Name of System & Subsystem/ Unit Operation/ Utility /Equipment /Process/Product: Risk assessment for the product Levonorgestrel 150 mcg and Ethinylestradiol 30 mcg Tablets

Process step /Function/ Item	Potential Failure Mode (Failure Mode)	Potential effect of failure	Severity (S)	Potential Cause	Probability(P)	Current Control/ Current Testing	Detection (D)	RPN= SXPXD (High*/ Medium/ Low)	Risk Accepted (Y/N)
Documentation	• Improper review of master batch manufacturing record. • Non availability of authorized Batch Manufacturing Record (BMR) for product manufacturing. • Authorization of incorrect document.	• Impact on patient health due to manufacturing of non GMP product. • Product recall / market complaint may happen due to manufacturing of quality impacted product. • Impact on business due to product may not be manufactured/delay in manufacturing.	5	• Inappropriate procedure to handle the master BMR (Batch Manufacturing Record). • Usage of not reviewed and/or unauthorized document. • Untrained person is involved in review and handling of master document.	2	• Master BMR is being prepared and reviewed against documents PTD (Product transfer details) provided by DRA through QA department. • As per SOP new BMR is incorporated in system through change control procedure. Change control is being reviewed and approved by cross functional team. • BMR is being reviewed and approved by cross functional team such as production/QA/DRA. • As per procedure only authorized and effective documents are issued for usage by QA. • Production planning is being done on monthly basis. Availability of authorized documents is being verified by production personnel against monthly production plan.	1	10	Y

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Dispensing	• Dispensing of un approved 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.	4	• Improper storage/handling of material. • Improper selection of material for dispensing. • Improper labelling of material in various stages (under test/approved /rejection) • Improper procedure of dispensing. • Inadequate checks during dispensing. • Inadequate balance calibration. • Inadequate checks of raw materials status before dispensing. • Improper handling of materials during dispensing & improper cleaning of tools and vessels to be used during dispensing.	2	• The status of each material is verified in SAP system before dispensing, material is being dispensed according to FIFO system as per respective SOP. • Upon release approved label is being pasted on each container of approved material by QC person and simultaneously the material is release in SAP. 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. • API calculation is a part of BMR and being checked by QA. • Dispensing is done as per standard quantity of BMR/BPR by warehouse personnel, checked by production personnel and verified QA personnel. • 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.	1	8	Y

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Material verification	• Improper handling of material	• Different material may be used in the batch.	4	• No verification of the material before processing. • Untrained person	3	• All the dispensed materials are verified against BMR before processing. • Trained person are for specified activity.	1	12	Y
	• Usage of uncalibrated weighing balances.	• product recall due to Wrong material quantity usage Error in material verification.	3	• No established calibration procedure. • Untrained personnel.	3	• Calibration of the weighing balance is to be performed as per SOP. • Calibration is being verified during line clearance by IPQA person. • Trained personnel are engaged for specified activity.	1	9	Y
	• No label in the dispensed material.	• Mix up	4	• No procedure for labeling. • No verification of labels.	3	• All the product containers, equipments are properly labeled as per SOP. • Labeling verified during line clearance. • Dispensed material label is verified against BMR at the time of usage.	1	12	Y

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Sifting	• Improper sifting & Particle size distribution.	• Product recall / market complaint may happen due to impact on quality of the product.	4	• Improper checking of sieve number and Sieve integrity.	1	• Sieve is selected as per BMR and integrity checks before and after usage done by production and same recorded in BMR.	2	8	Y
	• Wrong sieve usage. • Usage of damage sieve. • Sifter gasket torn/damage during sifting.	• Non uniform product blend.	4	• Poor quality of sifted material. • Sieve not fix properly. • No checking procedure of gasket. • Poor assembling of sifter.	2	• Verification of sieve done before operation by production & QA person as per specified size & ID No & recorded in BMR & log book. • Preventive maintenance of the sifter is performed as per the respective SOP. • During line clearance assembly of sifter should verified by production & QA. • Trained personnel are engaged for specified activity.	2	16	Y
	• Sieve torn or de shaped during sifting.	• Impact on product quality.	4	• Poor quality of sieve material used .	2	• Sieve integrity check before start and after completion of operation. • Certificate is available for all sieves and verified before use of new sieve.	2	16	Y

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Cont…	• Dust generation during sifting operation	• Contamination of the product • Low product yield	4	• Improper closing of dust extraction hood	2	• Wear hand gloves, nose mask over gown and pressure suit properly • Assemble the Dust collector system over sifter • Yield is being monitor in BMR.	1	8	Y
Blending and lubrication	• Improper mixing	• Product recall / market complaint may happen due to impact on quality of the product.	4	• Inadequate mixing time. • No specification for setting VFD and revolution time • The mixing time and lubrication time is not specified. • No process validation performed for the batch. • Untrained personnel.	1	• 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 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.	2	8	Y
	• No dust extraction system	• Contamination of the product	4	• No dust extraction system installed	2	• Suitable dust extraction system installed in the area to remove excess powder.	1	8	Y

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Cont…	• Improper cleaning of equipments and accessories	• Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator	4	• No procedure for cleaning of the equipments and accessories	2	• All the equipments and accessories are cleaned as per the respective cleaning SOP.	1	8	Y
	• Improper transfer of equipment assembly to wash area.		4	• No procedure available for sifting the assembly parts to wash area.	2	• 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 mentioned in respective equipment SOP.	1	8	Y
	• Un cleaned containers.		4	• No procedure available for cleaning of the containers.	2	• Containers are cleaned as per SOP.	1	8	Y
	• Un –cleaned dust collector assembly		4	• No procedure for cleaning of dust collector assembly. • Untrained personnel	2	• Dust collector is cleaned as per SOP. • Trained personnel are engaged for specified activity.	1	8	Y

