	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
	DEPARTMENT: QUALITY ASSURANCE		Supersedes: OHC/II/SOP/QA/020-06
			Page No. 1 of 8
Area:	General	Copy No:	
Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

# **TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE**

## **1.0 PURPOSE :**

The purpose of this SOP is to lay down the procedure for “Allocation of Job Responsibility & Maintenance of Specimen Signature”.

## **2.0 SCOPE:**

This SOP shall be applicable for “Allocation of Job Responsibility & Maintenance of Specimen Signature” of all employees working at Olive Healthcare, Unit II, Daman.

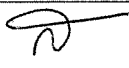
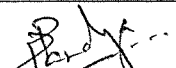

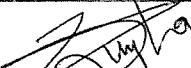

## **3.0 RESPONSIBILITY:**


### **3.1 Concern Department Head shall be responsible:**

- 3.1.1 To prepare and approve job responsibility of personnel.
- 3.1.2 Allotment of job responsibility number.
- 3.1.3 To submit acknowledge copy of job responsibility to QA.
- 3.1.4 For Maintenance of controlled copy of index & job responsibilities of concern departments
- 3.1.5 To prepare and update master list of job responsibility.
- 3.1.6 To approve request for change in specimen signature

### **3.2 Quality Assurance Officer/Executive shall be responsible:**

- 3.2.1 To make Master copy of job responsibility submitted by Concern Department Head.
- 3.2.2 To issue the controlled copy of job responsibility to the concern department.
- 3.2.3 For Maintenance of Master Index & Master job Responsibilities of all departments.
- 3.2.4 To take specimen signature of employee and maintain the specimen signature log.
- 3.2.5 For Maintenance & Distribution of Master list of Job responsibility.

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
	DEPARTMENT: QUALITY ASSURANCE		Supersedes: OHC/II/SOP/QA/020-06
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Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

# TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE

## 3.3 Manager QA / Designee shall be responsible:

3.3.1 To approve request for change in specimen signature.

3.3.2 To authorize the specimen signature of employee.

## 3.4 Head Quality / Designee shall be responsible:

3.4.1 To Authorize request for change in specimen signature.

## 4.0 ACCOUNTABILITY:

Manager - Quality Assurance and individual department head shall be accountable for the overall implementation and adherence to of the SOP.

## 5.0 PROCEDURE:

### 5.1 Preparation & Distribution of Job Responsibilities:

5.1.1 After completion of induction training & departmental SOPs training, the concern department Head shall prepare job responsibilities of employees of their Departments based on their qualification, previous experience (if any) and job allocated to the concerned.

5.1.2 Department Head shall assign Job responsibility number to job responsibilities of employees.

5.1.3 Job responsibility number shall be numbered as JR/XX/NNN-ZZ.

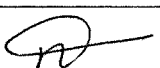
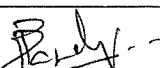

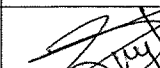

Where,


JR - Stands for job responsibilities

XX- Respective Department Code

NNN - job responsibility number allotted to the employee

ZZ - Revision number of the job responsibility starting from 00, 01, 02...

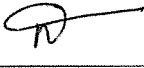

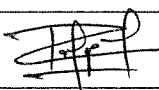


	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023


	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
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**TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE**

Name of the department	Code	Name of the department	Code
Quality Assurance	QA	Administration & Personnel	AP
Quality Control	QC	Warehouse	WH
Microbiology	QM	Production	PR
Packaging	PK	Engineering	EN
Information Technology	IT	Regulatory Affairs	RA

