



STANDARD OPERATING PROCEDURE

Department: Production (Softgel)	SOP No.:
Title: Cleaning of Utensils and Accessories	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for Operation and Cleaning of Degreasing Pan.

2.0 SCOPE:

This procedure is applicable for the Operation and Cleaning of Degreasing Pan in Softgel Department.

3.0 RESPONSIBILITY:

Technician/ Officer /Executive/ Manager-Production.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Operation

- 4.1.1 Ensure cleanliness of the equipment and area.
- 4.1.2 Ensure that environmental conditions are within the limit as per given in the BMR.
- 4.1.3 Ensure that all the doors are closed and no chance of cross-contamination.
- 4.1.4 Ensure that BMR is available and all the entry is properly complete till this stage.
- 4.1.5 Ensure that "CLEANED" label affix on the Degreasing Pan.
- 4.1.6 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.
- 4.1.7 Take line clearance from QA as per SOP No. PRD/009.
- 4.1.8 Remove "CLEANED" label from the Degreasing Pan and affix the "STATUS LABEL" with duly filled and signature of production officer.
- 4.1.9 Enter the operation start time of Degreasing Pan in equipment usage log book as per SOP.
- 4.1.10 Collect the capsules into the SS container, which is kept below the Fluidizer Tumbler Dryer discharge point.
- 4.1.11 Switch "ON" the main switch of Degreasing Pan and put the lint free cloth in it.
- 4.1.12 Transfer the collected capsules into the Degreasing Pan.



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- 4.1.13 Rotate capsules in Degreasing Pan for 15 minutes or according to the capsules quantity.
- 4.1.14 Remove the lint free cloth from Degreasing Pan.
- 4.1.15 Use the SS scoop to remove the capsules from the Degreasing Pan.
- 4.1.16 Spread the capsules in cleaned and dry SS tray in uniform single layer.
- 4.1.17 Continue the process till batch completion.
- 4.1.18 Switch "OFF" the main switch of Degreasing Pan after batch completion.
- 4.1.19 Enter the operation complete time in equipment usage log book as per SOP.
- 4.1.20 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.
- 4.1.21 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.2 Precaution

- 4.2.1 Do not run the Degreasing Pan without capsules.
- 4.2.2 Never leave the capsule in Degreasing Pan at the stop condition.

4.3 CLEANING PROCEDURE

4.3.1 Cleaning procedure Type A

Change over from one batch to next batch of the same product and potency and of similar product with ascending potency.

- 4.3.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine with date and signature of the production officer as per SOP.
- 4.3.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.1.3 Ensure there are no capsules in the Degreasing Pan.
- 4.3.1.4 Wipe the outer and inner body of Degreasing Pan with dry lint free cloth followed by 70 % v/v IPA.
- 4.3.1.5 Clean the area as per SOP.
- 4.3.1.6 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer.
- 4.3.1.7 Record the cleaning complete time in equipment usage log book as per SOP.

4.3.2 Cleaning procedure Type B



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This is a cleaning procedure for changeover of product with different actives / colour / descending potency or after maintenance of contact parts.

- 4.3.2.1 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and signature of the Production officer and enter cleaning time in log book.
- 4.3.2.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.2.3 Ensure there are no capsules in the Degreasing Pan.
- 4.3.2.4 Clean the inside and outside of Degreasing Pan with the help of scrubber and 1.0% v/v Teepol solution and rinse with the sufficient purified water to remove trace of Teepol solution.
- 4.3.2.5 Finally rinse with sufficient purified water.
- 4.3.2.6 Dry the Degreasing Pan with compressed air.
- 4.3.2.7 Wipe out the inner and outer body of Degreasing Pan with cloth wetted in 70% v/v IPA solution.
- 4.3.2.8 Clean the area as per SOP.
- 4.3.2.9 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the production officer.
- 4.3.2.10 Record the cleaning complete time in equipment usage log book as per SOP.

5.0 ANNEXURE (S) :

Nil

6.0 REFERENCE (S):

SOP: Cleaning and sanitization of production area.

SOP: Status Labeling in Production Department.

SOP: Procedure for Area line clearance.

SOP: Procedure of filling of equipment log book.

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

v/v : Volume/Volume

ml : Millilitre

Q.A : Quality Assurance

REVISION CARD

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