OUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE							
Depa	rtment: Quality Assurance	SOP No.:					
Title:	Preparation of Schedule	Effective Date:					
Super	Supersedes: Nil Review Date:						
Issue	Date:	Page No.:					
1.0	PURPOSE						
1.0	PURPOSE To provide a procedure for preparation, compilation scheduled activities.	, execution, review and closure of various schedules					
1.0 2.0	To provide a procedure for preparation, compilation	, execution, review and closure of various schedules					
	To provide a procedure for preparation, compilation scheduled activities.						
2.0	To provide a procedure for preparation, compilation scheduled activities. SCOPE						

3.2 **Attachments**

In house

3.1.1

- 3.2.1 : List of Schedules Attachment- I
- 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 : HVAC, LAF, RLAF Periodic Validation/ Verification Schedule Attachment- V
- 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**

Nil 4.1.1



QUALITY ASSURANCE DEPARTMENT

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4.2	A hhr	eviations
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- 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:

QUALITY ASSURANCE DEPARTMENT

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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

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDUR	E
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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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	STANDARD O	PERATING PROCEDURE								
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Attachment- I LIST OF SCHEDULES Block:										
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DECODING PHARMA QUALITY ASSURANCE DEPARTMENT

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*Example of tests to b	be performed are	Assay, Physical, B	io load etc.				
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DECODING PHARMA QUALITY ASSURANCE DEPARTMENT

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDUR	E
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Attachment-XIV

DOCUMENT REVIEW SHEET

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DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Department: Quality Assurance	SOP No.:
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CLOSURE R	EVIEW SHEET

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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.