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Cont…	• Incomplete log books and other records.	• cGMP non compliance	3	• No online documentation. • Untrained personnel	2	• Completeness of the previous log books and records are verified during line clearance. • Personnel are trained for good documentation practice.	1	6	Y
	• Improper environmental condition.	• Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator. • cGMP non compliance	4	• No environmental monitoring before or during the process.	2	• Environmental monitoring is a part of BMR and same is verified during line clearance. • Environmental monitoring is done as per SOP.	1	8	Y

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Compression Cont…	• Non-compliance of physical appearance tablets	• Failure in critical quality attribute	4	• Wrong selection punches and die	2	• 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	1	8	Y
	• Improper performance of metal detector	• Product will get contaminated with metal particles which may cause temporary medically reversible adverse health condition of patient.	3	• Improper performance of Metal detector Challenge test. • Scheduled Preventive maintenance of metal detector not performed. • Improper handling of metal detector.	3	• 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. • Rejection criteria are verified at the start and end of the process as per SOP.	1	9	Y

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Cont…	• Improper performance of dedusting device.	• Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator	4	• Improper handling of dedusting device • Scheduled Preventive maintenance of metal detector not performed.	2	• Dedusting device is operated and cleaned as per SOP. • Preventive maintenance of dedusting device is performed as per the respective SOP.	1	8	Y
	• Improper performance of dust extractor unit.	Contamination of product which may cause temporary, medically reversible adverse health condition of patient/operator	4	• No dust extraction system installed along with the equipment. • Efficient dust extraction units is not operated and cleaned as per SOP	2	• dust extraction system installed along with the equipment. • Efficient dust extraction units is operated and cleaned as per SOP.	1	8	Y
	• Improper performance of compression machine	• Failure in critical quality attributes	4	• Preventive maintenance of the Compression machine is not performed as per the respective SOP. • Trained personnel are not engaged for specified activity	2	• Preventive maintenance of the Compression machine is performed as per the respective SOP. • Trained personnel are engaged for specified activity.	1	8	Y

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Cont…	• Emptying of hopper not detected	• Weight variation. efficacy	4	• No indication in case of hopper is empty. • Powder level sensor is not provided.	2	• 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.	1	8	Y
	• Generations of defective tablets during compression	• High rejection in the Product	4	• Improper setting of compression machine • Preventive maintenance not done properly	2	• 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 handling of rejects tablets as per SOP. • Preventive maintenance of the Compression machine is performed as per the respective SOP.	1	8	Y

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Coating	• Non-compliance of physical appearance of tablets after coating.	• Failure in critical quality attributes.	4	• Improper setting of coating machine.	2	• Coating activity is handle by trained personnel's and instruction are followed as per SOP and BMR.	1	8	Y
	• Generation of defect tablet during coating.	• Failure in critical quality attributes.	4	• Variance in coating parameters against standard limit.	2	• Proper parameter during coating are monitored and recorded in BMR at regular intervals.	1	8	Y
Tablets Inspection	• Non compliance of physical appearance of tablets after inspection.	• Failure in critical quality attributes.	4	• Untrained personnel are engaged for tablets inspection.	2	Trained personnel are engaged for specified activity.	1	8	Y
Sampling	• Improper sampling	• Improper estimation of the quality of the Blend	4	• No procedure mentioned for sampling. • Improper operation of sampling device. • Untrained personnel.	3	• Sampling is to be done as per the SOP. • Sampling rod and compaction machine used for blend sampling is done as per SOP. • All the personnel's are well trained for the specified activity.	1	12	Y

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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.	4	• No procedure for cleaning of area and machine. • No verification procedure for cleaning. • No status label in area and equipment.	2	• 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. • 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'.	1	8	Y

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Storage	• Improper storage	• Degradation of Product	4	• Storage of product in quarantine area with uncontrolled condition of temperatures and relative humidity	2	• Environmental monitoring for temperatures and relative humidity is done by production on daily basis. • Maintained temperature 22± 5 and relative humidity NMT60% as mention in SOP manufacturing of bulk product.	1	8	Y
Movement of material /personnel from one processing area to another processing area	• Improper movement of material /personnel	• Impact on product quality. • Personal hazard.	4	• Procedure is not available for movement of material / personnel in processing areas.	2	• Manufacturing of one product at a time in the process area as given in SOP "Manufacturing of bulk product". • Before entry in the process are 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 personnel.	2	16	Y

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ABBREVATION(S):

S.No.	Abbreviation(s)	Description
1.	No.	Number
2.	PTD	Product transfer details of Manufacturing
3.	DRA	Drug Regulatory Affair
4.	SOP	Standard Operating Procedure
5.	IPQA	In Process Quality Assurance
6.	BMR	Batch Manufacturing Record

Based on RPN Number prioritize the risk and plan accordingly.

P: Probability, S: Severity, D: Detectability, RPN: Risk Priority Number, Y: Yes, N: No

*High risk shall be escalated to senior management by Head QA / Designee immediately through the urgent quality notification form.

	Compiled By	Reviewed By					Approved By
Name							
Signature & Date							
Designation							**QA Department Head /Designee**