RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

GxP RELATED GAPS IN RAPID MIXER GRANULATOR

Document No.:

Effective From/Approval Date: ……

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

1.0 Table of Contents:

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

2.0 Quality Risk Management Team:

Following team members were involved during risk identification, assessment & brain storming session. Team nomination was done by the head of department.

S.No.	Team Member	Department	Designation	Sign / Date

HOD Approval			
Name	**Department**	**Designation**	**Sign / Date**

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

3.0 Introduction:

Validation Team has conducted "Gap Assessment" based on below details and followed GAMP 5, 21 CFR part 11, EU Annex 11 guidelines, and SOP (Validation of Computerized Systems).

The GAP analysis has determined the difference between what is in place and what is required to demonstrate that the system has a complete documentation set, is in a state of control, and can be operated and maintained properly.

- Validation documentation – Validation deliverables shall be verified as per GAMP 5, 21 CFR part 11, EU Annex 11 guidelines and SOP validation of computerized systems.
- Administration of Backup and Restore - Backup and Restore process is assessed for each system.
- Security – User management and system security process.
- Audit trail - Audit trail availability and Audit trail setting.
- Operational Control – System maintenance and SOP's.
- Periodic Review – periodic review schedule for systems and procedure for the same.
- System Technical Details – Operating system and application details.

Assessment Areas has been prioritized based on Operational Areas. The gap assessment has been performed phase-wise to cover the below mentioned areas & departments at respective site/location.

(1) Phase-I - Manufacturing Area

(2) Phase-II - Packaging Area

(3) Phase-III - IPQA Dept.

(4) Phase-IV - Utility Area

(5) Phase-V - Quality Control (QC)

Computerized System of Rapid Mixer Granulator has been assessed for gap assessment against the GxP requirements.

4.0 Objective:

The objective of this document is to perform the Quality Risk Management for evaluation of risk associated with the identified GxP related gaps in the computerized system of Rapid Mixer Granulator, assessment of severity of the identified risk, probability of its occurrence and available control measures that can detect and control the identified risk.

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

5.0 Scope:

The scope of this document is applicable to Rapid Mixer Granulator located in Pilot Plant.

The purpose of this document is to offer a systematic approach to quality risk management. It serves as a foundation or resource document that is independent of, yet supports other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the manufacturing facility.

This document provides risk assessment by means of Failure Mode and Effect analysis and identifies key areas where process shall be mostly likely to fail and shall provide evaluation of failure that will have the extreme or severe impact on the process/ quality for the product.

6.0 Risk Assessment Approach:

- The quality risk assessment has been planned for evaluation on the basis of failure mode effect analysis (FMEA) tool.
- The evaluation of the risk shall be based on scientific knowledge and ultimately linked to safety of the patient.
- Various risks associated / anticipated shall be identified for identified GxP related gaps in the system of rapid mixer granulator.
- Risk over the quality of products manufactured over the equipment shall be identified, analyzed and evaluated. Control measures shall be evaluated and risk shall be categorized based on calculated risk priority number.
- Action recommendations shall be given (if required) for mitigation and acceptance of risk.
- Acceptance of the risk with its mitigating measures shall be decided and endorsed based on the risk assessment carried out.
- The control mechanism and the risk communication shall be enforced / verified in the operating documentation.

7.0 Responsibilities:

Quality Assurance Department is responsible for preparation and review of quality risk assessment and coordinate the QRM team members and they shall be take the decisions about quality risk control & action plan.

Production Department is responsible for review of quality risk assessment and its execution.

Engineering Department is responsible for review of quality risk assessment and support to its execution.

Information Technology Department is responsible for review of quality risk assessment and support to its execution.

Head Operation is responsible for review adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

Head Quality Assurance is responsible for review adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

8.0 Reference Documents:

The relevant SOP's & Document for monitoring, control are listed below:

1. SOP "Computerized System Validation"
2. SOP "Vendor Audit and assessment of GxP computerized system and services"
3. SOP "Backup and restoration procedure for electronic data"
4. SOP "User management and password policy"
5. SOP "Performing of Equipment Validation (Equipment Qualification)"
6. SOP "Procedure for Breakdown Maintenance"
7. SOP "Document and Data Control"
8. SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons"
9. SOP "Event Management"
10. SOP "Entry and Exit of Personnel in core area through access control system"
11. SOP "Batch Release Procedure"
12. SOP "Process Performance Qualification"
13. SOP "Self-Inspection"
14. SOP "SOP on Electronic Records and Electronic Signatures"
15. SOP "Change Management System"
16. SOP "Critical Alarm Control Management"
17. Gap Assessment Checklist cum Report for GxP Computerized Software System of Rapid Mixer Granulator Doc. No……..

9.0 Background:

The site is engaged in manufacturing of solid oral dosage form at Baddi unit. Oral solid dosage form manufacturing "Granulation" activity has been carrying out by using Rapid Mixer Granulator located in Pilot. GAP assessment study of Rapid Mixer Granulator (Document no: …….) has been done and identified the GAP's, Related risk shall be assessed in line with 21 CFR Part 11, EU Annex 11 Guidelines.

