PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: In Process Checks and Failure Handling During Manufacturing, Filling and Packing Operation	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for in-process check activity during the product manufacturing at stage of dispensing, granulation, compression, encapsulation, coating, inspection imprinting and packing operation and handling of failures reported during the in-process check.

2.0 SCOPE:

2.1 This procedure is applicable for in-process check activity and failure reported for in-process check during the manufacturing operation at site.

3.0 RESPONSIBILITY:

3.1	Production/IPQA Officer/Executive	:	For execution in-process check activity & report any failure of in process check.
3.2	IPQA	:	Issuance of incident form
3.3	Production/IPQA Shift In-charge	:	Evaluation of incident report
3.4	Head Production/QA	:	SOP Compliance.

4.0 DEFINITION (S):

4.1 **Incident:** An occurrence or event that interrupts normal procedure or precipitates a situation and does not provide a result or conclusion.

4.2 **In-process Check:** Checking and recording the physical parameters of a product at any stage of manufacturing. In-process is a process of monitoring a critical variable of process to ensure the quality of a final product. Which are acceptable in standard range.

4.3 **Event:** Any divergence / any dis-obeyance from the written approved procedure/ instruction or from laid down quality system or established standard in the organization.

5.0 PROCEDURE:

5.1 **Verification of Dispensed Material:**

5.1.1 Ensure the intactness and appropriateness of dispensed materials / Container before transferring of the dispensed material in the product processing area.

5.1.2 Verify the material Lot Number, Item code, Pack Number, AR Number, Batch Number, and Gross weight on label of each dispensed material as per material issuance sheet mentioned in the respective BMR/BPR.

5.1.3 After the verification of individual dispensed materials production personnel and IPQA personnel shall sign on dispensed material sheet.

5.1.4 During the verification of the dispensing of the materials, if any failure will report it will be subjected to the event as per the site procedure SOP ("Event management"). The fate of dispensed materials shall be determined by the outcome of reported event.

5.2 **Granulation:**

5.2.1 Production personnel shall check the sieve/ screen for integrity by visually with appropriate light source after each and every use and after the cleaning. Production personnel shall check the finger and filter bag visually after each and every use and after the cleaning. If any damages were observed or reported before or after the operation activity same shall be stopped immediately.

5.2.2 Production Personnel shall inform to the HOD / Shift in-charge for the reported issues, and event shall be initiated as per site procedure SOP ("Event management") and fate of batch shall be decided as per the outcome of event.

5.2.3 **Loss On drying (Powders/Granules):** Collect the sample and perform the test as per SOP ("In process check in manufacturing area"). Record the in process result in product BMR with affix the print out of reported result. The test of LOD shall be carried out as per product requirement as per mentioned in the BMR. However in case of validation batch outlet temperature limit will be validated with respect to specified LOD in BMR.

Note:

- For regular batch when desired LOD is not achieved at lower limit of outlet temperature then further drying to be continue till reach the desired LOD with in specified outlet temperature limit.

  Example: Outlet temperature 30-35ºC is validated limit for desired LOD 2±1% w/w is specified in BMR but drying stop to check the LOD at achieved outlet 32ºC. LOD observed 3.2 % w/w then further continue the drying operation up to achieved the outlet 35ºC to achieve the desired LOD.

5.2.4 During the in process check, if it was found that outlet temperature of FBD/ FBP is achieved but specified LOD limit of product is not achieved as per mentioned in BMR, event shall immediately

report to Production HOD/ Shift In charge, and it will subjected to event as per the site procedure ("Event management"). The fate of batch shall be determined as per the outcome of the event.

5.2.5 After start of operation doesn't aborted or stopped Moisture analyzer, till the test completed. If test aborted or stopped in between it shall be handle through event procedure as per SOP ("Event management").

5.2.6 At the granulation stage or compaction stage, any validated parameters of the product if found out of range during the routine manufacturing operation, it shall be reported as event as per the site procedure ("Event management"). The fate of batch shall be determined as per the outcome of the event.

