

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Assurance	SOP No.:		
Title: Operation and Cleaning of Hot Plate	Effective Date:		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

1.0 **OBJECTIVE**:

To lay down the procedure for Operation and Cleaning of Hot Plate.

2.0 SCOPE:

This procedure is applicable for the Operation and Cleaning of Hot Plate in gelatin and medicament manufacturing area.

3.0 RESPONSIBILITY:

Technician/ Officer/Executive/Manager-Production.

Head of Department: 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 completed till this stage.
- 4.1.5 Ensure that "CLEANED" label affix on the Hot Plate.
- 4.1.6 Ensure that the all containers are closed and kept properly on the pallet in a proper place with status label.
- 4.1.7 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.
- 4.1.8 Take line clearance from QA.
- 4.1.9 Remove the "CLEANED" label from the Hot Plate and affix the "STATUS LABEL" with duly filled and signature of production officer.
- 4.1.10 Enter the operation start time of Hot Plate in equipment usage log book as per SOP.
- 4.1.11 Put the container with the material on the Hot Plate.
- 4.1.12 Switch "ON" the electric supply of the Hot Plate.



PHARMA DEVILS

PRODUCTION DEPARTMENT

CTANDADD ODED A TIME DEOCEDIDE							
STANDARD OPERATING PROCEDURE Department: Quality Assurance SOP No.:							
-	tion and Cleaning of Hot Plate	Effective Date:					
Supersedes: Nil		Review Date:					
Issue Date:		Page No.:					
4.1.13	Set the temperature of the Hot Plate by thermostat as per required temperature limit described in the BMR.						
4.1.14	Add the raw materials stepwise into the container as per the procedure described in the applicable BMR.						
4.1.15	Switch "OFF" the power supply after proper melting of the materials and bring down the container.						
4.1.16	Enter the operation complete time of the Hot Plate in equipment usage log book as per SOP.						
4.1.17	Remove the "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.						
4.2	Precaution						
4.2.1	Do not heat the Hot Plate without container on it.						
4.2.2	Do not clean the Hot plate during process or on heating condition.						
4.3	CLEANING PROCEDURE:						
4.3.1	Remove "TO BE CLEANED" label from the equipment with duly filled and signature of						
	production officer.						
4.3.2	Enter the cleaning start time in equipment usage log book as per SOP.						
4.3.3	Ensure that Hot Plate is cooled and switched "OFF".						
4.3.4	Clean the heating part of Hot Plate with moistened dry lint free cloth.	lint free cloth followed by					
4.3.5	Clean the outer SS part by using lint free cloth with	h 70 % v/v IPA.					
4.3.6	Affix "CLEANED" label on the equipment with d						
	officer.						
4.3.7	Record the cleaning complete time in equipment us	sage log book as per SOP.					
5.0	ANNEXURE (S): NIL						



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Assurance	SOP No.:		
Title: Operation and Cleaning of Hot Plate	Effective Date:		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

6.0 REFERENCE (S):

SOP: Procedure of filling of equipment log book.

SOP: Preparation, approval, distribution control, revision and destruction of standard

operating procedure.

7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

v/v : Volume / Volume

QA : Quality Assurance

PRD : Production Department

REVISION CARD

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