PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Quality Risk Assessment for Batch Processing

1. Risk Assessment:

Risk Assessment (Problem statement and reference no. if any)
a) To identify the potential risks for the manufacturing procedure in the existing facility.
b) To describe the available control measures to prevent the potential risk of product manufacturing.
c) This Risk Assessment describes the control measures in place, with respect to facility, equipment, personnel training, procedures and practices to prevent any potential risk identified and the requirement of any additional control measures.

A.	**Risk Identification**				**Risk Analysis/ Evaluation**				
S.No.	**Item or Process Step**	**Potential risk and/or Failure mode**	**Probable impact of potential risk and/or failure mode**	**Current control measures**	**S**	**O**	**D**	**RPN**	**Risk Level**
1.	**Documentation**	MFC Not Followed during Preparation of master batch manufacturing record. Improper review of master batch manufacturing record. Non-availability of authorized Batch Manufacturing Record (BMR) for product manufacturing.	Transcription error may lead to manufacturing of non GMP product. Impact on patient health due to manufacturing of non GMP product. Product recall / market complaint may happen due to manufacturing of quality impacted product.	As Per SOP, BMR shall be reviewed and checked by Production, IPQA, Production Head & Head Quality personnel. Elaborated procedure is available in SOP for material verification and preparation of batch manufacturing record. Change control procedure is in place for tracking of documentation w.r.t BMR/BPR preparation.	4	2	1	8	Low Risk

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		Authorization of incorrect document.	Impact on business due to product may not be manufactured/delay in manufacturing.						
2.	**Dispensing**	• Dispensing of unapproved materials. • Dispensing of wrong AR No. of material. • Dispensing of wrong quantities of raw material. • Dispensing of expired or under test materials. • Mix up and contamination of materials during dispensing.	• Impact on patient health due to manufacturing of product by using incorrect material. • Product recall / market complaint may happen due to manufacturing of quality impacted product. • Impact on business due to supply of non GMP product	• Dispensing of material shall be done as per SOP and status of each material is verified in ERP system before dispensing. Provision for verification of material is given in batch manufacturing record. • Dispensing of material shall be done as per SOP and status of each material is verified in ERP system before dispensing. • Upon release approved label is being pasted on each container of approved material by QC person and simultaneously the	4	2	1	8	Low Risk

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				material is release in ERP system. • Dedicated storage locations are provided for storage of material as per relevant stages (Approved/Under teat / Rejected). • Dispensing activity is being carried out as per respective SOP • Line clearance is a part of BMR and being done as per BMR . • Verification of cleaning of dispensing area and accessories is a part of Line clearance.					
3.	**Material verification**	Improper handling of material.	Different material may be used in the batch.	All the dispensed materials are verified against BMR before further processing, duly signed by trained persons from Warehouse department, Production	4	3	1	12	Low Risk

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				followed by QA person.					
		Usage of uncalibrated weighing balances.	Wrong material usage in product manufacturing leads to Product recall due to failure of product. Error occurred during material verification.	Procedure for verification of weighing balance shall be carried out as per SOP is available. Calibration is being verified during line clearance by IPQA person. Trained personnel are engaged for specified activity.	3	3	1	9	Low Risk
		No label in the dispensed material.	Mislabeling or Mix up	All the product containers, equipment's are properly labeled as per SOP. Dispensed materials are issued through QA and is verified against BMR at the time of usage.	4	3	1	12	Low Risk
		Improper sifting & Particle size distribution.	Product recall / market complaint may happen due to impact on quality of the product.	Sieve is selected as per respective BMR and integrity checks before and after usage done by	4	1	2	8	Low Risk