5.2.7 During process if any malfunction/breakdown of machine observed, stop the specific activity, segregate the ongoing process material, and close the all open storage containers properly. Label all in process material with site procedure. Inform to HOD/Shift in charge, Engineering through work order as report the event as per the site procedure ("Event management").

5.3 **Compression:**

5.3.1 Issuance the archival of the punches and dies shall be carried out as per product specific BMR as per site SOP (Issuance, use and retrieval of punches and dies). Any damages reported before or after the use of dies and punches shall be reported as event as per the site procedure ("Event management"). The fate of impacted batches shall be determined as per the outcome of reported event.

5.3.2 Production operator shall ensure the compression machine setting as per the respective SOP and product specification as per mentioned in the BMR. The rejected tablets shall be handling through site procedure (Disposal in production department).

5.3.3 After setting load the blend into hopper, set the weight then thickness and followed by hardness, friability, DT etc. until set the desire parameter as per BMR. Tablets / blend generated during machine setting are separated labeled as rejects and handled as per SOP (Disposal in production department).

5.3.4 After completion of machine setting start up test of compression machine product specific in process check shall be carried out as per mentioned BMR and same shall be recorded. In process checks for product shall be carried out but not limited to. Appearance / Description , Dimension, Average weight, Uniformity of weight, Thickness, Friability Test, Hardness, Disintegration Time, Metal Detector challenge test and Uniformity of dispersion. All in process check shall performed as per site procedure SOP (In process check in manufacturing area).

5.3.5 Any error reported during the in process check of hardness test of tablets, like position in jaw, tablet slip from jaw, wrong number of sample, communication error, test shall not be aborted. Complete the

test and same printout slips shall be affixed in the respective BMR, considering sample quantity during reconciliation, print out slip shall be treated as invalidated. Stop the activity and initiate the incident failure report form as per procedure SOP (Cleaning, Operation and Calibration of Tablet Hardness Tester).

5.3.6 In process sample for compression activity shall be collected directly form outlet of Metal detector chute. Approximate required number of tablets shall be collected as per product specification specified in BMR. Sample shall collect in labeled self sealing bag; sample shall collect separately for LHS (left hand side of machine) and RHS (Right hand side of machine) as mentioned in BMR.

5.3.7 The appearance test of compressed tablet shall be checked as per the compression machine used for the compression activity so that impression of all upper and lower punches used during the compression activity can be verified. The sample shall be collected as per BMR instruction.

Note:- In case of Hardness and weight variation verification during compression process the print out shall be attached in BMR and only minimum and maximum value shall be recorded.

5.3.8 Complete set of in process check shall be carried out during any interruption reported.

5.3.9 Any abnormalities reported related to product specification during the compression activity beyond the validated range of the product, it will subjected to the event as per the Event procedure as per SOP (“Event management”).

5.3.10 Material shall be segregated and kept on “Hold” and further investigated. Fate of the batch shall be determined by the outcome of the reported event.

5.3.11 After start of operation doesn’t abort or reset friability test, Disintegration test and Hardness Test, till the test completed. If test aborted or stop in between it shall be handle through Event procedure as per SOP (“Event management”).

5.3.12 In case of event reported for a batch, for which sample has been collected for QC analysis (pooled sample) shall be persevered as per product recommended condition till the fate of batch decided?

5.3.13 “If any machine interrupted during running operation than following activity shall be carried out, remove powder from hopper /feed frame, Remove of all upper / lower punches from turret, setting of feed frame & scrapper plate shall be done by remove feed frame from machine, further proceed with startup of product as per respective BMR and resume the compression activity.

5.3.14 Compression activity carried out with mean of hardness at the time of startup, if mean hardness shift to upper and lower side from the start up parameter of mean hardness than machine re-setting carried out and there after resume the compression activity by in-process checks. Set range for the mean hardness is mentioned below :

For Mean hardness range - 0 - 50N Limit of mean hardness is ± 10 N, For hardness range - 51 - 100 N Limit of mean hardness is ± 15 N, For hardness range - 101 -150 N Limit of mean hardness is ± 20 N, For hardness range – 151-250 N Limit of mean hardness is ± 25 N, For hardness range - 251 - 300 N Limit of mean hardness is ± 30 N.

