PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production (Softgel)	**SOP No.:**
Title: Cleaning of Utensils and Accessories	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down the 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/ Manager-Production.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Medicament Preparation

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

4.1.2 Check the weight of dispensed raw materials with material issuance sheet of BMR.

4.1.3 Record the all parameters i.e. relative humidity, temperature and differential pressure into the BMR and area equipment log book.

4.1.4 Ensure the heating temperature from BMR prior to melting the materials on the hot plate. Set temperature should not to be exceed as specified in BMR.

4.1.5 Check all the materials mixing procedure as per given in the BMR and its mixing time and speed of the stirrer as per given in BMR.

4.1.6 Check the proper setting and function of lobe pump and homogenizer during homogenizing process.

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4.1.7 Check the proper shifting of medicament with Vibro Sifter as per the instruction given in BMR.

4.1.8 Check the chilled water in-let and out-let supply to the colloid mill during milling process.

4.1.9 Check the medicament temperature during milling of colloid mill and mixing process.

4.1.10 Check the proper handling process of ultrasonic water bath during materials dissolution. The operation process should be done in presence of production officer.

4.1.11 Check the proper nitrogen supply in medicament preparation vessel during manufacturing process, to avoid oxidation reaction of active material as per the instruction given in BMR.

4.1.12 Before de-aeration process check the proper setting for lid of medicament preparation vessel to the medicament preparation vessel.

4.1.13 Check the proper vacuum process of the medicament at the time of de-aeration process.

4.1.14 De-aeration process is apply to remove the entraped air from the medicament paste as per given instruction in BMR.

4.1.15 After completion of medicament manufacturing process calculate the actual yield of medicament and record into the respective BMR.

4.1.16 Inform to Q.A, if any deviation found from BMR specified limit.

4.2 Gelatin preparation:

4.2.1 Check and record the reading of relative humidity, temperature and differential pressure of the area in log book and respective BMR.

4.2.2 Check the weight of dispensed raw materials with material issuance sheet of BMR.

4.2.3 Before transfer of liquid materials into gelatin preparation vessel, properly check the anchoring of all connected flexible hose pipe and valve.

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4.2.4 Before starting the process check the temperature of jacket of gelatin preparation vessel.

4.2.5 Check the proper vacuum pressure limit of gelatin preparation vessel as per given in the BMR. The limit of the vacuum pressure should not be less or exceed to the prescribed in BMR.

4.2.6 Check the speed of the stirrer (RPM) and temperature of the material in the gelatin preparation vessel during mixing. It should not be maximum speed as per limit given in the BMR.

4.2.7 Check the chilled water supply and the temperature of the colour slurry during milling process. Record the milling time of the colour slurry into the respective BMR and in log book.

4.2.8 Check the proper filtration and mixing of the colour slurry.

4.2.9 Record all the in-process parameters into the BMR and log book simultaneously.

4.2.10 Check the water level into the jacket of gelatin holding tank and proper working of the heater and heating sensor.

4.2.11 Before unloading the gelatin mass properly check the consistency, presence of entraped air, black particles.

4.2.12 After completion of gelatin mass manufacturing process calculate the actual yield of gelatin mass and record into the respective BMR.

4.3 Encapsulation:

4.3.1 Check and record the reading of relative humidity, temperature and differential pressure of the area in log book and respective BMR.

4.3.2 Check the proper flow of medicament and gelatin mass from holding tank to the encapsulation machine during encapsulation process.

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4.3.3 Check the heating temperature of the spreader box, segment wedge, gelatin mass transfer pipe and gelatin holding tank as per limit given in the BMR.

4.3.4 Check the cooling drum duct temperature as per limit given in the BMR.

4.3.5 Check the ribbon thickness as per the limit given in the BMR.

4.3.6 Take out the all capsules from one row of die and check the filled net weight of the medicament in soft gel capsules as per given in the BMR.

4.3.7 Check the proper sealing of the soft gelatin capsule, lubrication roller, net loss of the medicament at a interval of time.

4.3.8 All these above parameters should be record in the respective BMR and log book.

4.3.9 Check the proper operational process of the tumbler dryer and the capsule discharge time into the capsule collection tray.

4.3.10 After batch completion in the Encapsulation process record the quantity of rejected capsules, gelatin mass consumption and gelatin net generated into the BMR.

4.4 Drying process

4.4.1 Transfer the filled capsules SS trolley into drying room. The trolley should be placed in the sequence and row.

4.4.2 The first entered capsules SS trolley should be kept in front of supply air and next capsules SS trolley kept in front of the return air.

