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1.0 PURPOSE

To provide a procedure for action plan to be taken during failure of in-process checks.

2.0 SCOPE

2.1 This procedure is applicable for all solid oral dosage forms such as Tablets and Capsules at …….

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-house

3.2 Attachments

3.2.1 Nil

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Nil

4.2 Abbreviations

4.2.1 **IPC:** In-process Container

4.2.2 **LOD:** Loss on drying

4.2.3 **%:** Percentage

4.2.4 **QC:** Quality Control

4.2.5 **DT:** Disintegration time

4.2.6 **NFD:** Non-filling Detection

4.2.7 **ALU-ALU:** Aluminum-Aluminum

4.2.8 **QA:** Quality Assurance

4.2.9 **SOP:** Standard Operating Procedure

4.2.10 **No.:** Number

5.0 RESPONSIBILITY:

5.1 Production:

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5.1.1 To perform in-process tests as per the frequency.

5.1.2 To Stop the activity/machine immediately and inform Department Head and Quality Assurance.

5.1.3 To isolate the containers/IPC/Shipper, packed blister/strip/sachet and container between previous interval.

5.1.4 To investigate the matter with Quality Assurance.

5.2 Engineering:

5.2.1 To rectify the technical problem of equipment's if any.

5.3 Quality Assurance:

5.3.1 To perform in-process tests as per the frequency.

5.3.2 To inform the production Head and Quality Assurance Head.

5.3.3 To investigate the matter with Production.

5.4 Quality Assurance Head:

5.4.1 To ensure implementation of the defined procedure.

5.5 Plant Head:

5.5.1 To ensure implementation of the defined procedure.

6.0 Distribution:

- Quality Assurance
- Production
- Engineering

7.0 PROCEDURE:

7.1 In-process tests and their acceptance criteria shall be available for each stage during the production run.

7.2 User departments shall perform in-process tests as per the frequency specified in batch record.

7.3 Quality Assurance shall perform and record in-process tests as per the frequency specified in batch record during the batch run.

7.4 Following action shall be taken in case the results are not within the specified acceptance criteria.

7.4.1 Stop the activity/machine immediately and inform Department Head and Quality Assurance.

7.4.2 Isolate the containers/IPC/Shipper, packed blister and strip between previous interval where the same in-process test was performed and label as quarantine. Check whether results are within the acceptance criteria.

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Note:

1) In case of any **Reworking/Reprocessing** done on the batch/packs (such as de-foiling and repacking), subject the batch for **Stability Studies** (wherever applicable).

2) Check the **Calibration Status** of instrument/Equipment wherever applicable during the failures.

Production officer shall inform Department Head and Quality Assurance and investigate matter with Quality Assurance.

STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
Blending (Tablets/ capsules)	1. Loss on drying (LOD/water content) 2. Water activity (in case of effervescent products) 3. % Fines 4. Bulk density and Tapped density 5. Flow ability (Angle of Repose)	1. Repeat the test. Check whether results are within limit or not. 2. If still does not meet acceptance criteria, inform department head and Quality assurance. 3. Withdraw 5 samples at different location (i.e. composite) depth and perform the test for which results were out of specification. 4. If LOD is less, then add moisture and if it is more, then dry the granules and re-blend the batch. 5. If % fines are more, then add moisture (in case of FBE Product) or prepare the slug at compression stage then perform the sizing of the slug, followed by sifting and re-blend the batch. If it is less, then perform sizing of the granules and re-blend the batch. 6. If bulk density and Tapped density is more, then prepare the slug at compression stage then perform the sizing of the slug followed by sifting the granules and re-blend the batch. If it is less then perform sizing of the granules and re-blend the batch. 7. If flow ability is more, then decrease the % fines by preparing the slug at compression stage then perform the sizing of the slug followed by sifting and re-blend the batch. If flow ability is less, then perform sizing of the granules and re-blend the batch. 8. If still does not meet the acceptance criteria then take the compression trial. 9. If trial meets the QC/BMR specification, fill the deviation approval form.
Tablet Compression	1. Individual Tablet diameter variation. 2. Individual Tablet length	1. Stop the machine and inform Department head and Quality Assurance. 2. Repeat the test, check whether the results are within limit