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

10.0 Risk Ranking Parameters:

10.1 Rating Parameters for Severity:

Effect	Scale	Assessment of Severity of Impact (Based on the anticipated negative impact & detrimental effect)
No effect	1	No impact to product quality and process robustness
Very Slight	2	Very slight effect on product and process performance. The customer may notice non-vital fault. Customer is not annoyed or impacted
Slight	3	Slight effect on performance. Non-vital fault notice most of the time. Customer is slightly annoyed.
Minor	4	Minor effect on product quality and process performance. Fault does not require repair or rectification. Non-vital fault or deficiency always noticed. Customer experiences minor nuisance.
Moderate	5	Performance moderately affected. Fault requires repair. Customer experiences some dissatisfaction.
Significant	6	Product or Performance hindered but usable /operable and safe. Non-vital part inoperable. Customer experiences discomfort.
Major	7	Product or performance severely affected but functional and safe. Customer dissatisfied.
Extreme	8	Item inoperable but safe. Customer very dissatisfied.
Serious	9	Potential hazardous effect. Able to stop without mishap. Regulatory compliance in jeopardy.
Hazardous	10	Occurrence without warning. Safety related. Regulatory non-compliance.

10.2 Rating Parameters for Occurrence:

Occurrence	Scale	Parameter
Almost never	1	Almost impossible probability of occurrence. A failure, which has never been encountered but may be possible theoretically (1 in 15,00,000).
Remote	2	Remote, rare number of historical failure (1 in 1,50,000).
Very slight	3	Very few failure likely (1 in 15,000)
Slight	4	Few failure likely (1 in 2,000)
Low	5	Occasional number of failures likely (1 in 400)
Medium	6	Medium number of failures likely (1 in 80)
Moderately High	7	Moderately high number of failures likely (1 in 20)
High	8	high number of failures likely (1 in 8)
Very High	9	Very high number of failures likely (1 in 3)
Almost Certain	10	Failure almost certain (≥ 1 in 2)

10.3 Rating Parameters for Detection Control:

Detection	Scale	Parameter
Almost Certain	1	Almost certain that the design control will detect potential cause. Proven detection methods with high reliability.
Very High	2	Very high chance design control will detect potential cause. Proven detection methods available.
High	3	High chance design control will detect potential cause. Detection tools have high chance of detecting methods.
Moderately High	4	Moderately high chance design control will detect potential cause. Almost certain not to detect failure.
Moderate	5	Moderate chance design control will detect potential cause. Detection tools have moderate chance of detecting methods.
Low	6	Low chance design control will detect potential cause. Detection tools have a low chance of detecting failure.
Very Low	7	Very low chance design control will detect potential cause. Detection tools may not detect failure.
Remote	8	Remote chance design control will detect potential cause. Detection tools will probably not detect failure.
Very Remote	9	Very remote chance design control will detect potential cause. Detection tools most likely will not detect failure.
Absolute Uncertainty	10	No design control or design control will not detect potential cause. Failure not detected.

Note: Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

11.0 Acceptance Criteria for Risk Assessment by FMEA:

Acceptance criteria for FMEA are as follows:

Risk Category	Risk Classification (Quantitative) Risk Index	Action Status
High	≥ 500	CAPA required
Medium	126 - 499	CAPA may be required
Low	≤ 125	CAPA not required

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

12.0 Risk Assessment as per FMEA:

Name of Facility/ Utility/ Equipment / Process/ Operation: Rapid Mixer Granulator

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
Validation Documentation/Equivalent documents																	
1.	Standalone validation master plan for GxP equipment is not in place to ensure compliance of all requirements for GxP equivalent CSV.	1.Which may lead to lack of 21 CFR Part 11 requirements for electronic signature and CSV may not be carried out as per aforementioned requirements. 2. Inadequate computer system validation i.e. non	6	1. Unavailability of CSV. 2. Lack of procedures related to CSV for the GxP requirements.	5	1. Validation Master Plan is available having document number, which includes chapter of PLC validation. Moreover; PLC validation annexure is in place to track the PLC validation activity of all equipment throughout the year and is part of validation master plan. 2. PLC validation of applicable equipment is carried out with consideration of GAMP 5 & 21 CFR part 11 requirement i.e. test like verification of access right, power failure & communication failure, verification of audit trail	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for conducting CSV for GxP equipment as per the SOP "Computerized system validation". 2. Validation master plan for PLC validation chapter may be revised accordingly. 3. Site VMP shall be revised to link corporate VMP for CSV and same shall	QA: Revision of SOP TCD: ….. Revision of VMP TCD: …..						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		consideration of all GxP requirements during CSV due to non-availability of Validation plan.				(if available), verification of safety features and interlocking is carried out during PLC validation which alleviates the risk of unauthorized access to equipment and process failure. 3. SOP "Performing of Equipment Validation (Equipment Qualification)" is in place to ensure the PLC validation of all new equipment (If applicable) which mitigates the risk of probable skip of the PLC validation activity.				be followed. 4. Validation Plan for individual PLC system shall be prepared inline with VMP during CSV.							
2	Supplier / Vendor Assessment document for GxP computerized software system compliance of Rapid Mixer Granulator is not available.	1. System may not be supplied as per GxP requirement. 2. System may not work as	6	1. Procedure for assessing the GxP requirement was not available at the time of equipment procurement as well as CSV.	5	1. Procedure is available for vendor assessment (SOP "Vendor Audit and assessment of GxP computerized system and services"). 2. Procedure in place for URS, FAT and design qualification as per SOP.	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision i.e. URS shall be generated by site & project team	QA: Revision of SOP TCD: …… Eng: Vendor						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		desired. 3. System may not comply with cGMP and GxP requirement.				3. Equipment has been qualified as per SOP "Performing of Equipment Validation (Equipment Qualification)" prior to use for production activity. 4. GxP requisites like access rights (privileges), audit trail, printout etc if applicable is verified during PLC validation which alleviates the risk for non-compliance for GxP requirements; however, complete requirements of CSV is not covered. 5. Qualified and trained persons have been involved in preparation of URS and qualification of equipment. 6. Procedure is in place				will procure equipment from approved vendor only. Approved documents shall be provided to site with purchase order as per SOP. 2. For Equipment, machine manufacturer is GANSONS Pvt. Ltd. hence; same should be considered for Vendor assessment as per SOP as on date to ensure adequacy of vendor assessment requirement.	Assessment (Part of CSV) TCD: ……..						