4.4.3 Check and ensure that the relative humidity and temperature of the drying room not to be exceed as per specified limit in the BMR.

4.4.3 Double colored capsules shuffling should be done after every hours or as per description in the BMR.

4.5 Inspection:

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4.5.1 Check and record the relative humidity, temperature and differential pressure of the area into respective BMR and log book.

4.5.2 Take the inspected capsules poly bag randomly and check for rejected capsules as slugs, leakage, de-shape, black particles, and colour migration.

4.5.3 If found rejected capsules in poly bags. Then re-check the same poly bags.
In-process check is to be done at every 60 minutes intervals and record in BMR.

4.5.4 Ensure and check that all inspected and un-inspected capsules should be kept separately with proper labeling.

4.5.5 After completion of capsule inspection process, all good capsules are to be kept into double poly bags and tie with cabal tie.

4.5.6 Then it kept into HDPE container with status labeling and transfer to the inspected room.

4.5.7 All in-process checks should be record into respective BMR and log book.

4.5.8 Calculate the % yield of good capsule and rejected capsule and record into respective BMR.

4.6 Packing:

4.6.1 Before starting the packing process, properly check the packing materials that it should be same as per the respective BPR.

4.6.2 Before unloading the printed aluminium foil and PVC/PVDC film on liding, properly check the specification as per BPR.

4.6.3 Check the relative humidity, temperature as per specified limit of respective BPR and record the parameter into log book and BPR.

4.6.5 After line clearance from QA or before starting the machine due to break down or shift end attached the approved specimen of printed aluminum foil, overprinted carton, catch cover, leaflet into BPR.

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4.6.6 Record the all In-process parameters in BPR and log book according to the described interval of time as per BPR.

4.6.7 Record the forming and sealing heater temperature in BPR of blister machine at a regular interval of time.

4.6.8 Check the chilled water supply to the forming die should be checked during blistering process at a time of interval.

4.6.9 Check the challenge test for camera at the start of the batch, every four-hour and at the end of batch packing.

4.6.10 Check the blister knurling, horizontal cutting, printed text matter, proper cavity formation and capsules sticking at regular interval of time as per BPR.

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

4.6.12 Visually check and ensure carton over printing during packing process and record in the BPR of in-process check.

4.6.13 Verify the insertion of leaflet in carton packing during packing process and record into BPR.

4.6.14 Check the individual weight of 20 packed cartons according to the average weight. Set the lower/upper weight of the carton. The carton weight limit is set by adding ½ weight of blister for upper weight of carton and minus ½ weight of blister for lower weight of carton and record in respective BPR.

4.6.15 Check the net weight of 20 packed shippers and record in respective BPR then calculate shipper net weight limit as per calculation provided in BPR. Give the minimum and maximum weight range for shipper weighing.

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4.6.16 If total packed quantity of shipper for a batch is less than 20 shippers, then the entire shipper packed except loose shipper shall be consider for calculation. In case of only one loose shipper, the shipper shall be verified physically by production & QA personnel.

4.6.17 If the shipper net weight is differ to the weight limit, then check the shipper for physical verification by production and QA, and again weight the shipper and record in BMR.

4.6.18 If all shippers net weight is within the specified limit then separate the minimum and maximum net weight shipper and physically re-check by production and QA officer.

4.6.19 Check the written net weight and container numbering on the shipper during packing after a time of interval.

4.6.20 Check the dispensed quantity of printed aluminum foil, PVC/ PVDC with respective BPR and transfer to primary packing area.

4.6.21 Verify the specimen of printed aluminium foil at every change of printed roll/joint in roll and attached to BPR.

4.6.22 Store the overprinted cartons in S.S cage under lock and key in separate area with proper labeling.

4.6.23 Ensure that during break down or shift end there should not be any capsules, blisters, carton, leaflet and catch cover present in the machine or in packing line.

4.6.24 De-blistering process should be start at the end of packing process.

4.6.25 De-foiled good capsules to be polished and then transfer for the blistering.

5.0 ANNEXURE (S):

Nil

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6.0 REFERENCE (S):

SOP: Preparation, Approval, distribution control, revision and destruction of Standard Operation procedure.

7.0 ABBREVIATION (S) /DEFINITION (S):

BMR : Batch Manufacturing Record

BPR : Batch Packing Record

PVC : Poly Vinyl Chloride

PVDC : Poly Vinyldine Chloride

QA : Quality Assurance

SOP : Standard Operating Procedure

SS : Stainless Steel

REVISION CARD

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