Further, ensure that hardness of tablet (Mean) of in process tablets always towards optimum mean hardness of the startup mean hardness. Ensure that all tablets hardness is within specified limit.

Note: Do not manually tap the hopper (Filled with powder blend) of compression machine during compression activity.

5.4 **Coating:**

5.4.1 In process checks for product shall be carried out but not limited to Appearance / Description, Dimension, Average weight, Average weight gain, Uniformity of weight, Thickness, Disintegration Time and spray rate. All in process check shall perform as per site procedure SOP (In process check in manufacturing area).

5.4.2 In-process sample for in process checks shall be collected directly from all containers, lot wise after completion of coating. Approximate number of tablets shall be collected as specified in BMR. Sample shall collect in labeled self-sealing bag.

5.4.3 For any parameter of coated tablets after coating does not comply as per specification during in-process then next lot shall not initiate for coating until finds the proper justification for failure. Put “Hold” on the status label of all container of effected lot.

5.4.4 If coating operation is paused in between process due to interruption in utility resources, machine breakdown, then stop the peristaltic pump and pull out the gun assembly from coating pan. Inform to HOD/shift in charge and engineering as per SOP (Procedure for breakdown Maintenance).

5.4.5 If take more than 30 minute for rectification then dry the tablets at specified temperature and cool at room temperature, unloaded the partially coated tablets with status label mentioned “Partially coated tablets”. Closed properly the remaining solution till rectification. Before restart the operation ensure hold time of coating solution is within use before date. If coating solution has crossed the established hold time period, event shall be raised as per SOP (“Event management”). The fate of impact batch shall be determined based on the outcome of reported event.

5.4.6 In case of schedule stoppage like shift change, lunch/dinner/tea break, any training activity, stop the peristaltic pump, warm the partial coated tablets, stop the inlet temperature /blower, exhaust blower/ damper and machine keep in inching mode. After resuming start the exhaust blower/damper, inlet

temperature. After reaching the bed temperature with in limit restarts the operation and records the same in BMR.

5.4.7 Any abnormalities reported related to product specification during the coating activity beyond the validated range of the product, it will subjected to the event as per SOP ("Event management").Material shall be segregated and kept on "Hold" and further investigated. Fate of the batch shall be determined by the outcome of the reported event.

5.5 **Capsule filling:**

5.5.1 Production operator shall ensure the encapsulation machine setting as per the respective SOP and product specification as per mentioned in the BMR. The rejected capsules shall be handling through site procedure (Disposal in production department).

5.5.2 In process sample shall be collected directly from outlet of metal detector chute. Approximate number of capsule shall be collected as per specified in BMR. Sample shall collect in labeled self-sealing bag.

5.5.3 In-process test shall be carried out for Appearance / Description, Average weight, Uniformity of weight, weight of net content, weight of empty shell, lock length of filled capsule, disintegration time, Metal detector challenge test as per site procedure SOP ("In process check in manufacturing area").

5.5.4 Any abnormalities reported related to product specification during the encapsulation activity beyond the validated range of the product, it will subjected to the event as per SOP ("Event management"). Material shall be segregated and kept on "Hold" and further investigated. Fate of the batch shall be determined by the outcome of the reported event.

5.5.5 At inspection stage Critical, Major, Minor defects shall be identified. For description of defects refer SOP (current version) Format /current version. Limits are to be followed for inspection stage as mentioned below in the Table - I, %age of Limits will be calculated directly from std. batch size of the product. If nos. crosses the alert limit value up to action limit no action is recommended. If nos. crosses the action limit value, event shall be logged and detailed investigation shall be conducted and attach in respective BMR. For any critical defect observed event shall be logged. Following limits are to be followed for inspection stage:-

Table - I

For single layer product:

Minor defects	Major defects	Critical defects
Alert limit :- 0.3% Action limit:- 0.4%	Alert limit :- 0.2% Action limit:- 0.3%	Alert limit :- 0% Action limit:- 0%

For Bi- layer product:

Minor defects	Major defects	Critical defects
Alert limit :- 0.6% Action limit:- 1.0%	Alert limit :- 0.3% Action limit:- 0.5%	Alert limit :- 0% Action limit:- 0%

Note: During compression, coating and capsule filling operation, the sampling container and the container containing rejected tablets/capsules shall not be placed at a same platform.