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RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						for periodic validation of the equipment to assess the qualification status. 7. Procedure "Computerized System Validation") is in place for periodic review of computer system.											
3	GxP Assessment document of Rapid mixer granulator is not available.	1. Equipment system may not be assessed for its impact over product quality and not evaluated for requirement of it CSV needs.	6	1. Lack of procedures.	5	1. Procedure in place for URS, FAT and design qualification as per SOP. 2. Equipment has been qualified as per SOP "Performing of Equipment Validation (Equipment Qualification)" prior to use for production activity. 3. Qualified and trained persons have been involved in preparation of URS and qualification of equipment.	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to conduct GxP assessment of equipment as per SOP "Computerized system validation". 2. For Equipment, GxP assessment shall be performed as per SOP.	QA: Revision of SOP TCD:……. IT/Eng: GxP Assessment (part of CSV) TCD: ……						

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RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						4. GxP requisites like access rights (privileges), audit trail, printout etc if applicable is verified during PLC validation which alleviates the risk for non-compliance for GxP requirements; however, complete requirements of CSV is not covered. 5. Procedure is in place for periodic validation of the equipment to assess the qualification status. 6. Procedure (SOP "Computerized System Validation") is in place for periodic review of computer system.											
4	Category is not defined in PLC validation document as per GAMP 5.	1. CSV may not be performed as required by the Category of PLC	6	1. Inadequate procedures were available for CSV.	5	1. Procedure "Computerized system validation") is in place in which system categorization is defined. Validation deliverables are also specified for all	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for	QA: Revision of SOP TCD:……. IT/Eng: System						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		software.				system categories in the SOP.				categorizing the equipment system prior to generation of URS as per SOP "Computerized System Validation". 2. For Equipment, system categorization should be done as on date and CSV shall be planned (if required) as per SOP …….. and adequacy of addendum URS shall be verified.	Categorization (part of CSV) TCD: …..						
5	Detail description of required functions of the computerized system, i.e. technical requirement, business requirement, etc. was not described in the available URS Document.	1. Equipment may not be designed inline with GxP requirements for CSV.	6	1. Inadequate procedures might be available regarding specifying requirements for GxP requirement of CSV.	5	1. Procedure in place for preparation of URS (SOP No.: "Computerized System Validation") with respect to GxP requirement. 2. URS prepared by user department in consultation with engineering Department	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for making of URS as per the GxP requirements listed for system in the SOP	QA: Revision of SOP TCD:…….. Production: Addendum URS (part of CSV) TCD: ……						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						and approved by QA. 3. SMEs are involved in the preparation and approval of URS/ DQ. 4. Procedure is in place for verification of URS requirement during Design qualification.				"Computerized system validation". 2. For Equipment, addendum URS should be prepared for as per SOP.							
6	Functional requirement specification (FRS), functional risk assessment (FRA) and Requirement Traceability Matrix (RTM) / Traceability Matrix (TM) are not available.	1.Inadequate design, build and testing of the required system that shall not conform the business needs and may not comply the requirement of GxP.	6	1. Lack of procedures.	5	1. SOP "Computerized system validation" is in place that contains provision of functional requirement specification, functional risk assessment (FRA) and requirement traceability matrix. System Requirement Specification (SRS) is available. Risk assessment document of PLC based control system document is available.	4	120	Low	1. It is recommended to prepare addendum URS for Equipment and accordingly functional requirement specification, functional risk assessment and requirement traceability matrix shall be prepared in line with SOP and adequacy shall be verified in addendum URS. 2. SOP "Performing	Production: Addendum URS (Part of CSV) TCD:…. IT/Eng:: Requirement traceability matrix, FRS and FRA (part of CSV) TCD: ……						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
										of Equipment Validation (Equipment Qualification)" shall be revised to include the requirement for Functional requirement specification (FRS), functional risk assessment (FRA) and Requirement Traceability Matrix (RTM) / Traceability Matrix (TM).							
7	Specific System Release Certificate (SRC) is not available to handover system/ equipment for further usage.	1. Invalidated system/ equipment may be used for operational activity.	6	1. Lack of procedures.	4	1. Procedure is in place for system release for operational use based on PQ activity and controlled as per SOP. Qualification document Number: . 2. Procedure for preparation of equipment qualification certificate is in place as per SOP	2	48	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for generation of System Release certificate (SRC) after successful completion of qualification of each	QA: Revision of SOP TCD:……..						