- 5.1.4 Job Responsibility of employee shall contain the employee detail like Name, Department, Designation, Job Responsibility number, Date of joining, Reporting to, Employee code, with effective from and descriptions of job assigned.
- 5.1.5 The department head shall ensure while preparing the job responsibilities that, there is no gap and / or unexplained overlaps between the responsibilities of personnel within the department.
- 5.1.6 The responsibilities placed on any one individual must not be so extensive as to present any risk to quality.
- 5.1.7 Job responsibility shall be prepared as per Annexure-I.
- 5.1.8 Employee shall be aware/accept his/her job responsibilities by signing and accepting the prepared job responsibility.
- 5.1.9 Departmental work shall be allotted to new joined employee as per his/her signed off job responsibilities.
- 5.1.10 In absence of the employee the work shall be allotted to his/her designee therefore the job responsibility of concern employee shall be also signed by his designee.
- 5.1.11 Head of the Department shall submit duly signed copy of job responsibility to QA Department for control and distribution.
- 5.1.12 QA shall check the Job responsibility format for correctness.

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
	DEPARTMENT: QUALITY ASSURANCE		Supersedes: OHC/II/SOP/QA/020-06
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Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

**TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE**

- 5.1.13 Approved format of job responsibility shall be stamped as "MASTER COPY" in red ink at top left corner.
- 5.1.14 Make the photocopies of master Job responsibility and stamp "CONTROLLED COPY" to the each photo copy.
- 5.1.15 One "CONTROLLED COPY" shall be handover to department Head of concern persons & second copy shall be kept in personnel individual training file and "MASTER COPY" shall be retained with QA department.
- 5.1.16 Head of the Department shall explain the job responsibility to the personnel.
- 5.1.17 Individual job responsibility shall be reviewed and revised as and when required or when there is any change in the responsibilities of an individual.
- 5.1.18 Previous controlled copy of Job responsibility shall be retrieved and destroyed and master copy shall be stamped as obsolete copy with effective from.
- 5.1.19 The revision history shall be maintained with reason for revision with revision number in chronological order i.e. 00, 01, 02, 03.....so on.

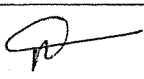
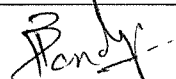
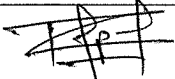
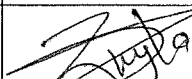

**5.2 Master List of Job responsibility**

- 5.2.1 Master list of the Job responsibility shall be prepared by the individual department as per annexure-III.
- 5.2.2 Master list of individual department shall be numbered as OHC/II/ML/JR/XX-ZZ


Where,

- OHC/II - Stands for Olive Healthcare Unit-II  
 ML - Master List  
 JR - Job Responsibility  
 XX - Department Code  
 ZZ - Revision number of the Master list starting from 00, 01, 02...

For e.g. First version of the master list of Job responsibility for QA department shall be numbered as OHC/II/ML/JR/QA-00.

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	07/06/2023



	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
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Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

**TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE**

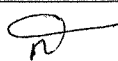
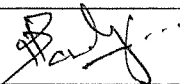
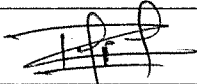
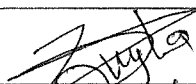
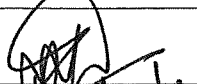
- 5.2.3 Master List of Job responsibility shall be periodically revised every year or as and when required.
- 5.2.4 Any revision or addition or deletion of any Job responsibility shall be included by entering Job responsibility details manually in the Space provided for addendums on the last page of the Master List & shall be included in the next version of Master List. Detail of revision shall be maintained in reason for revision.
- 5.2.5 If any employee leaves the organization, then he/she shall be marked as "D i.e. Deletion" in Master JR list and JR list shall be verified of all other employees, where he/she is marked as a designee and JR of those employee shall be revised accordingly.
- 5.2.6 Master list shall be revised by concerned department and shall be reviewed by Quality Assurance department.
- 5.2.7 QA shall stamp the Master List of Job responsibility as 'MASTER COPY' and distribute to concerned department as 'CONTROLLED COPY'.


**5.3 Job responsibility of Key Personnel**

- 5.3.1 Job responsibilities of the key personnel but not limited to is attached as Annexure – IV.