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STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
	variation. 3. Individual Tablet breadth variation.	or not. 3. If the tablets are not as per standard given in BMR with the punch set used, then check the punch set for dimension and if they are out of limit, then the punch set cannot be used. 4. If still does not meet acceptance criteria, inform department Head and Quality Assurance.
Capsule Filling	Sealed/ Locked length of filled capsules	1. Stop the machine. 2. Isolate the Container / IPC and label it as quarantine. 3. Repeat the test, check whether the results are within limit or not. 4. Check the lock length of product collected in previous container, between previous in process sampling intervals by random sampling and isolate the containers which are not meeting the particular process parameter acceptance criteria. 5. Machine operator shall rectify the problem in consultation with production officer and or department head. **6. Put fresh container and set the machine as follows:** 7. Counter check the length of locking pins. 8. Check the alignment of locking pins with respect to cap and body bushes. 9. Check the empty capsules body and cap length with respect to QC specification. 10. Check the locking pad for dimple formation on the locking pad. 11. Put fresh container with label as trial, set the machine and perform the in process test. If it meets the requirement, perform the test on double the number of capsules. If it meets the limit, remove the containers and start collecting in the fresh containers/ IPC. 12. Go ahead with the routine capsule filling run. 13. Quarantined containers shall be 100% visually inspected for lock length variation and sorted capsules can be segregated. Activity shall be verified by Quality Assurance, and after approval of Quality Assurance container can be used for further stages.
Tablet Compression/	Appearance	1. Stop the machine.

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Capsule filling		2. Isolate the Containers/IPC's and label it as quarantine. 3. Check the appearance of product, collected in previous container between previous in-process sampling intervals by random sampling and isolate the containers in which in process parameters it is failing. 4. Production officer shall rectify the problem in consultation with Department Head and Quality Assurance. 5. Place fresh container, set the machine and perform the in process test. If it meets the requirement, start the Compression / Filling. 6. Quarantined containers shall be 100% visually inspected for appearance defect which can be segregated and activity shall be verified by Quality Assurance. After approval of Quality Assurance containers can be used for further stage.
Tablet Compression/ Capsule filling	1. Group Weight 2. Individual wgt variation/ uniformity of mass. 3. Average weight. 4. Individual thickness variation. 5. Individual hardness variation. 6. Disintegration time/ fizz time for effervescent tablet. 7. Dispersion time and uniformity of dispersion of dispersible tablets.	1. Stop the machine. 2. Isolate the Container/IPC and label it as quarantine. 3. Check the in process parameters of product collected in previous container between previous in process sampling intervals by random sampling. Isolate the containers in which in process parameter it is failing. 4. The decision for failing Containers/ IPCs shall be taken in consultation with Quality Assurance and Unit Head. 5. Place fresh container with label as trial, set the machine and perform the in process test. If it meets the requirement, perform the test on double the number of tablets. If it meets the limit, remove the containers used for trial and start collecting in fresh containers/IPCs. 6. Keep the trial Tablets/Capsules as rejects. 7. Go ahead with the routine compression run.
Tablet/ Capsule	1. Disintegration Test	1. Stop and check the machine. **FOR DISINTEGRATION TEST:** 2. **For Apparatus A:** If one or two tablets/capsules under test fail to disintegrate completely at the end of the specified time limits, repeat the test on 12 additional dosage units. Not less than 16 of the total 18 dosage unit tested shall disintegrate. 3. **For Apparatus B:** Test 6 tablets either by using 2 basket