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RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						"Performing of Equipment Validation (Equipment Qualification)".				equipment/ system. 2. Currently no action is required in view of SRC as all equipment are under use after successful completion of qualification as per Document Number:							
8	Service Level Agreement (SLA)/ formal agreements/ Technical Agreement/Service Contract is not available.	1. Supplier / Vendor may not provide support for unwritten activity which may impact on business continuity. 2. Supplier may not inform up gradation of software / hardware if any.	6	1. Lack of procedure to sign a technical agreement between contract giver (MPL) and contract acceptor (Vendor/ supplier).	5	1. Procedure is in place for service level technical agreement SOP "Vendor audit and assessment for GxP computerized systems and services). 2. Breakdown SOP is available at site "Procedure for Breakdown Maintenance") accordingly vendor/ external agency support accessible on case to case basis /as and when required.	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for making of Service Level Agreement (SLA) (optional) as per SOP "Vendor audit and assessment for GxP computerized systems and services". 2. For Equipment, service level	QA: Revision of SOP TCD: …….. Eng: Service level agreement (part of CSV) TCD: …….. IT: Revision of SOP……. TCD: ……						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
										agreement shall be prepared as per SOP. 3. SOP "Vendor Audit and assessment of GxP computerized systems and services" is to be revised to provide SLA with vendor during purchase order or part of PO to ensure availability during qualification.							
Administration of Backup and Restore																	
9	Data backup and restoration testing was not performed as backup is not taken. Data backup is not taken for the system, so Integrity and accuracy of backup data and the ability to restore the data was not checked during qualification also periodic monitoring was not performed.	1. Electronic data shall not be backed up from the system and restoration facility is not available, which may lead to non-retrieval of	6	1. Due to limitation of HMI/PLC system. 2. Lack of procedure.	5	1. Procedure is in place for preparation of URS (SOP "Performing of Equipment Validation (Equipment Qualification)" and "Computerized System Validation") with respect to GxP requirement. 2. SOP "Backup and restoration procedure for electronic data" is in	4	120	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for making of URS as per the GxP requirements listed for system in the SOP "Computerized system validation".	QA: Revision of SOP TCD:… Production: Addendum URS (part of CSV) TCD: …….. Revision of SOP TCD:…… Implementatio						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		data in case data erased from the system itself.				place. 3. Electronic data is stored in the system. Recipe printouts are generated and attached to respective BMR. 4. Procedure for recording the process parameters and manufacturing details in respective BMR and logbooks is in place paper based recording and control are available in which controlled documents and formats are used for recording of all data as per (SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)".				2. For Equipment, addendum URS should be prepared as per SOP additionally; that include requirement of data backup and restoration facility and shall be evaluated to upgrade/ change the system. 3. CSV shall be performed for data backup and restoration feature. 4. Periodic monitoring of integrity and accuracy of backup data shall be performed as per "Backup and restoration procedure for electronic data"	n of new SOP for verification of electronic data TCD: …….. IT/Eng: CSV TCD:……..						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						5. Personnel involved in the equipment operation are trained for SOP "Document and data control" and data integrity topic as schedule of training as per Data integrity Policy/procedure. 6. Procedure for handling of event is in place as per SOP "Event Management" in case of any deviation observed. 7. Biometric access procedures are in place as per ("Entry & Exit of personnel in core area through access control system") and only authorized person can enter in to the area to monitor the operational activities of equipment.				and Relevant equipment SOP shall be revised for the same after implementation of long term (Up gradation of System) plan however new sop shall be implemented for electronic data verification of each Batch.							

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RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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10	Training records are not available for administrator.	Untrained personnel as administrator may lead to following: 1. Incorrect setting of equipment. 2. Improper control over user management. 3. Wrong privilege may be granted to user.	6	1. Lack of Procedure.	3	1. SOP is in place for system operation (SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)"). User levels are well defined in SOP. 2. SOP in place for user management and password policy (SOP "User management and password policy"). 3. Rights of system administrators are available with IT login. All the personnel involved in the activity are well trained for data integrity related policy and procedures as well as for SOP "Document and data control".	3	54	Low	1. System administrator rights should be given only to independent group which is not part of activity i.e. IT personnel and same shall be updated in the equipment SOP. Training to all user levels including administrator shall be conducted for equipment SOP. Linkage of SOP shall be mentioned in the SOP in order to define procedure for granting access to a new user, for changing privileges for an existing user and for disable/deleting user. 2. CSV for this feature shall be performed as per	Production: Revision of SOP TCD:……. SOP shall be prepared by production for all the requirement details regarding user privileges TCD: … IT/Eng: CSV TCD: …… Production:						