5.6 **Imprinting:**

5.6.1 Production Operator shall set machine setting (Process parameter) as per SOP and as per product specification mentioned in the BMR. Tablets used during machine setting will be treated as rejection and handle through SOP (Disposal in production department).

5.6.2 In process shall be performed as per frequency mentioned in BMR and in process check shall be carried out as per site procedure SOP (In process check in manufacturing area).

5.6.3 For in-process sample shall be collected directly form discharge chute. Sample shall collect in labeled self-sealing bag for appearance check and same is used as a good tablets.

5.6.4 Any abnormalities reported related to product specification during the imprinting activity subjected to the event as per procedure SOP ("Event management"). Material shall be segregated and kept on "Hold" and further investigated. Fate of the batch shall be determined by the outcome of the reported event.

5.7 **Liquid Manufacturing:**

5.7.1 During In process checking in liquid Manufacturing.

5.7.1.1 Follow the procedure of dispensed material refer point 5.1.

5.7.1.2 Visually check the clarity of the syrup till acceptance. If not complies stop the further process and investigate the reason of failure.

5.7.1.3 Check the pH of the bulk in pH meter. If pH is not in define limit then adjust the pH as per mentioned in respective batch manufacturing record.

5.7.1.4 Check the integrity of sieves visually against light source before, after every use and after cleaning.

5.7.1.5 Visually check the integrity of nylon cloth before filtration. If found any discrepancy before use then destroy as per SOP ("Disposal in production department"). Use the new nylon cloth for filtration.

5.7.1.6 Check the final volume of batch after completion of manufacturing process. If volume is less than make up the volume as instruction in batch manufacturing record.

5.7.1.7 If any failure or abnormalities were reported in the liquid filling operation, stop the activity immediately, inform to HOD/shift in-charge, report the event as per SOP ("Event management"). The fate of batch shall be decided through the investigation outcome.

5.8 In-process Checks during Packing Operation

5.8.1 In process checking of cartons and carton coding:

5.8.1.1 Item code of carton; check it against the material requisition slip (if applicable).

5.8.1.2 Check Batch number, Mfg. date, Exp. Date, Code Number. , Mfg. License Number, MRP (In domestic pack check against the MRP approved list) and any other special instruction (if applicable) on carton as per the printing instruction mentioned in the BPR.

5.8.1.3 If any mismatch/ illegible of information against mentioned specification observed then stop the printing activity in-case printing on carton printing machine. All printed carton shall be checked. Rectify the discrepancy and start the activity after approval of the proof of printed carton.

5.8.1.4 In case re-setting of carton coding done carton proof shall be re-checked and verified by production and QA officers and re-setting proof shall be kept in BPR.

5.8.2 In-process checking during container cleaning

5.8.2.1 Check the air pressure of the nozzle with respect to the respective batch packing record.

5.8.2.2 Check the Machine speed with respect to the respective batch packing record.

5.8.2.3 Check the cleanliness of the container.

5.8.2.4 Rejected containers shall be destroyed as per the site procedure.

5.8.3 In-process Checks during Primary Packing (Tablet / Capsule for Bulk Packing / Tablet / Capsule for Pouch Packing).

5.8.3.1 The machine setting shall be carried out as per the respective SOP and BPR. During the bulk filling operation, if any error reported related to count issue, same shall be reported as event as per SOP ("Event management"). The fate of batch shall be decided as per the outcome of the event.

5.8.3.2 Weight of container, Descant inserter, cotton inserter, capping of container, Container closing is checked during in-process as specified in BPR.