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STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
		rack assemblies in parallel or by repeating the procedure. In each of the 3 tubes, place 1 tablet/capsule and if prescribed add a disc. Suspend the assembly in beaker containing the specified liquid. Operate the apparatus for prescribed period. Withdraw the assembly and examine the state of tablets/capsules. To pass the test, all 6 tablets/capsules must be disintegrated. 4. If the tablets being tested fail to comply DT limit (as per product specification) because of adherence with the disc, repeat the test further on six tablets omitting the disc.
Tablet	2. Friability Test	**FOR FRIABILITY TEST:** 1. Repeat the test twice and mean of the three tests shall be determined. 2. If the size or shape of tablet causes irregular tumbling, adjust the drum base so that it forms an angle of about 10° with horizontal and tablet do not bind together as it prevents them from falling freely when lying next to each other. 3. If still does not meet acceptance criteria, isolate the containers/IPCs and label it as quarantine. 4. Check the in-process parameters of product collected in previous container between previous in-process sampling intervals by random sampling. Isolate the container in which process parameter it is failing. 5. The decision for failing containers/IPCs shall be taken in consultation with Quality Assurance and Unit Head. 6. Production officer shall rectify the problem in consultation with Department head and Quality Assurance. 7. Put fresh container with label as Trial and set the machine. Perform the in-process test and if it meets the requirement, perform the test on double number of tablets. If it meets the limit, remove the containers and start collecting in the fresh containers/ IPC. 8. Keep the trial Tablets/Capsules as rejects. 9. Go ahead with the routine compression run/filling run.
Tablet compression/ Capsule filling	Metal Detection	1. Stop the machine. 2. Isolate the containers / IPCs and label it as quarantine.

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STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
		3. Repeat the metal detection sensitivity test by using the standard chips. If it meets the requirements, pass the isolated product containers/ IPCs once again and confirm the metal particle presence in the product. Record the details in Batch manufacturing record. 4. If repeat test fails, check the presence of metal particle in product collected in previous container between previous in-process sampling intervals by random sampling. Isolate the container in which in-process parameters it is failing. 5. The decision for failing containers/ IPCs shall be taken in consultation with Quality Assurance and Unit Head. 6. Production officer shall rectify the problem in consultation with Department head and Quality Assurance. 7. Put fresh container and set the machine. Perform the in-process test and if meets the requirement, then start collecting product in fresh containers/ IPCs. 8. Go ahead with the routine compression run.
Coating	Appearance, Thickness, Disintegration	1. Isolate the Lot/Batch and label it as quarantine. 2. Draw the samples from five different positions from each IPC and check all the parameters. 3. The decision for failing containers/ IPCs shall be taken in consultation with Quality Assurance and unit head. 4. Quarantine containers (Applicable for in-process test failing in appearance) shall be 100% visually inspected for appearance defect which can be segregated, and activity shall be verified by Quality Assurance. After approval of Quality Assurance, container can be used for next stage. 5. Stop the machine. 6. Isolate the Container/IPC and label it as quarantine. 7. Check the in-process parameters of product collected in previous container between previous in process sampling intervals by random sampling isolate the container in which in-process parameters it is failing. 8. Put fresh container, set the machine and perform the in process test and if it meets the requirement then perform test and if it meets the requirement, then perform the test

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STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
		on double the number of labels. If it meets the limits then start collecting in fresh Containers/ IPCs.
Packing	Camera/ NFD failure	1. Stop the machine and inform Department head and Quality Assurance. 2. Quarantine the strips/ blisters packed between the previous intervals where same test was performed and check whether the results are within acceptance criteria. 3. Ensure that no packed Strips/ Blisters/ Containers shall be online. 4. Check all the quarantined Strips/ Blisters by performing 100% inspection (Previous interval). 5. Rectify the NFD/ camera device. 6. In case of amber ALU-ALU opaque blister, defoil all the packed blisters in previous interval. 7. Check proper functioning of NFD and the loop sensor count and alert the checker. 8. Start the line for packing after QA certification.
Packing	Overprinting details, Embossing	1. Stop the machine. 2. Quarantine the Strips/ Blisters/ cartons packed between previous intervals where same test was performed and check whether results are within acceptance criteria. 3. Check 100% blister for overprinting/ embossing details from previous interval. 4. Check for damage of embossing stereo, web guide setting. Metallic stereo position in punch tool block, indexing rachet position and temperature in case of hot melt embossing. 5. Check the quality of ink, ink roller, felt roller for proper overprinting. 6. Check for overprinting/ embossing details. If found ok, start the line for packing. 7. Start overprinting/ embossing activity after checking proof from two production officer and Quality Assurance officer.
Packing	Pharmacode / 2D reader / Barcode reader failure	1. Stop the machine along with complete pack line and inform department head and Quality Assurance. 2. Quarantine the packs packed between previous intervals. 3. Ensure that no packed carton shall be on line. 4. Manually check item code of all the packs packed in

