PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production (External Preparation)	**SOP No.:**
Title: Recording of Equipment Log	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Recording of Equipment Log.

2.0 SCOPE:

This SOP is applicable for Recording of Equipment Log in Ointment and Oral liquid Section.

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR	Batch Production Record
No .	Number
SOP	Standard Operating Procedure
Pvt.	Private
Ltd.	Limited
PO	Production Ointment

6.0 PROCEDURE:

- Every Equipment related with its Inspection, Operation & cleaning, it will be recorded in "Equipment Log" Format separately for the entire individual machine as per below mentioned instruction. Format for the same is enclosed as **Annexure I.**
- Every Equipment related with its Inspection, Operation, Cleaning & Sanitization, to be use in ointment and oral liquid manufacturing it will be recorded in "Equipment Log with Sanitization Record" Format separately for the entire individual machine as per below mentioned instruction. Format for the same is enclosed as **Annexure II.**

6.1 Write the Name of Department at specified place in the format.

6.2 Write the Name of Equipment, relevant Equipment ID No. as well as its Location.

6.3 Write the Month & Year activity is performed.

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6.4 First of all in the given table Inspection & Approval of Equipment before use, write the Date, Time on which a particular activity is performed.

6.5 Write Date, Product Name & Batch Number for processing of which the Equipment has been utilized.

6.6 Write the time duration taken for completion of a particular activity e.g. Down Time/Cleaning, Operation.

6.7 After completion of Operation or Cleaning activity Production personnel as well as QA Personnel monitoring the same will put his signature at specified column in the Equipment Log.

Note: During cleaning verification of equipment's i.e. gaskets, filter housing, tubing, connecting valves and its associated parts should be checked by user department & verified by the QA. If any discrepancy observed, it should be mentioned in the remark column along with further action, wherever applicable.

6.8 After completion of maintenance activity Engineering Personnel as well as QA Personnel monitoring the same will put his signature at specified column in the Equipment Log.

6.9 Specific Observation observed during any activity will be recorded in the Remark column, In case of lack of space the same will be recorded in the Back side of the format but writing P.T.O. in remark column.

6.10 Any Equipment related with Processing or Dispensing will be Cleaned its release from QA will be taken prior to its startup for Processing activity.

6.11 Cleaning and sanitization of any equipment is to be done as per respective Equipment SOP and its release from QA will be taken prior to its startup for processing activity.

6.12 In Case of maintenance work done on a particular Machine the machine will be cleaned. Its release for Cleaning will be taken by QA prior to startup of its startup for processing activity.

6.13 In Case of continuous Operation for different Batch of a similar Product or only one Batch of Large Batch size, Machine will not be Operated continuously for more than 72 hours and after completion of this period remaining Bulk solution/Materials will be discarded and Machine will be Cleaned and it's release from QA will be taken prior to its startup for Processing activity.

6.14 In Case of Product Change over Machine will be cleaned and its release from QA will be taken prior to its startup for Processing activity.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Equipment Log	
Annexure-II	Equipment Log with Sanitization Record	

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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE – I
EQUIPMENT LOG

Department: **Name of Equipment:**
Area: **Equipment ID No.:**
Month: **Year:**

Inspected and Approved Before Use				Equipment Used For			Operation Time		Down Time / Cleaning			Done By	Checked By (Sign & Date)	Verified By (Sign & Date)	Remarks
Date	Time	Inspected By Production (Sign & Date)	Approved By QA (Sign & Date)	Date	Product Name	Batch No.	From	To	From	To	Code				

Down Time Code:

A- Machine Cleaning (Batch Changeover)
B- Machine Cleaning (Product Changeover)
C- Machine Setting
D- Machine Breakdown
E-Lunch / Dinner / Tea
F-Material Problem
G- Others (Specify)
NA- No Activity

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ANNEXURE – II
EQUIPMENT LOG WITH SANITIZATION RECORD

Department: **Area:**

Equipment ID No.: **Month & Year:**

Date	Time	Equipment Used For		Operation Time		Down Time / Cleaning			Sanitization time/ Temperature			Done By	Checked By (Sign & Date)	Verified By (Sign & Date)	Remarks
		Product Name	Batch No.	From	To	From	To	Down Time Code	From	To	Hot Water (80°-85°)				

Down Time Code:

A- Machine Cleaning (Batch Changeover)
B- Machine Cleaning (Product Changeover)
C- Machine Setting
D- Machine Breakdown
E- Lunch / Dinner / Tea
F- Material Problem
G- Others (Specify)
NA- No Activity