5.8.3.3 During induction sealing conveyor speed, color of text on induction liner in closure, challenge test for induction sealing machine, and power of induction sealing shall be verified as per frequency mentioned in BPR.

5.8.3.4 Check the leak test of bottle or container as per frequency mentioned in BPR. In-case failure of leak test stopped the packing activity. It shall be reported as event and shall be investigated as per SOP ("Event management"). The fate of batch shall be decided based on the event outcome.

5.8.4 In-process Checks during Secondary Packing (Tablet/Capsule for Bulk Packing/Tablet/Capsule for Pouch Packing).

5.8.4.1 Pharmacode challenge test to be performed online/offline as per frequency mentioned in BPR.

Coding details on label, Pharmacode reader performance, Camera challenge test (If applicable) ,No label conveyor challenge test, appearance of label, appearance of carton, quantity of bottle in the carton, quantity of leaflet in the carton, details on carton, details on shipper, quantity of carton in one shipper, numbering of shipper are checked during packing. If any discrepancy found during in-process, inform to HOD/ Shift in-charge for further step.

Note: Generation of specimen and proof checking after intermediate setting in between the running operation in critical equipment (Printers).

5.8.5 In-process checks during Primary Packing and Secondary Packing of Tablet / Capsule for Blister and Strip Packing.

5.8.5.1 Machine setting - during initial machine setting change parts lay out no. shall be verified from BPR. Rejects generated during machine setting shall be isolated and labeled as "Rejects".

5.8.5.2 After machine setting done cutting piece of web having impression of all embossing letters/stereo fixed on machine shall be re-checked and verified by production and QA officer and kept as proof in BPR.

5.8.5.3 Over printing / embossing on blister/strip, knurling cutting, horizontal cutting, vertical cutting, appearance of blister/strip shall be checked as per respected BPR.

5.8.5.4 If any abnormality found during in-process, rectify the problem and effected blister/strip shall be treated as rejects. During the course of time all the blister/strip shall be re-inspected for ensure any discrepancy.

5.8.5.5 In case re-setting for embossing letters/stereo done proof shall be re-checked and re-verified by production and QA officer and re-setting proof shall be kept in BPR.

5.8.5.6 Machine parameter like sealing temperature, air pressure (if applicable), machine speed, camera performance shall be recorded as define in BPR. If any abnormalities related to sealing temperature and air pressure reported in the operation of machine it shall be investigated as per SOP ("Event management"). All material shall be segregated and kept on the hold till the decision made through the event.

5.8.5.7 Check the leak test as per frequency mentioned in BPR. In-case failure of leak test stopped the packing activity. It shall be reported as event and investigated as per SOP ("Event management"). The fate of batch shall be decided based on the event outcome.

5.8.5.8 Embossing/over printing details, quantity of tablet/capsule per strip / Blister Number. of blister / strip insert in carton, no of leaflet insert in carton shall be checked during in-process as per frequency mentioned in BPR. If any discrepancy found inform to HOD/shift in-charge for further action.

5.8.5.9 Weighing of printed carton, carton to be packed as per respective pack profile. If any discrepancy observed then inform to the HOD/ Shift in-charge.

Precaution: During execution of cartons overprinting of products having serialization (Serial No to be overprint) on cartons for EU market (Blister lines and Bulk lines) which to be execute without aggregation procedure, following precaution shall be taken:

- Serial code status for attached specimen proof in batch packing record shall be updated after completion of batch packing activity by the production personnel in Reetrack system with remarks for code status changed.
- Serial code status for sample withdrawn in batch shall be updated after completion of batch packing activity by the QA personnel in Reetrack system with remarks of code status changed.
- If any overprinted carton with accepted code status is rejected due to defect in carton/FMD label application defect; same shall be rejected in Reetrack system by the production personnel with remarks of code status changed.
- On completion of batch packing activity, code status shall be updated and accepted carton quantity must be equal to dispatch quantity in Reetrack communicator. It shall be verified by both production and QA. Reconciliation shall be recorded in the Annexure-I "Annexure for reconciliation of available accepted codes with respect of accepted Code displayed in the Reetrack communicator".
  for the available accepted codes (Dispatch Quantity, Sample, and Specimen Proof) with respect of accepted code displayed in the Reetrack communicator. If any discrepancies observed then immediately stop the line and rescan the codes to verify the status in Reetrack Communicator till it complies. If after rescanning quantity not matches same shall be reported as event and investigated as per SOP ("Event management"). based on the outcome, decision shall made and fate of batch shall be decided.