**5.4 Employee specimen signature**

- 5.4.1 The specimen signature copy of the employee working in each department shall be prepared as per Annexure-II, authorized by Manager QA and updated as and when required.
- 5.4.2 In case if any employee leave the organization, Mark as "LEFT ON – Date of Leaving" in remark column of specimen signature record and same shall be updated by quality assurance personnel.
- 5.4.3 New join employee specimen signature must be taken during induction period followed by authorization of Manager QA.
- 5.4.4 If any person of department requires changing the specimen signature he/she need to raise the request form as per Annexure-V.

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

	STANDARD OPERATING PROCEDURE		SOP No: <b>OHC/II/SOP/QA/020-07</b>
	DEPARTMENT: QUALITY ASSURANCE		Supersedes: <b>OHC/II/SOP/QA/020-06</b>
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### TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE

5.4.5 After approval of Head Quality, the employee's specimen signature can be changed on the document.

5.4.6 The Employee's revised specimen shall be taken in specimen signature log.

#### 6.0 TRAINING:

Trainer : Manager-QA

Trainees : All Departmental / Sectional Heads



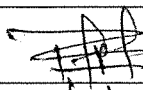
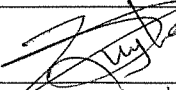
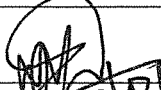
#### 7.0 DISTRIBUTION:


Original Copy : Manager - QA  
 Controlled Copy No. 1 : Quality Assurance  
 Controlled Copy No. 2 : Quality Control  
 Controlled Copy No. 3 : Microbiology  
 Controlled Copy No. 4 : Production  
 Controlled Copy No. 5 : Packing  
 Controlled Copy No. 6 : Ware house  
 Controlled Copy No. 7 : Administration and Personnel  
 Controlled Copy No. 8 : Engineering  
 Controlled Copy No. 9 : Information Technology  
 Controlled Copy No.10 : Regulatory Affairs

#### 8.0 ATTACHMENTS:

Annexure-I : Specimen copy of job Responsibility (OHC/II/FM/1/03-SOP/QA/020)

Annexure-II : Specimen Signature and Details of the Staff (OHC/II/FM/2/03-SOP/QA/020)

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
	DEPARTMENT: QUALITY ASSURANCE		Supersedes: OHC/II/SOP/QA/020-06
			Page No. 7 of 8
Area:	General	Copy No:	
Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

# TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE

- Annexure-III : Master List of Job Responsibility (OHC/II/FM/3/02-SOP/QA/020)
- Annexure-IV : Job Responsibility of Key Personnel (OHC/II/FM/4/02-SOP/QA/020)
- Annexure-V : Request form for Change in Specimen Signature  
(OHC/II/FM/5/01-SOP/QA/020)

## 9.0 REFERENCES:

In house

## 10.0 REFERENCE OF OTHER SOP's

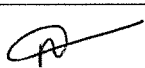
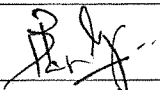
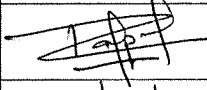

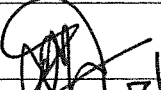
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## 11.0 VERNACULAR LANGUAGE SOP

Not Applicable

## 12.0 REVISION HISTORY:


Revision No.	Reason for revision	Effective Date
00	• New SOP	28/03/2012
01	• Reference Document Change control no.: DCR/14/003	21/02/2014
02	• Reference DCR No.: DCR/QA/14/008 • Reference CCF No.: D/14/07/004	26/08/2014
03	• Reference DCR No.: DCR/QA/15/004 • Reference CCF No.: D/15/02/004	23/03/2015
04	• Reference CAPA No.: CAPA/15/009 • Reference DCR No.: DCR/QA/15/007	18/05/2015
05	• Reference CCP No. CCP-U2-QA-18-0012.	12/06/2018
06	• Refer CCP No. CCP-U2-QA-21-0026	11/06/2021
07	• Periodic review and revision of job responsibility is discontinued and Job responsibility shall be revised as and when required as per change Job responsibility • Annexure-3 (MASTER LIST OF JOB	