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QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						4. PLMS system is available for training control.				SOP "Computerized System Validation". 3. SOP shall be prepared that shall contain all the requirement details regarding user privileges.							
Security																	
11	User account management is available in system; however user account management is not available in operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons". There is no controlled and documented process available for granting access to a new user, for changing privileges for an existing user and for disable/deleting user.	1. Unauthorized user can access the equipment. 2. Incorrect privileges can be assigned to any unauthorized user.	6	1. Lack of procedure.	5	1. User account management rights are with Manager login. 2. Controlled documented procedure available for granting access to user "User management and password policy"). 3. Trained person are involved in the activity.	4	120	Low	1. Detailed user account management shall be defined in the operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons" and linked with SOP for granting access to a new user, for changing privileges for an existing user and for disable/deleting user	Production: Revision of SOP TCD:……						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
										accounts.							
12	There is no verification of active user for the application.	1. A user ID for the user that has left the organization may be available in the system and any unauthorized system access may occur in by using its ID and password.	6	1. Lack of procedures.	5	1. Individual unique user ID can be generated in the system but it is not used currently. 2. Procedure available for preparation of active user list for system (SOP "User management and password policy") but not currently implemented completely.	4	120	Low	1. Operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons" shall be revised to include procedure for making of active user list and its periodic updating at every Quarterly Basis frequency. 2. Procedure shall be made to inactivate user ID during relieving from organization.	Production: Revision of SOP. TCD:……. Procedure shall be made to inactivate user ID during relieving from organization TCD: ……						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
13	Unique user ID creation is available in system but Verification of unique User ID is not performed during PLC validation. Individual ID creation facility is available in the system but not implemented till date.	1. Nonfunctioning of unique user ID feature may result into access of unauthorized user to the system due to common ID and password.	6	1. Lack of procedures.	5	1. Procedure in place for verification of unique user ID during GXP system validation. (SOP No.:…….. "Computerized System Validation") however; it was not performed during PLC validation. 2. Documented procedure available ("User management and password policy") for ID/Password creation and granting access to the users. 3. Trained manpower is involved in system administration activity.	4	120	Low	1. Unique user ID shall be created for all individual users and that shall be used during operation of equipment. 2. Unique user id verification shall be performed during CSV. 3. Procedure shall be made for individual ID creation to use the system as per "User management and password policy".	Production: Addendum URS (part of CSV) Procedure shall be made for individual ID creation for individual login to use available system TCD:……. IT/Eng: CSV TCD: ……..						
14	Minimum length for a strong password is neither defined in SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" nor	1. Small password policy may result into easy access of the system by	6	1.Lack of procedures	5	1. Procedure is defined for minimum length of password in SOP "User management and password policy" but didn't enforce.	4	120	Low	1. Facility for minimum length of strong password shall be enabled in the system for individual login i.e. password length	IT/Eng: Facility for minimum length of strong password shall be enabled in						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
	enforced in the computerized system. However, facility for minimum length of strong password is available in the system i.e. password length should be 1 to 32 characters and complexity of password with capital letter, small letter, number and special character is available.	unauthorized users.				2. Facility for minimum length of strong password is available in the system i.e. password length should be 1 to 32 characters and complexity of password with capital letter, small letter, number and special character, however it was not enabled.				should be 1 to 32 characters and complexity of password with capital letter, small letter, number and special character. 2. Minimum length for a strong password shall be defined in SOP. 3. CSV shall be performed as per "Computerized System Validation".	the system for individual login TCD: ….. CSV TCD: …… Production: Revision of SOP TCD:…….						