5.8.6 During In process checking of bottle washing, check the following details.

5.8.6.1 Water Pressure (If purified water is used for cleaning of bottles): Check the smooth and accurate water flow in the bottle from the water nozzles and record the water pressure from both pressure gauges situated on the panel of the machine in respective BPR at start of the batch and then after every 2 hours or as mentioned in respective BPR.

5.8.6.2 Vacuum line alignment (If Air is used for cleaning of bottles): Check the alignment of vacuum line to the bottle for proper cleaning before starting the bottle washing.

5.8.6.3 **Air Pressure**: Check the accurate flow of air in the bottle from air nozzle (If purified water is used for cleaning of bottle then air is used from last 3rd wash cycle and during air wash cleaning of bottles air flows through all the three wash cycle) and record the air pressure from the pressure gauge situated on the panel of the machine at start of the batch and then after every 2 hours or as mentioned in respective BPR.

5.8.6.4 **Clarity Check:** At start of the bottle cleaning process, put 12 bottles on conveyor belt for cleaning and run the machine, take these 12 bottles from washing machine from the washed bottle unloading side.

5.8.6.4.1 Fill purified water to these bottles with the help of conical flask.

5.8.6.4.2 Pour the content of bottles into clean conical flask and visually check the clarity of water. The water should be clear. Record it in respective BPR.

5.8.6.4.3 In case water is not clear, then recheck water pressure (if purified water is use for cleaning), Smooth water flow from nozzles and cleanliness of water storage tanks to find out the cause of contamination and recheck the water pressure.

5.8.6.4.4 In case water is not clear, then recheck air pressure (if only air is used for cleaning), Smooth air flow from nozzles in the bottles and vacuum line alignment to find out the cause of contamination and recheck the air pressure.

5.8.6.4.5 Carry out the clarity check again after correction and record in respective BPR.

5.8.6.5 During In process checking of bottle filling and cap sealing, check the following details:

5.8.6.5.1 **Fill Volume and Torque test:** After machine setting and as per frequency mentioned in the BPR, check the bottles for fill volume and Torque test.

5.8.6.5.2 Take one filled bottle from each nozzle and number them accordingly.

5.8.6.5.3 Perform the torque test on bottles as per reference SOP (“Cleaning, operation & calibration of digital cap torque tester”).

5.8.6.5.4 Pour the solution of bottle in standardized measuring cylinder, leave the bottle in inverted position till complete drainage of liquid from the bottle, and check the volume.

5.8.6.5.5 Repeat the same procedure for rest of the '7' bottles and record in respective BPR.

5.8.6.6 **Leak Test:** Check the bottles for leakage as per reference SOP ("Cleaning and Operation of leak test apparatus for filled and sealed bottle") and record.

5.8.6.7 **Inversion Test for sealed bottle:** Place 1 bottle from each sealing head and number them accordingly & keep it in inverted position at the start of batch and after every 30 minutes interval till completion of batch, check the appearance of bottle and seal for leakage, If found satisfactory then use these bottle for further packing process.

If any bottle found leak then immediately stop the line and reported as event and investigated as per SOP ("Event management") based on the outcome, decision shall made and fate of batch shall be decided.

Note: Inversion Test and torque test is applicable only for product in which ROPP cap sealing is done.

5.9 During In process checking of bottle unit packs, check the following details where ever applicable:

5.9.1 Take three labeled bottles from the line before its packing in to corrugated boxes.

5.9.2 Check for correct and legible coding over the bottle and carton label, Item code (if applicable), Batch number, Mfg. Date, Exp. Date, Code Number, Manufacturing License Number)as per respective BPR.