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STAGE	INPROCESS TEST	ACTION IF RESULTS ARE NOT WITHIN SPECIFIED LIMIT
		previous hour.
Packing	Functioning of Blister sensor, leaflet sensor, carton sensor of cartonator.	1. Stop the machine and inform department head and Quality Assurance. 2. Remove the filled cartons from rejection bin and check weigher. 3. Rectify the problem immediately and check proper functioning before starting the line after QA certification. **Note:** In this case shippers need not be quarantined because such packs are rejected by check weigher.
Packing	Check weigher	1. Stop the machine operation along with complete packing line. 2. Quarantine the packs weighed between the previous intervals. 3. Inform packing head and Quality Assurance for investigation. 4. Rectify the problem in Check weigher. 5. Verify/Calibrate the Check weigher as per respective SOP. 6. Pass all the quarantined packs packed in previous batch in presence of QA. 7. Restart the complete packing activity.
Packing	Loop sensor failure	1. Stop the machine and inform the Department Head and Quality Assurance. 2. Remove all blisters which are in Cartonator magazine, bucket, conveyor belt, Rejection box of Cartonator and Check weigher. 3. Ensure that no packed blister shall be on line. 4. Quarantine the shippers packed between the previous intervals. 5. Check each blister visually for missing tablet, forming quality, sealing quality, embossing quality/ overprinting quality/ perforation quality which was removed from cartonator magazine. Bucket or on Conveyor belt and packed between the intervals. 6. Pack the good blisters which are removed from cartonator or conveyor belt, rejection box of cartonator and check weigher and rejected quantity from quarantined shipper shall be replaced with good quantity

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		with all controls. 7. Set the loop sensor properly and shall be checked before starting the line. 8. All blisters of ALU-ALU pack and opaque foil shall be defoiled 100%.
Packing	Wrong force rejection counts observed in blister pack machine.	1. Stop the machine and inform department head and Quality Assurance. 2. Remove all blisters which are in Cartonator magazine, Bucket or on Conveyor belt, Rejection box of cartonator and check weigher. 3. Ensure that no packed blisters shall be on line. 4. Quarantine the shipper packed between the previous intervals. 5. Check each blister visually which was removed from cartonator magazine, Bucket or on conveyor belt rejection box of cartonator and check weigher packed between the intervals. 6. Pack the good blisters which are removed from cartonator or conveyor belt and rejected quantity from quarantined shipper shall be replaced with good quantity. 7. Reset the force rejection count and same shall be checked before starting the line. 8. All blisters of ALU-ALU pack and opaque foil shall be defoiled 100%.
Packing	Overprinting problem of inner carton / outer carton	1. Stop the machine and inform department head and Quality Assurance. 2. Quarantine the shipper packed between the previous interval and check 100%. 3. Ensure that no overprinted pack shall be on line. 4. Check all overprinted pack visually. 5. Rejected quantity from quarantined shipper shall be replaced with good overprinted pack. 6. Reset the overprinting and line officer shall ensure overprinting quality before starting the line.
Packing	Failure of overprinting quality on sticker label or carton	1. Inform department head and Quality Assurance. 2. Quarantine the shipper packed between the previous intervals. 3. Remove all the cartons from conveyor belt. 4. Each carton in the quarantined shipper shall be checked

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		for overprinting quality in descending number of shipper until good pack found. 5. Pack the good cartons which are removed from conveyor belt and rejected quantity from quarantined shipper shall be replaced with good quantity. 6. Reset the printer and overprinting quality shall be checked before starting the line.
Packing	Failure of vision system	1. Stop the machine and inform department head and Quality Assurance. 2. Remove all overprinted label/cartons from line. 3. Quarantine the shippers packed between the previous intervals. 4. Check each label/cartons visually for overprinting details. 5. Check the item code of sticker label for Pharmacode reader. 6. Rectify the problem in machine. 7. Line officer shall ensure proper functioning of vision system before starting the line.
Packing	Scoring/perforation	1. Stop the machine and inform department head and Quality Assurance. 2. Rectify the problem in machine. 3. Check all the quarantined packs packed in previous intervals. 4. Restart the complete packing activity after QA certification.
Packing	Pin Hole	1. Stop the machine and inform Department head and Quality Assurance. 2. Replace the roll with next good one. 3. Check all the quarantined packs packed in previous intervals. 4. Restart the complete packing activity. 5. If required reject the material.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared.			