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

**MASTER COPY****UNCONTROLLED COPY**

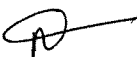
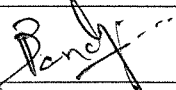
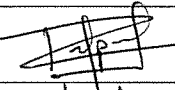
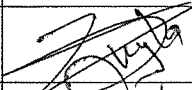
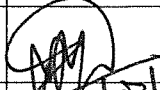
OHC/II/FM/1/02-SOP/QA/001

(FOR RESTRICTED CIRCULATION ONLY)

	STANDARD OPERATING PROCEDURE		SOP No: OHC/II/SOP/QA/020-07
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Effective Date	27 JUN 2023	Next Review Date:	26 JUN 2026

**TITLE: ALLOCATION OF JOB RESPONSIBILITY & MAINTENANCE OF SPECIMEN SIGNATURE**


Revision No.	Reason for revision	Effective Date
	RESPONSIBILITY) is updated accordingly and the provision for entering next review date has been removed. <ul style="list-style-type: none"><li>Annexure V: Request for Change in Specimen signature revised to include Regulatory Affairs department.</li><li>Refer Change control No. CCP-U2-QA-23-0027</li></ul>	27 JUN 2023

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	NEEL DESAI	PRATIK PANDYA	KRUNAL RAJPUT	VIKASH JHA	RAJAN DESAI
Designation	OFFICER-QA	MANAGER-QA	Sr. OFFICER-QA	HEAD-QA	HEAD-QUALITY
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023



**MASTER COPY**Annexure – I

OHC/II/FM/1/03-SOP/QA/020

	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 1 of 1
	<b>Specimen Copy of Job Responsibility</b>	

**Name :** \_\_\_\_\_ **Job Responsibility Number :** \_\_\_\_\_  
**Department :** \_\_\_\_\_ **Date of Joining :** \_\_\_\_\_  
**Designation :** \_\_\_\_\_ **Employee code :** \_\_\_\_\_  
**Reporting To :** \_\_\_\_\_ **With Effective from :** \_\_\_\_\_

Sr. No.	Description

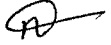




I \_\_\_\_\_ have read and accepted the above Job responsibilities.

In the absence of Mr. / Ms. \_\_\_\_\_, the assigned responsibilities can be handled by his / her designee \_\_\_\_\_ or as approved by the undersigned.

**REVISION HISTORY:**

Revision No.	Reason for revision	Effective Date

	Accepted By Employee	Accepted By Designee	HOD
<b>Name</b>			
<b>Signature</b>			
<b>Date</b>			

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	09/06/2023








DEPARTMENT: QUALITY ASSURANCE

**SPECIMEN SIGNATURE AND DETAILS OF THE STAFF**

Page No. 1 of 1

[illegible]


	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	09/06/2023

MASTER COPY

## Annexure-III

OHC/II/FM/3/02-SOP/QA/020

(FOR RESTRICTED CIRCULATION ONLY)

	MASTER LIST OF JOB RESPONSIBILITY		ML No: <b>OHC/II/ML/JR/XX-ZZ</b>
	DEPARTMENT:		Supersedes: Nil
			Page No. X of Y
Effective Date:		Copy No:	

Sr. No	Name of Employee	Designation	Date of Joining	JR No.	Version	Designee	Effective Date	Remarks

## Addendums:

Sr. No	Name of Employee	Designation	Date of Joining	JR No.	Version	Designee	Effective Date	Dept. (Sign/Date)	QA (Sign./Date)	Remarks (R/A/D)

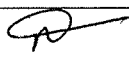
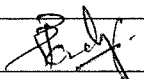

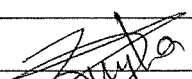
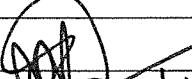
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A: New Addition

D: Deletion from the List

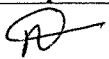




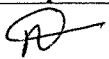




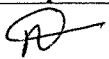




Revision No.	Reason for Revision	Effective Date
00	New Master List of Job responsibility	