5.9.3 Check for the presence of dropper / measuring cup/ leaflet as per respective BPR.

5.9.4 Check the item code number of leaflet as per material requisition slip (if applicable).

5.9.5 Record the in process check as per the frequency mentioned in the BPR.

5.10 **During In process checking of Packed and weighed corrugated box, check the following details:**

5.10.1 Size / No. of shipper and its ply against material requisition slip.

5.10.2 Coding details on the shipper label i.e. Product's Name, Batch number, Mfg. date, Exp. Date and Quantity packed in shipper.

5.10.3 In case of export products, special marking on the label and shipper.

5.10.4 Verification of the pack style of the shippers as per respective BPR.

5.10.5 Loose shippers are sealed with Red color BOPP tape (Printed with "LOOSE" in black color) and stamped with marking of "LOOSE PACK".

5.10.6 Stamp of "PHYSICIAN'S SAMPLE NOT TO BE SOLD" on the shipper of sample packed goods.

6.0 ABBREVIATIONS:

6.1 SOP : Standard Operating Procedure

6.2	Mfg.	: Manufacturing
6.3	Exp.	: Expiry
6.4	No.	: Number
6.5	BOPP	: Biaxial Oriented Poly Propylene.
6.6	BPR	: Batch Packing Record
6.7	Lic.	: License
6.8	ROPP	: Roll On pilfer proof
6.9	BMR	: Batch Manufacturing Record.
6.10	FBP	: Fluid bed processor
6.11	LOD	: Loss on drying

7.0 REFERENCE(S):

7.1 SOP for “Event management”.

7.2 SOP for In process check in manufacturing area.

7.3 SOP for In process checks during packing operation.

7.4 SOP for Destruction of material.

7.5 SOP for Status labeling.

7.6 SOP for Acceptable quality level Inspection for tablets & capsules.

7.7 SOP for Root cause analysis.

7.8 SOP for Inventory and storage of FBD finger bag / FBP finger bag /RMG filter bag.

7.9 SOP for Disposal in production department.

7.10 SOP for Checking of sieve integrity.

7.11 SOP for Issuance, use and retrieval of punches and dies.

7.12 SOP for Destruction of rejected dies and punches.

7.13 SOP for Cleaning, operation & calibration of digital cap torque tester.

7.14 SOP for Procedure for breakdown Maintenance.

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8.0 ANNEXURE(S):

Annexure no.	Tittle of Annexure	Format no.	Mode of Execution
Annexure- I	Annexure for reconciliation of available accepted codes with respect of accepted Code displayed in the Reetrack communicator.		Controlled Copy

9.0 DISTRIBUTION:

9.1 **Master copy :** Quality Assurance

9.2 **Controlled copy (s) :** Production department (02), Quality Assurance (01)

9.3 **Reference copy (s) :** Production Department (4 Copy)'

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	NA

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ANNEXURE I

Annexure for reconciliation of available accepted codes with respect of accepted Code displayed in the Reetrack communicator.

Frequency for reconciliation: Every two hours, after any breakdown and at the end of operation

Product Name: **Batch No.**

Table for Recording of Observation:

Date	Time	Recording of Observation for reconciliation of available accepted codes # with respect of accepted Code Displayed in Reetrack Communicator.		Shipper No.	Checked by (Production)	Verified by (IPQA)
		*Satisfactory	$ Not satisfactory			

Available accepted code include the dispatch quantity, Specimen proof attached in BPR, Sample withdrawn from product.

* Mark ‘‘OK’’ if reconciliation is found satisfactory and mark ‘‘NOT OK’’ if reconciliation is found not satisfactory.

$ if reconciliation of serial code not found satisfactory then immediately stop the activity and then rescan the serial code to verify.

Recoding of the rescanning activity:

Date	Start time	Stop time	Done by Prod. (Sign/Date)	Checked By Prod. (Sign/Date)	Verified by IPQA (Sign/Date)	@Remarks

@ If reconciliation not matched then handles the same as per instruction given in SOP.