



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Preparation of Schedule	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 PURPOSE

To provide a procedure for preparation, compilation, execution, review and closure of various schedules and scheduled activities.

2.0 SCOPE

2.1 This SOP is applicable to all scheduled activities in

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In house

3.2 Attachments

3.2.1 Attachment- I : List of Schedules

3.2.2 Attachment- II : Equipment Qualification/ Requalification Schedule

3.2.3 Attachment- III : Area Qualification/ Requalification Schedule

3.2.4 Attachment- IV : HVAC system Qualification/ Requalification Schedule

3.2.5 Attachment- V : HVAC, LAF, RLAF Periodic Validation/ Verification Schedule

3.2.6 Attachment- VI : Periodic Process Verification Schedule

3.2.7 Attachment- VII : Performance Verification Schedule

3.2.8 Attachment- VIII : GMP/ Technical Agreement Renewal Schedule

3.2.9 Attachment- IX : Cleaning Validation Schedule (Concurrent and Periodic)

3.2.10 Attachment- X : Periodic Re-Audit Schedule of Laundry Service

3.2.11 Attachment- XI : Hold Time Study Schedule

3.2.12 Attachment- XII : Process Validation (Concurrent) Schedule

3.2.13 Attachment- XIII : Calibration Schedule

3.2.14 Attachment- XIV : Document Review Sheet

3.2.15 Attachment- XV : Closure Review Sheet

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Nil



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4.2 Abbreviations

- 4.2.1 SOP : Standard operating procedure
- 4.2.2 No. : Number
- 4.2.3 HVAC : Heating Ventilation and air conditioning
- 4.2.4 QA : Quality Assurance

5.0 RESPONSIBILITY:

5.1 User Department:

- 5.1.1 To prepare schedule.
- 5.1.2 To identify requirement of any additional schedule.
- 5.1.3 To take approval of the prepared schedule from Quality Assurance Head and Plant Head.
- 5.1.4 To update the execution details in the respective schedules.
- 5.1.5 To raise Change control in case of any changes in a schedule and to address the changes in the Document review sheet.
- 5.1.6 To review the applicable schedules.
- 5.1.7 To maintain the Closure review sheet.

5.2 Quality Assurance/Validation QA:

- 5.2.1 To prepare the list of schedules and schedule and to take approval from Quality Assurance Head and Plant Head.
- 5.2.2 To identify requirement of any additional schedule.
- 5.2.3 To take approval of the prepared schedule from Quality Assurance Head and Plant Head.
- 5.2.4 To update the execution details in the respective schedules.
- 5.2.5 To raise Change control in case of any changes in a schedule and to address the changes in the Document review sheet.
- 5.2.6 To review the applicable schedules.
- 5.2.7 To maintain the Closure review sheet.

5.3 User Department Head:

- 5.3.1 To review and sign the Closure review sheet.

5.4 Quality Assurance Head:

- 5.4.1 To approve the schedule.
- 5.4.2 To ensure implementation of the defined procedure.

5.5 Plant Head:



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5.5.1 To authorize the schedule.

5.5.2 To ensure implementation of the defined procedure.

6.0 Distribution

- I. Quality Assurance
- II. Quality Control
- III. Production
- IV. Engineering
- IV. Warehouse

7.0 PROCEDURE:

7.1 All activities required to be executed periodically at definite frequency shall be identified and listed in Attachment-I by Quality assurance.

7.2 Preparation of Schedule/Matrix:

7.2.1 A list of schedule/ matrix shall be prepared as per Attachment-I by QA for the activities which are required to be tracked, executed and followed up.

7.2.2 A schedule/matrix shall be prepared by user department/Quality Assurance/Validation QA as applicable for the next calendar year preferably in month of December of existing calendar year. While preparing schedule for next year, previous year schedules shall be referred.

7.2.3 Refer Attachment-I for activities which are required to be scheduled annually but is not limited to, any other activity if required to be scheduled, then shall be scheduled in line with respective SOP. The list shall be maintained by Quality Assurance.