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QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
15	Non person system account (generic accounts) are available i.e. Administrator, A, ADMIN, Operator, supervisor and manager.	1. May result into loss of data /Wrong data generation. 2. Unauthorized access to system. 3. Event traceability may be impacted as it is non-attributable.	6	1.Lack of procedures	5	1. Procedure is available for user management and password policy (SOP "User management and password policy"). 2. Control and documented process is available for granting access to a new user, for changing privileges for an existing user and for disable/ deleting user. 3. Procedure is in place to record the data with performed by/ verified by so; loss of data or wrong data generation and unauthorized access may be controlled. 4. Procedure is in place to review real time data during and after batch manufacturing; so event traceability is in place.	4	120	Low	1. Available generic account in the system shall be deactivated and unique user id shall be created. 2. SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised to include requirement for creation of individual user IDs. 3. CSV for this feature shall be performed as per SOP "Computerized System Validation". 4. Batch electronic	Production: Available generic account in the system shall be deactivated and unique user ID shall be created. TCD: ……. Revision of SOP TCD:……. Implementation of new SOP for verification of electronic data TCD: …. IT/Eng: CSV TCD:…….						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						5. Biometric access procedures are in place as per SOP "Entry and exit of personnel in core area through access control system") and only authorized person can enter in to the area to monitor the operational activities of equipment. 6. Audit trail facility is available in the system, so user activity traceability can be ensured.				data (each) shall be taken and shall be verified for adequacy. Respective SOP shall be revised for the same after implementation of long term (Up gradation of System) plan however; new sop shall be implemented for electronic data verification of each Batch.							
16	There are four active groups/levels available in the system, i.e. 1) Operator, 2) Supervisor, 3) Manager and 4) Admin. However, As per qualification document: There are five groups available in the system i.e. 1) Operator, 2) Supervisor, 3) Manager, 4) Maintenance and 5) Admin.	1. Incorrect user privilege may be assigned during user ID creation and that leads to unauthorized user activity.	6	1. Due to lack of procedure.	4	1. User access rights are given based on job profile of personnel as per groups available in the system i.e. operator, supervisor, manager and administrator. 2. System automatically records unauthorized login attempt or failed	2	48	Low	1. User groups shall be defined in the operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" as per available system and	Production: Revision of SOP: …….. TCD:…….						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
	Three groups/levels are defined in operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" i.e. operator, supervisor and manager. Password verification and privilege verification testing for the system has been performed for five groups i.e. 1) Operator, 2) Supervisor, 3) Manager, 4) Maintenance and 5) Admin. Reference document: ……... However, system has four groups.					login attempts i.e. audit trail report shall capture all login attempts. 3. Password verification testing as well as privilege verification testing for the system has been performed during PLC validation.				accordingly CSV shall be performed for existing user groups.							
17	The computerized system supports the password – aging (expiry) facility but it is not enabled and verified during physical verification. Admin can configure the password – aging parameter.	1. Keeping same password for long period of time increases risk of password breach by	6	1. Due to lack of procedures.	5	1. Procedure is available for user management and password policy (SOP- "User management and password policy"). 2. The computerized system supports the password – aging (expiry) facility, but it is	4	120	Low	1. For Equipment, password – aging (expiry) feature shall be enabled and CSV for this feature shall be performed as per SOP "Computerized System Validation". 2. SOP "Cleaning	IT/Eng: CSV TCD: ……..						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		unauthorized user.				not enabled.				and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised to include requirement of password aging (expiry).	Production: Revision of SOP. TCD:……						
18	System does not ask for password change on first login and verified during physical verification. However facility is available for individual login and can be enabled at admin level.	1. Keeping same password as provided at the time account creation increases risk of password breach by unauthorized user.	6	1. Due to lack of procedure	5	1. Procedure is available for user management and password policy (SOP "User management and password policy") but not implemented currently. 2. Procedure is in place to online record the data in BMR with doer and verification option. Additionally; log is available in BMR to identify all involved person in the activity.	4	120	Low	1. For Equipment, requirement to ask for password change on first login facility feature shall be enabled and CSV for this feature shall be performed as per SOP "Computerized System Validation". 2. SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic	IT/Eng: CSV TCD: …… Production: Revision of SOP TCD: …..						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						3. System automatically records unauthorized login attempt or failed login attempts i.e. audit trail report shall capture all login attempts.				pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised to include requirement of password change on first login. 3. Batch printout (electronic) data shall be taken and verified for adequacy which includes signing of doer/ checker so; risk shall be minimized for password breaching. Respective SOP ……. shall be revised for the same after implementation of long term (Up gradation of System) plan however new sop shall be implemented for electronic data	Implementation of new SOP for verification of electronic data TCD: ……..						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
										verification of each Batch.							
19	Computerized system is unable to lock a user account after unsuccessful attempts for login and verified during physical verification. However facility is available and can be enabled at admin level.	1. If system allows user to enter unsuccessful passwords multiple times; then it will increases risk of password breach by unauthorize d user.	6	1. Due to lack of procedure.	5	1. Biometric access procedures are in place as per SOP "Entry and exit of personnel in core area through access control system" and only authorized person can enter in to the area of equipment. 2. Only authorized person with user ID and password can login into system. 3. SOP "User management and password policy" is in place which includes instructions to keep passwords confidential. 4. System automatically records unauthorized login attempt or failed login attempts i.e. audit	4	120	Low	1. For Equipment, requirement to lock a user account after multiple unsuccessful attempts for login to the system shall be enabled and CSV for this feature shall be performed as per SOP "Computerized System Validation". 2. SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised to include requirement to lock a user account after multiple	Production: Revision of SOP to include requirement to lock a user account after multiple unsuccessful attempts for login and automatically record un authorized login attempt or failed login attempts TCD: …… IT/Eng: CSV TCD: ……						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						trail report shall capture all login attempts.				unsuccessful attempts for login.							
20	Automatic logout provision is available in the system but is not enabled and verified during physical verification. Admin can configure automatic logout provision.	1. If any user may leave the logged in system for some time; then it will increase risk to access the system by unauthorize d user.	6	1. Due to limitation of current HMI/ PLC.	5	1. Biometric access procedures are in place as per SOP "Entry and exit of personnel in core area through access control system" and only authorized person can enter in to the area of equipment 2. Only authorized person with user id and password can only login into system. 3. Persons are dedicated to manufacturing area on Weekly basis as per SOP "Entry and exit of personnel in core area through access control system" so; they are not allowed to enter into different manufacturing area other than access permitted on day. Only	4	120	Low	1. For Equipment, requirement for automatic logout of a user account after specified time period shall be enabled and CSV for this feature shall be performed as per SOP "Computerized System Validation". 2. SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised for automatic logout feature of the system.	IT/Eng: CSV TCD……. Production: Revision of SOP TCD:…						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						lunch/ tea breaks are allowed to leave so; risk is mitigated for unauthorized user. 4. System automatically records unauthorized login attempt or failed login attempts i.e. audit trail report shall capture all login attempts.											
21	Approved matrix for user access privilege for the system is not available and is not attached to operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)".	1. In the absence of privilege matrix; wrong rights may be granted to the users that can result into access to the restricted system features and data by unauthorized users.	6	Lack of procedures regarding privilege matrix.	5	1. Procedure is available for user management and password policy "User management and password policy").	4	120	Low	Privilege matrix shall be prepared and attached with the SOP.	Production: Revision of SOP TCD:……						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
22	Recipe management is not defined in operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)".	Due to lack of procedure for recipe management , equipment may be inappropriat ely operated and have impact over the quality of product.	7	Lack of procedures.	2	1. System has recipe management and is controlled at Manager level as per qualification document. 2. Procedure is in place for PPQ study (SOP "Process Performance Qualification") and product specific recipe is finalized after completion of PPQ study.	3	42	Low	SOP shall be revised to define recipe management.	Production: Revision of SOP TCD:…….						
24	The system has offline printing capability, but only recipe printouts are attached with BMR. Batch wise production report, audit report and alarm report are not attached with BMR.	1. Non generation of online generated batch processing data may lead into variation in recorded data of BMR. 2. Document	6	1.Lack of procedure	5	1. Procedures for recording of in-process parameters in respective BMR are in place as per SOP "Document and Data Control". 2. Procedure (SOP-"Document and data control") is in place and same is being followed during creation and recording of data. 3. Data recorded in BMR,	3	90	Low	1. Operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised to include the procedure for generation of batch printouts for review and attached to the BMR and after	Production: Revision of SOP TCD:…… Implementatio n of new SOP for verification of electronic data TCD: 10/21						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		may not be complying to ALCOA.				log book, format, and supportive documents are being reviewed online after completion of step wise activity/ stage wise activity by production person followed by IPQA personnel for adequacy, accuracy and completeness of activity. Procedure (SOP "Batch Release Procedure") is in place for review of batch records. 4. Complete granulation process instructions are given in the BMR for each significant step. 5. Data in BMR and equipment log books are recorded in a manner that it comply all attributes of Data integrity i.e. ALCOA+. 6. Procedure is in place to					implementation of long term (Up gradation of System) plan however new sop shall be implemented for electronic data verification of each Batch.							

