STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: In-process checks during batch manufacturing and packing	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for In process checks during batch manufacturing and Packing.

2.0 SCOPE:

This SOP is applicable for In process checks during batch manufacturing and Packing.

3.0 RESPONSIBILITY:

Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Granulation:

4.1.1 Check the cleanliness of the area.

4.1.2 Check the relative humidity, temperature and differential pressure of the area.

4.1.3 Check the dispensed material with respective to BMR.

4.1.4 Transfer the sieve as per the instruction given in BMR.

4.1.5 Check the integrity of the sieve before and after sifting activity.

4.1.6 Transfer the screen as per the instruction given in BMR.

4.1.7 Check the integrity of the screen before and after milling activity.

4.1.8 Check the ampere reading at the end point granulation.

4.1.9 Product dedicated finger bag to be used.

4.1.10 Check the loss on drying of granules as per BMR instructions.

4.1.11 Check the yield of sifted and milled granules and lubricated granules.

Note: Ensure that the lubricated granules transfer to clean IPC bin and with proper status label.

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4.1.12 In case of any deviation inform to Q.A.

4.1.13 Check all the In process checks during granulation stage as per frequency and parameter given in Batch Manufacturing Record

4.2 Compression:

4.2.1 Check the cleanliness of the area.

4.2.2 Check the relative humidity, temperature and differential pressure of the area.

4.2.3 Check the individual weights of tablet from all station according to the total number of stations on the machine.

4.2.4 Check the weight of tablets as per Batch manufacturing record at the initial and after every 30 minutes.

4.2.5 Check the thickness and hardness initially and then at regular interval as per batch manufacturing record.

4.2.6 Check the disintegration time of tablet initially and then at regular interval as per batch manufacturing record.

4.2.7 Check the friability of tablets as specify in Batch manufacturing Record initially and then at regular interval as per batch manufacturing record.

4.2.8 Check the individual weight variation of all station initially and then at regular interval as per batch manufacturing record.

4.2.9 Pass the tablets through the metal detector. Challenge test with the test pieces is to be done at the start of operation, end of operation, at power failure and at every break in operation.

4.2.10 Check the yield of compressed tablets.

4.2.11 Check all the In process checks during Compression stage as per frequency and parameter given in Batch Manufacturing Record.

4.2.12 For slugging check hardness of slug and record the same in BMR.

Note: Ensure that the compressed tablets in SS container lined with double poly bags with proper status label.

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4.3 Coating:

4.3.1 Check the cleanliness of the area.

4.3.2 Check the relative humidity, temperature and differential pressure of the area.

4.3.3 Check the Inlet and exhaust temperature every 30 minutes.

4.3.4 Check the compressed air pressure and bed temperature.

4.3.5 Check the weight gain every 30 minutes and at the end of the coating operation.

4.3.6 Check the individual weight of 20 tablets after coating operation.

4.3.7 Check the disintegration time of coated tablets.

4.3.8 Check the thickness of coated tablets.

4.3.9 Check the filtration of coating solution in Muslin cloth.

4.3.10 Check all the In process checks during Coating stage as per frequency and parameter given in Batch Manufacturing Record and record the same in BMR.

4.4 Inspection:

4.4.1 Check the cleanliness of the area.

4.4.2 Check the relative humidity, temperature and differential pressure of the area.

4.4.3 Pass the tablets/Capsules on the inspection roller and find out the defect tablet/capsule .process to be checked at every 30 minutes intervals and record it in BMR.

4.4.4 After completion of Inspection collect the good tablets/capsules in ss container with proper status label and collect the rejected tablet/capsules in separate poly-bag and dispose it into water for destruction and note down the rejected qty. of tablets/capsules in respective BMR.

4.5 Packing:

4.5.1 Check the cleanliness of the area.

4.5.2 Check the relative humidity, temperature specified as per respective BPR and differential pressure of the area.

4.5.3 Check the relative humidity and temperature of blister / strip packing room.

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4.5.4 Forming temperature of blister pack machine to be checked at regular interval as per BPR.