7.2.4 Numbering of the schedules shall be as follows:

Format of schedule Numbering is as: **SCH/B/YY/XX**

SCH: Abbreviation denotes Schedule

B= Denotes: B1 for Block1

B2 for Block2

U for Utility area

Q for Quality Control area

YY: Last two digit of the year for which schedule is being prepared.

XX: Serial number



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Note: New schedule number will be changed with the change of the year.

7.2.5 Refer Attachment- I to Attachment- XIII for specimen copies of schedules required to be prepared at Unit.

7.2.6 In case any additional schedule is required to be prepared for any scheduled activity other than those mentioned as attachments to this SOP, the same can be prepared after approval of Quality Assurance Head and the number shall be allotted in continuation to the last allotted number as per Attachment-I and shall be recorded in the list. During subsequent revision of the SOP the format of new schedule prepared shall be included in the SOP.

7.2.7 With every change in the schedule version no. of the schedule shall be changed and shall be addressed in Document review sheet as per applicable change control and brief description of change control and Document review sheet shall be attached to the respective schedule. Refer Attachment- XIV.

7.2.8 Execution details shall be updated in schedule after completion of successful validation/verification/qualification.

7.3 Review of schedule:

All schedules shall be reviewed in the last week of every month to identify the activities to be planned in next month and appropriate action shall be initiated. Review shall also be done to identify the pending activity in the month.

7.4 Execution of scheduled activity:

Based on schedule, activity shall be executed and details of execution shall be included in the schedule after successful completion preferably soon after completion of activity and not later than prior to the end of the month.

7.5 Closure Review:

All schedules shall be reviewed in the last week of every year to ensure that the activities planned in calendar year are completed. If not, appropriate action shall be mentioned in Closure review sheet and activity shall be carried forward to the next year as applicable. A closure remark shall be mentioned in Closure review sheet of last month of calendar year for the respective year for all schedules. Refer Attachment- XV.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			



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Attachment- I

LIST OF SCHEDULES

Block: _____

S.No.	SCHEDULE NAME	SCHEDULE NUMBER	REMARKS

Prepared By: _____
(Quality Assurance)
Date:

Approved By: _____
(QA Head)
Date:



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Attachment- II

EQUIPMENT QUALIFICATION/REQUALIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION NO.: _____

DEPARTMENT: _____

S.No.	Equipment Name	Code No.	Frequency (In Years)	Last Qualification/ Requalification done on	Next to be done on	Next due in the Year					Actual Date of Execution	Remarks
						2020	2021	2022	2023	2024		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- III

AREA QUALIFICATION/ REQUALIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No	Area Name	Code No.	Frequency (In Years)	Last Qualification/ Requalification done on	Next to be done on	Next due in the Year					Actual Date of Execution	Remarks
						2020	2021	2022	2023	2024		

Prepared By: _____
(Validation QA)

Approved By: _____
(QA Head)

Authorized By: _____
(Plant Head)

Date:

Date:

Date:

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- IV

HVACSYSTEM QUALIFICATION/REQUALIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

S.No.	AHU Code No.	Supplied to Area Name	Frequency (In Years)	Last Qualification/ Requalification done on	Next to be done on	Next due in the Year					Actual Date of Execution	Remarks
						2020	2021	2022	2023	2024		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- V

HVAC, LAF, RLAf PERIODIC VALIDATION/VERIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____ **VERSION NO.:** _____

S.No.	Equipment Code No.	Supplied to/ Installed in Area Name	Frequency (In Years/ Months)	Last Validation/ Verification done on	Next to be done on	Next due in the Year					Actual Date of Execution	Remarks
						2020	2021	2022	2023	2024		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- VI

PERIODIC PROCESS VERIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No.	Product Name	Batch Size Kg./ Nos./ lit. pack size (if applicable)	No. of Batches planned	Reason for Validation	Stage for Validation	Validation Status		Remarks	Checked by/ Date
						Batch No.	Date of Validation		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

