags maintained with identity?
380.	Is balance used for receipts of materials calibrated with zero error checks and documented / updated?
381.	Are safety instructions (MSDS) available for RM and followed?
382.	Are solvents stored in a secured flameproof area with proper ventilation and authorized entry?
383.	Whether the hoist used for handling of material is safe for handling? (Whether provided with limit switch, double door system, safety sign instructions and boards)
384.	Are any deviations from specified storage conditions recorded, investigated and corrective actions taken for the materials affected and documented?
385.	Is reconciliation system maintained? Is stock reconciliation done for all materials? Is the documentation of reconciliation is online traceable either by manually or through the software? If is a software system documentation, has it been validated?
386.	Are timely entries made in the daily logs and are the entries legible?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Sl. No.	Parameters to be Checked
Retesting	
387.	Is there an effective system to highlight / identify materials due for retesting?
388.	Are there systems to prevent accidental usage of materials due for retesting in product batches?
Handling and Storage of Printed Packing Materials	
389.	Are the printed and unprinted packing materials segregated and stored properly? Are there systems for segregated storage of Quarantined and approved materials?
390.	Is system in place to ensure that only authorized personnel enters into Printed packing materials stores?
391.	Are printed foils stored under temperature controlled A/C area?
392.	Are all printed packaging materials version controlled? Are codes indicated prominently on QC approved labels?
393.	Are printed labels stored in cup boards with lock and key arrangement?
394.	Are printed packing materials like cartons / outers stored separately in the racks with lock and key system for the area?
395.	Is the printed packing material like foil / cartons stored in pallets (or) racks with partitions and away from wall?
396.	Is there location identification system available and followed for traceability of Printed Packing materials stored? (Location Board with current entries)
397.	Are there adequate controls with detailed procedures for handling of code / version change due to art work changes?
Handling of Rejected Material	
398.	Is there a separate secure rejected material store?
399.	Is rejected material Stores Access to authorized personnel only and is approved list displayed?
400.	Are rejected materials stored with segregation and proper rejected label?
401.	Are the rejection details for the rejected materials documented?
402.	Is material rejection details communicated to concerned departments (Stores / QA) by QC through a written communication and is supplier communicated regarding rejection details in time and the same documented?
403.	In case of printed packing materials, does of the destruction of PPM takes place in-house in presence of QA with adequate documentation?
404.	Is a system maintained to control online rejected packing materials and is the online rejection note raised for the same, communicated to the supplier and documented?
405.	Is there a system maintained to ensure all unused and out of dated materials are removed from normal stock with adequate labeling before disposal?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Material Dispensing	
Sl. No.	Parameters to be Checked
406.	Is system in place to ensure that only authorized personnel enters into Dispensing materials stores?
407.	Is the Dispensing of raw materials is carried out under safe zone in dispensing booth as per SOP in a clean environment?
408.	Is dispensing activity carried out under supervision of QA? (Is accuracy of all weights and measures verified by QA chemist during dispensing?)
409.	Is line clearance procedure followed before start up of dispensing?
410.	What systems are followed for raw materials to be dispensed – FIFO / FEFO? Are there system controls to prevent violation of FIFO / FEFO?
411.	Whether Raw materials taken for dispensing is checked for approval / retest / use before date status before dispensing? Are the systems manuals or system based?
412.	Whether the Weighing Balances used for dispensing is checked for calibration status before dispensing activity? (Do the balances used for dispensing calibrated and daily zero error checks done?)
413.	Is dispensing area environment controlled? Whether pressure differential of booth and area are maintained within the limits and documented?
414.	Do all employees follow secondary dress discipline and carry out dispensing with personal protective equipments like, gloves / mask etc.,?
415.	Whether dedicated scoops are being used for active raw materials to be dispensed?
416.	Whether a single material taken for dispensing at a time?
417.	Whether the dispensed material is packed with double poly bag and labeled with dispensing label / relevant details?
418.	Whether the dispensed materials are stored safely with authorized handling and control? Does the storage system prevent accidental mix up of different materials?
419.	Is MSDS used and followed for safe way of handling hazardous raw materials?
420.	Are hazardous solvents dispensed safely under flameproof area? (whether any safety risk observed?)
421.	Are dispensing details entered correctly in batch dispensing sheet / dispensing slip with relevant details like name of the material, quantity, A.R no. with signature during activity
422.	Are there logs for usage and cleaning of dispensing booth ? Are timely entries made in the daily logs and dispensing issue records and are the entries legible?
423.	Are Primary packing materials dispensed in clean area? Are all outer coverings removed for foils?
424.	Is a system of weighing or counting in place for issue of packaging materials? Are dispensed materials adequately labeled and is it ensured that at least one QC approved label be available for each of the dispensed packing material?



LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

Handling of Excess Returns of Packing Materials	
Sl. No.	Parameters to be Checked
425.	Is system in place for handling excess returns from packing?
426.	Are all returns adequately packed and labelled? Are there checks to ensure returns are reconciled and taken to actual stock?
427.	Are all online rejects labeled and stored in a way that prevents mix-ups?
Packaging and Labeling System:	
Packing (Specific to Packing operations Only)	
Stereo control	
428.	Are QA approved stereos segregated / labeled and stored properly product wise?
429.	Is dedicated storage system maintained for storage of stereos?
430.	Are issue of stereos and usage controlled by line supervisors?
431.	Are stereos retrieval done systematically and recorded?
432.	Is destruction of stereos done immediately after completion / dispatch of the batch (Is any used stereos pertaining to completed batch found in the stereo cupboard)?
Coding	
433.	Is coding activity done separately for each product in designated cubicles (Is any coding activity carried out simultaneously in a single coding line / table)?
434.	Are over printed packing materials segregated / checked / labeled with relevant details and sealed and stored in designated racks properly (Is any overprinted packing material found without proper label and identification)?
435.	Are printed packing materials received from stores for over printing purpose segregated and stored properly?
436.	Are used stereos used for over printing retrieved immediately after completion of batch coding (Is any used stereos found not pertaining to current running batch coding)?
437.	Are rejects of over printing destroyed immediately after batch coding and recorded?
438.	Are the excess returns packing materials after batch packing returned to PM stores with appropriate label with relevant details like Product / Material name, AR No. with Date / Signature?
Supply Chain controls to ensure Product availability	
439.	Are there any variabilities in the process, which can impact Batch output or continuity of manufacturing?

Approved By: Satisfish Babu. V S

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LIST OF ACTIVITIES OR OPERATIONS OR AREAS FOR QUALITY RISK ASSESSMENT

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|------|------------------------------------------------------------------------------------------------|
| 440. | Are variations in the process monitored through in-process controls? |
| 441. | Are the facility & equipment designed to suit the requirements of product manufacturing? |
| 442. | Are equipment & facility performance monitored at defined intervals? |
| 443. | Are facilities & equipment designed to minimize human intervention? |
| 444. | Are consistency in the process and quality parameters monitored? Are the variations addressed? |
| 445. | Are vendor/suppliers performance monitored & actions taken based on the monitoring? |

Note: Any additional checks required shall be included under respective activity headings.

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