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						take and verify processing details printout from equipment for each batch as per SOP. 7. Printouts are matched with the displayed information and this is verified during qualification.											
Audit Trail																	
25	SOP for audit trail review is not available. The audit trail is secured for any alteration/deletion in the system. However this is not verified during PLC validation. Computer generated audit trails does not contain reason for the change.	1. Document may not be complying with ALCOA. 2. Tracking of data related to alteration i.e. changes in process parameter, access level	6	1. Unavailability of requirement of Audit trail feature in the URS and due to limitation of current HMI/ PLC.	5	1. The Computerized system has viewing & printing capabilities for all relevant audits trails i.e. batch reports, audit reports, alarm reports, etc. 2. Data recorded in BMR, log book, format, printed batch records are reviewed online after completion of granulation activity by production person followed by IPQA person for adequacy and	3	90	Low	1. SOP "Performing of Equipment Validation (Equipment Qualification)" shall be revised to include provision for making of URS as per the GxP requirements listed for system and performing CSV as defined in the SOP ITD/034 "Computerized system validation".	QA: Revision of SOP TCD: …….. Production: Addendum URS (Part of CSV) TCD:…… Revision of SOP TCD: …. Implementation of new SOP						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
		(Who and when the changes done) and deletion of data is not available which leads to the lack of GMP and GxP requirement. 3. Event may not be traceable. 4. Data can be edited at any point of time.				completeness of activity. Procedure for review of batch records is in place as per SOP "Batch Release procedure". 3. Procedure (SOP "Document and data control") is in place and same is being followed during creation and recording of data. 4. Recorded data's contemporaneousness can be ensured by comparison of original record and available biometric punch records along with logs available with respective BMR for person involved in manufacturing. 5. Complete granulation process instructions are given in the BMR for each significant step.				2. For Equipment, addendum URS should be prepared as per SOP that shall include requirement for up gradation of existing audit trail facility with a provision to mention the reason for change during batch activity. 3. Batch printout as well as audit trail (electronic data) of each batch shall be taken and verified with BMR data online/ inline for adequacy so that each electronic data of batch can be ensured for data adequacy. Respective equipment SOP "Cleaning and	for verification of electronic data TCD: ….. Preparation of SOP for Audit trail review TCD: ……..						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						6. Check point for Data integrity, is part of self-inspection checklist and during inspection random verification of data is being performed as per SOP "Self Inspection". Data in BMR and equipment log books are recorded in a manner that it comply all attributes of Data integrity i.e. ALCOA+. 7. Procedure is in place to take and verify processing details printout from equipment for each batch as per SOP. 8. All completed documents are submitted to QA and stored at identified location in controlled area and readily available for review and reference				Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised for the same after implementation of long term (Up gradation of System) plan however new sop shall be implemented for electronic data verification of each Batch. 4. SOP for audit trail review shall be prepared.							

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						purposes.											
Operation control																	
26	System does not have electronic signature (ES) provision.	1. System data shall not be Attributable.	6	1. Unavailability of requirement of Electronic signature features in the URS and due to limitation of current HMI/ PLC.	5	1. Procedure for CSV contains provision for validation of electronic signature features as per SOP "Computerized System Validation". 2. Audit trail facility is available in the system that tracks all activity during batch processing by any user and same can be printed. 3. Procedure is in place for recording of all the process data over BMR with signature of the person who has recorded the data. 4. Procedure is in place to generate employee specimen signature log in each batch record to trace the personnel involved in	4	120	Low	1. For Equipment, addendum URS should be prepared as per SOP that shall include requirement of "electronic signature"; and evaluated for system up gradation. 2. CSV for this feature shall be performed as per SOP for upgraded parameters. 3. Batch printout as well as audit trail (electronic data) of each batch shall be taken and verified with BMR data online/ inline for adequacy so that each electronic data of batch can be	Production: Addendum URS (Part of CSV) TCD: ……. Revision of SOP TCD:…… Implementation of new SOP for verification of electronic data TCD: ……. IT/Eng: CSV TCD:…….						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						the activities. 5. Personnel are trained for data integrity process as schedule of training as per Data integrity Policy/procedure. Documents and formats used for recording of data are issued and controlled by QA. 6. Procedure is in place to record the data in a manner that covers batch operation /cleaning activity/ change over activity with start time/ date and end time/date with activity done by and cross checked by signature. 7. Procedure for electronic signature is available as per SOP "Electronic Records and Electronic Signatures".				ensured for data adequacy. 4. Operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)" shall be revised for the same and after implementation of long term (Up gradation of System) plan however new sop shall be implemented for electronic data verification of each Batch.							