4.5.5 Sealing temperature of blister/strip machine to be checked at regular interval as per BPR.

4.5.6 Leak test of blisters /strips to be checked initially and then at regular interval as per batch packing record.

4.5.7 Perform all in-process checks if the machine is idle for more than 1 hour.

4.5.8 Printed text matter to be checked after each change of roll/joint and proof attach in BPR.

4.5.9 Check individual weight of 20 packed cartons. Based on the average weight of the cartons, give the minimum weight (after deducting weight of half strip/blister) and maximum weight (after adding weight of half strip/ blister) for carton weighing.

4.5.10 Check net weight of 20 packed shippers and record in respective BPR then calculate shipper net wt. limit as per calculation provided in BPR. Give the minimum and maximum weight range for shipper weighing. If total quantity of shipper for a batch is less than 20 shippers, The entire shipper packed except loose shipper shall be considering for calculation. In case of only one loose shipper, the shipper shall be verified physically by production & QA.

4.5.11 If the shipper net weight is more or less than the shipper net weight limit then check the shipper for physical verification by production & QA, reweigh the shipper & record the weight.

4.5.12 If all the shippers' net wt. is within the specified limit then note down the minimum & maximum net wt. of shipper and physically verify the same shipper by production & QA.

4.5.13 In Case of any abnormality found during weighing, isolate the material and check the actual quantity of blisters/strips/cartons in the shipper and inform to department head and Quality Assurance department for necessary corrective action.

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4.5.14 Check the challenge test for NFD (Non-filled detector) device/ Camera at the start of the batch, every four-hour and at the end of batch packing (if applicable).

4.5.15 Check the horizontal, vertical cutting and knurling initially and then at regular interval as per batch packing record.

4.5.16 Verify the insertion of leaflet / Spoon / Silica gel etc. (Which is applicable) and record the same in batch packing record.

4.5.17 Check 100% visually for the overprinted carton and label.

4.5.18 Check 100% visually pack inserts and blisters / strips before packing on the belt.

4.5.19 Check the dispensed quantity of aluminum foil / PVC of one batch and transfer to Primary packing area.

4.5.20 Attach initial and every start up specimen aluminum foil / blister with printing / embossing to BPR after approval by QA.

4.5.21 Verify the sample of foil at every change of printed roll/joint in roll and attached to BPR.

4.5.22 Attach initial and every start up specimens of overprinted carton and foil in BPR if machine is idle more than one hour after approval by QA.

4.5.23 Store overprinted cartons under lock and key.

4.5.24 Ensure that during breaks no tablet should present in the web /chute of the machine.

4.5.25 Pack the de-foiled / De-blister Inspected tablets / Inspected Capsule at the end of the batch packing.

4.5.26 Destroy the rejection of de-foiled / De-blister Inspected tablets / Inspected Capsule by putting in water.

4.5.27 During packing of de-foiled / De-blister tablets / Capsule /rejected blister / Strip shall be destroyed and not use for further.

4.5.28 Check all the In process checks during Manufacturing and Packing stages as per frequency and parameter given in Batch Manufacturing Record and Batch Packing Record and record the same in respective BMR/BPR.

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4.6 Capsule Filling

4.6.1 Check the cleanliness of the area

4.6.2 Check the relative humidity, temperature given as per BMR and differential pressure of the area.

4.6.3 Check appearance, locking length Disintegration time& uniformity of weights initially and then at regular interval as per batch manufacturing record of capsule.

4.6.4 Check weight of 20 filled capsules initially and then at regular interval as per batch manufacturing record.

4.6.5 Challenge the Empty capsule sorter as per procedure given in the BMR and record the same.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

Nil

7.0 ABBREVIATION (S) /DEFINITION (S):

BMR : Batch Manufacturing Record.

BPR : Batch Packing Record.

PVC : Poly Vinyl Chloride

PVDC : Poly Vinyl Di-Chloride

Q.A. : Quality Assurance.

SOP : Standard Operating Procedure.

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---