Month	January	February	March	April	May	June
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Month	July	August	September	October	November	December
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Attachment- VII
PERFORMANCE VERIFICATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No.	Titles	Frequency	Month													
			Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		
		S														
		A														
		S														
		A														

Prepared By: _____ Approved By: _____ Authorized By: _____
 (Validation QA) (QA Head) (Plant Head)
 Date: _____ Date: _____ Date: _____

S- Schedule, A- Actual

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- VIII

GMP/ TECHNICAL AGREEMENT RENEWAL SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____ **VERSION No.:** _____

Sr. No.	GMP/ Technical Agreement Name	Agreement Done With Service provider/ Party/ Other Company/ Other testing Laboratory Name	Frequency (In Years/ Months)	Renewal Due on	Renewal Done on	Remarks	Checked By (Sign & Date)

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

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Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- IX

CLEANING VALIDATION SCHEDULE (CONCURRENT AND PERIODIC)

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No.	Product Name	Equipment Name	API (Whose traces are to be detected)	Worst Case Criteria	Reason for validation	No of Batches to be validated	Validation Status		Remarks	Checked by/ Date
							Batch No.	Date of Validation		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

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Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- X

PERIODIC RE-AUDIT SCHEDULE OF LAUNDRY SERVICE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No.	Name of Laundry Service	Last Audit Done on	Re-Audit Due on	Re-Audit Completed on	Remarks

Prepared By: _____
(Quality Assurance)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- XI

HOLD TIME STUDY SCHEDULE

Block: _____

SCHEDULE NUMBER: _____ **VERSION No.:** _____

FORMULATION: _____

Product Name	Batch No.	Hold Time Study				Sampled by (Sign and Date)	Remarks
		Frequency of Sampling	*Tests to be Performed	Date of Sampling	Actual date of Sampling		

Prepared By: _____
(Validation QA)
Date: _____

Approved By: _____
(QA Head)
Date: _____

Authorized By: _____
(Plant Head)
Date: _____

*Example of tests to be performed are Assay, Physical, Bio load etc.

Month	January	February	March	April	May	June
Reviewed by (Sign and Date)						
Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- XII

PROCESS VALIDATION (CONCURRENT) SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S.No.	Product Name	Type of validation	Stage of validation	Batch size/ pack size	Reason for validation	No. of batches validated	No. of batches to be validated	Validation done on/ batch no.	Remarks

Prepared By: _____ (Validation QA) Date: _____	Approved By: _____ (QA Head) Date: _____	Authorized By: _____ (Plant Head) Date: _____
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Month	January	February	March	April	May	June
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Month	July	August	September	October	November	December
Reviewed by (Sign and Date)						



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Attachment- XIII

CALIBRATION SCHEDULE

Block: _____

YEAR: _____

SCHEDULE NUMBER: _____

VERSION No.: _____

DEPARTMENT: _____

S. No.	Instrument / Sensor / Equipment Code No.	Frequency (In Month/ Year)	Department/ Location/ Area Name	Calibration done by In house/ Outside Party	Make	Range	Least Count	Previous Calibration Done On	Calibration Due Date	Date of Execution	Sign & Date	Previous Calibration Done On	Calibration Due Date	Date Of Execution	Sign & Date

Prepared By: _____ (Engineering) Date:	Approved By: _____ (QA Head) Date:	Authorized By: _____ (Plant Head) Date:
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Attachment- XIV

DOCUMENT REVIEW SHEET

ITEM:

DOCUMENT No.:

Version No.	Reference Change Control Number	Page	Point	Change



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Attachment- XV

CLOSURE REVIEW SHEET

YEAR: _____

Block: _____

Topic Name	Document/ Schedule No.	Version No.	Details of Pending Activities	Details of Action to be taken	Reviewed By Sign/ Date	Department Head Sign/ Date	Closure Remarks

Note: Put 'NA' or '-' in case of Not Applicable.