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
27	Specific SOP for Business Continuity is not available.	1. Lack of procedure for business continuity may result in inability for continuing processes in case of adverse event/disaster.	6	1.Lack of procedures	5	1.In case of adverse event and disasters; procedure are in place to handle such situation i.e. SOP's are available for "Procedure for Breakdown Maintenance", "Change Management System" and "Event Management".	3	90	Low	1.SOP for business continuity /Plan shall be prepared	IT: Preparation of SOP for Business continuity /Plan TCD: …….						
28	Verification of recipe reports, audit reports and batch reports are not part of operational SOP "Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100)".	1. Mismatch in the system generated electronic data and hard copy data.	6	1.Lack of procedures	3	1. Procedure for batch record review is in place as per SOP "Batch Release procedure". As per the Batch record review checklist, electronic processing data of equipment shall be verified (whichever applicable). Discrepancy related to difference in electronic data and executed batch record shall be handled through SOP "Event	3	54	Low	1. SOP (Cleaning and Operation of Rapid Mixer Granulator with co-mill and Peristaltic pump (Capacity 100 Liters) make Gansons (HSMG 100) shall be revised to add procedure for verification of recipe reports, audit reports and batch reports and after implementation of	Production: Revision of SOP TCD:……. Implementation of new SOP for verification of electronic data TCD: …….						

RISK ASSESSMENT FOR GxP RELATED GAPS IN RAPID MIXER GRANULATOR

S.No.	Potential failure mode	Potential failure effect	SEV (S)	Potential causes	OCC (O)	Current Process control	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
						Management".				long term (Up gradation of System) plan however new sop shall be implemented for electronic data verification of each Batch.							
Electronic Record & Electronic Signature																	
29	No any documented system is in place for the data reviewer to review appropriate electronic and hardcopy data (including metadata, relevant audit trails, etc.) generated by the instrument/system.	1. Mismatch in the system generated electronic data and hard copy data.	6	1.Lack of procedure.	5	1. Procedure for batch record review is in place as per SOP "Batch Release procedure". As per the Batch record review checklist, electronic processing data of equipment shall be verified (whichever applicable). Discrepancy related to difference in electronic data and executed batch record shall be handled through SOP (Event Management).	4	120	Low	1. Electronic data of data processing shall be part of BMR and verified during batch processing itself so; review of electronic and hardcopy data shall be mitigated. However; procedure shall be made to review electronic data like metadata, relevant audit trails if current system is updated successfully.	Production: procedure shall be made to review electronic data like metadata, relevant audit trails if current system is updated successfully (Part of CSV) TCD: ……..						

13.0 Risk Control Measures:

Investigation / Findings:

- Risk analysis study performed against the identified gaps as per document number ……..; it is revealed that equipment …… make: Ganson has some lapses with respect GxP controls that were resulted due to non-availability of requirements in the initial URS and limitation of equipment.

Corrective Action:

- It has been proposed to upgrade the GxP requirement for Equipment …….. by preparing addendum URS as per SOP …… and by conducting addendum computer system validation after system up gradation. Detailed corrective actions are tabulated in the FMEA table.

14.0 Summary & Conclusion Report for Risk Assessment:

Summary:

On the basis of risk assessment study it is evident that Equipment …… has gaps related to GxP requirements which have resulted due to some gaps in the site procedures however; control measures like batch records, equipment logbooks, personnel training, data review and verification, Biometric access control in the manufacturing area etc are already in place for mitigation and acceptance of the risk. Further; corrective actions have been recommended to upgrade the system inline with the GxP requirements.

Conclusion:

Based on the above mentioned risk assessment; it is concluded that the current process controls are capable enough to mitigate the identified risk and equipment …… shall be used with acceptance of risk based on available process controls. Further system up gradation shall be performed inline with the GxP requirements.

15.0 Final Report Approval (Pre assessment):

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable). Signature in the block below indicates that all the control measures are in place/identified ,documented and have been reviewed and found to be acceptable.

Responsibility		Name	Signature	Date
Prepared By	**Quality Assurance**			
Reviewed By	**Quality Assurance**			
	Production			
	Information Technology			
	Engineering			
Approved By	**Head Operation**			
	Head Quality Assurance			

16.0 Final Report Approval (Post assessment):

The final report shall be signed after implementing all the recommended actions and based on the implementation of actions, reclassification of risk was completed. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates. All the control measures taken are documented and have been reviewed and found to be acceptable.

Responsibility		Name	Signature	Date
Prepared By	**Quality Assurance**			
Reviewed By	**Quality Assurance**			
	Production			
	Information Technology			
	Engineering			
Approved By	**Head Operation**			
	Head Quality Assurance			

17.0 Risk Communication:

The above quality risk assessment is shared with the following process owner and management.

1. Quality Assurance.
2. Production
3. Information Technology
4. Engineering
5. Corporate Quality Assurance

18.0 Abbreviation:

SOP	:	Standard Operating Procedure
FMEA	:	Failure Mode Effect Analysis
CFR	:	Code of Federal Regulation
CSV	:	Computer System Validation
PLC	:	Programmable Logic Controller
VMP	:	Validation Master Plan
URS	:	User Requirement Specification
GAMP	:	Good Automated Manufacturing Practice
PLMS	:	Pharmasol Learning Management Solution
TCD	:	Target Completion Date
HMI	:	Human Machine Interface
QRM	:	Quality Risk Management
QMS	:	Quality Management System
CAPA	:	Corrective Action and Preventive Action
GACR	:	Gap Assessment cum Report
RPN	:	Risk Priority Number
RAS	:	Risk Assessment
DI	:	Data Integrity
SME	:	Subject Matter Expert
PPQ	:	Process Performance Qualification
RMG	:	Rapid Mixer Granulator