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4.	**Sifting**			production and same recorded in BMR.					
		Wrong sieve usage. Usage of damage sieve. Sifter gasket torn/damage during sifting.	Non uniform product blend.	Provision of verification of sieve ID, Size of sieve, integrity testing before and after usage is specified in BMR. Preventive maintenance of the sifter is performed as per the respective SOP.	4	2	2	16	Low Risk
		Sieve torn or de shaped during sifting.	Impact on product quality.	Sieve integrity check before start and after completion of operation through sieve inspection assembly as per SOP No. Certificate is available for all sieves and verified before use of new sieve.	4	2	2	16	Low Risk
		Dust generation during sifting operation	Contamination of the product and person	Provision for wearing of secondary gowning as per SOP for general instruction is in place while working in processing area.	4	2	1	8	Low Risk

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				Dust collector system over sifter is available.					
5.	**Granulation**	Increase/decrease Inlet Temperature	Impact on product/ improper binding	Instruction for recording of inlet temperature is a part of BMR.					
		Improper fluidization	Yield loss	SFM process is in place					
		Inadequate drying	Impact on product, Tablet not compressed properly.	Provision of LOD monitoring is a part of BMR					
6.	**Blending and lubrication**	Improper mixing	Product recall / market complaint may happen due to impact on quality of the product. Failure of Assay	Mixing time is followed as mention in BMR. Specifications for setting VFD and time of revolution are mentioned on respective BMR. The mixing time and lubrication time is specified in the respective batch record. Process validation for the	4	1	2	8	Low Risk

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				product is performed as per SOP. Process is handled by the trained personnel as per BMR and blend uniformity study is conducted as per validation protocol.					
		No dust extraction system	Contamination of the product	Suitable dust extraction system installed in the area to remove excess powder.	4	2	1	8	Low Risk
		Improper cleaning of equipments and accessories	Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator	All the equipments and accessories are cleaned as per the respective cleaning SOP.	4	2	1	8	Low Risk
		Improper transfer of equipment assembly to wash area.		All the parts are enclosed in poly bag and then are transferred to wash area. All the parts are to be transferred by material transferring trolley. Cleaning Procedure is	4	2	1	8	Low Risk

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				mentioned in respective equipment SOP.					
		Un cleaned containers.		Containers are cleaned as per SOP.	4	2	1	8	Low Risk
		Un –cleaned dust collector assembly		Dust collector is cleaned as per SOP Trained personnel are engaged for specified activity.	4	2	1	8	Low Risk
		Incomplete log books and other records.	cGMP non compliance	Completeness of the previous log books and records are verified during line clearance. Personnel are trained for good documentation practice.	3	2	1	6	Low Risk
		Improper environmental condition.	Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator.	Environmental monitoring is a part of BMR and same is verified during line clearance. Environmental monitoring is done as per SOP no.	4	2	1	8	Low Risk

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			cGMP non compliance						
7.	**Compression**	Noncompliance of physical appearance tablets	Failure in critical quality attribute	Punch inspection shall be performed by Production and verified by QA as per SOP. Punch verification by production and QA before fixing to compression machine which is mention in BMR	4	2	1	8	Low Risk
		Improper performance of metal detector	Product will get contaminated with metal particles which may cause temporary medically reversible adverse health condition of patient.	Metal detector Challenge test Perform by trained production personnel, checked QA and record the same in respective BMR. Preventive maintenance of the metal detector is performed as per the respective SOP Metal detector is operated and cleaned as per SOP.	3	3	1	9	Low Risk

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				Rejection criteria are verified at the start and end of the process as per SOP.					
		Improper performance of dedusting device.	Improper handling of dedusting device Scheduled Preventive maintenance of metal detector not performed.	Dedusting device is operated and cleaned as per SOP. Preventive maintenance of dedusting device is performed as per the respective SOP	4	2	1	8	Low Risk
		Improper performance of dust extractor unit.	Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator	dust extraction system installed along with the equipment. Efficient dust extraction units is operated and cleaned as per SOP No.	4	2	1	8	Low Risk
		Improper performance of compression machine	Failure in critical quality attributes	Preventive maintenance of the Compression machine is performed as per the respective SOP Trained personnel are	4	2	1	8	Low Risk

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				engaged for specified activity.					
		Emptying of hopper not detected	Weight variation. efficacy	Sight glass is provided in the hopper. Powder level sensor is provided which will generate alarm and interlocked if powder level is lower than the limit.	4	2	1	8	Low Risk
		Generations of defective tablets during compression	High rejection in the Product	Proper checking of physical appearance defective tablets, uniformity of weight, thickness and hardness is monitoring during startup test and IPQA and then frequent monitoring by production and IPQA which are mention in BMR. Proper labeling and	4	2	1	8	Low Risk

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				handling of rejects tablets as per SOP. Preventive maintenance of the Compression machine is performed as per the respective SOP.					
8.	**Coating**	Non-compliance of physical appearance of tablets after coating.	Failure in critical quality attributes.	Coating activity is handle by trained personnel's and instruction are followed as per SOP and BMR.	4	2	1	8	Low Risk
		Generation of defect tablet during coating.	Failure in critical quality attributes.	Proper parameter during coating are monitored and recorded in BMR at regular intervals.	4	2	1	8	Low Risk
9.	**Tablets Inspection**	Non-compliance of physical appearance of tablets after inspection.	Failure in critical quality attributes.	Trained personnel are engaged for specified activity.	4	2	1	8	Low Risk
10.	**Sampling**	Improper sampling	No procedure mentioned for sampling. Improper operation of sampling device. Untrained personnel.	Sampling is to be done as per the SOP Sampling rod and compaction machine used for blend sampling is done as per SOP	4	3	1	12	Low Risk

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				All the personnel's are well trained for the specified activity.					
11.	**Machine and Area Cleaning**	Improper cleaning of Manufacturing area and Machine	Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator cGMP non-compliance.	Cleaning of production cubicle is done as per SOP Cleaning of machine is done as per respective SOP. The cleanliness status is verified from the 'Equipment Cleaning Checklist and area-cleaning checklist. Equipment cleanliness is checked by production and verified by IPQA personnel as part of line clearance prior starting activity. Area status is labeled properly as per respective SOP.	4	2	1	8	Low Risk

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				Equipment and area shall be considered as ready for use if the equipment bears a 'Cleaned' label, and is within the 'Use Before' date stated on the label and the area status label indicates that it is 'Cleaned'.					
12.	**Storage**	Improper storage	Storage of product in quarantine area with uncontrolled condition of temperatures and relative humidity	Environmental monitoring for temperatures and relative humidity is done by production on daily basis. Maintained temperature and relative humidity as mention in SOP manufacturing of bulk product.	4	2	1	8	Low Risk
13.	**Movement of material /personnel from one processing area to another**	Improper movement of material /personnel	Impact on product quality. Personal hazard.	Manufacturing of one product at a time in the process area as given in SOP no. "Manufacturing of bulk product".	4	2	2	16	Low Risk

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	processing area			Before entry in the process is the gowning procedure (Secondary gowning) is followed as per SOP. Cleaning and clearance of the process area/equipment prior to execution of Product. The process area and equipped with Air handling unit for proper maintain of differential pressure. Storage of batches/product in designated places with proper segregation and labeling. Movement of materials from one area to another area done through approved area and trained					

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				personnel.					

B.	Risk Reduction/ Acceptance					Risk Review					
S.No.	**Potential risk and/or Failure mode**	**Risk level**	**Risk Acceptance Yes / No**	**Justification**	**Any action/ Mitigation plan for reduction**	**S**	**O**	**D**	**RPN**	**Final Risk Level**	**Residual Risk**
1.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Quality Risk Assessment for Batch Processing

2. Conclusion:

3. Abbreviations:

S.No.	Abbreviation	:	Description
1.	SOP	:	Standard Operating Procedure
2.	IPQA	:	In Process Quality Assurance
3.	BMR	:	Batch Manufacturing Record
4.	No.	:	Number

4. Risk Review and Approval:

S.No.	Name	Designation	Department	Sign/Date