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Sign & Date	Sign & Date

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	07/06/2023

	<b>DEPARTMENT: QUALITY ASSURANCE</b>  <b>Job Responsibility of Key Personnel</b>	Page No. 1 of 15
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## ➤ HEAD QUALITY


Sr. No.	Description																		
1.	To develop & implement an organizational quality system that aligns with the mission GMP/GDP Regulations; commit to meet requirements and improving the quality system; and propose objectives are fulfilled.																		
2.	To ensure Medicinal products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice.																		
3.	To ensure effective Pharmaceutical Quality System is in place, adequately resourced and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organization.																		
4.	To ensure Product realization is achieved by designing, planning, implementing, maintaining and continuously improving a system that allows the consistent delivery of products with appropriate quality attributes throughout product life cycle.																		
5.	To ensure a state of control is established and maintained by developing and using effective monitoring and control systems for process performance and product quality.																		
6.	To ensure communication should be ongoing among research and development, regulatory affairs, manufacturing, and QU personnel on issues that affect quality, with management included whenever appropriate.																		
7.	To examine Complaints about products and to ensure the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent reoccurrence.																		
8.	To plan periodic management review with the involvement of senior management for the operation of the Pharmaceutical Quality System to identify opportunities for continual improvement of products, processes and the system itself.																		
9.	To ensure training needs are identified and relevant trainings are imparted to all levels appropriate to their duties including GMP regulation training.																		
10.	To train and certify internal trainers and auditors and to participate in self inspection & its effectiveness monitoring.																		
11.	To ensure all activity is running according to company SOP, protocol and with written procedure and complying to applicable norms.																		
12.	To facilitate Quality Risk Management exercise and to ensure steps are timely taken to minimize/avoid failures.																		
13.	To face an audits from Regulatory agency and audits of customer and to provide compliance report.																		
14.	To communicate with Management for necessary resources/facilities availability to achieve desired standards and output.																		
15.	To help creating and maintaining good organization and Quality culture.																		
16.	To ensure design, operation & monitoring of process & systems in order to comply with the principles of Data Integrity.																		
17.	To ensure arrangements are made for the manufacture, supply and use of the correct starting and packaging materials, the selection, monitoring & approval of suppliers and auditing them as required.																		
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## Annexure – IV

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	<b>DEPARTMENT: QUALITY ASSURANCE</b>  <b>Job Responsibility of Key Personnel</b>	Page No. 2 of 15
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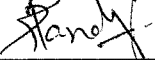

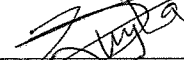

Sr. No.	Description
18.	Responsible for Final batch release / reject by taking in to account the results of product and processes monitoring , investigation of deviations, and, with a view to taking preventive action to avoid potential deviations occurring in the future and complying to the requirements of the Marketing Authorization and any other regulations relevant to the production, control and release of medicinal product.
19.	To maintain and continual improvement of system that allows the consistent delivery of products complying till its life cycle to agreed specification and relevant standards.
20.	To ensure product and process knowledge is managed through out its lifecycle.
21.	To review and approval of validation & qualification document and to ensure validations are carried out as per schedule.
22.	To monitor effectiveness of QMS and necessary CAPA is implemented.
23.	To ensure any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented.
24.	To ensure approval and notification to Contract Giver is given prior to implementation of changes /CAPA that may have impact on product Identity, Quality, safety and efficacy.
25.	To review and approval of Method of analysis, Specification, Stability report, OOC, OOT and OOS.
26.	To monitor and control outsourced testing activities.
27.	To ensure Production and control operations are clearly specified and Good Manufacturing Practice adopted.
28.	To set implementation priorities and develop action plans according to goals and target set by the management.
29.	To ensure continual improvement is facilitated through the implementation of quality improvements appropriate to the current level of process and product knowledge & regulations in force.
30.	To ensure arrangements are in place for the prospective evaluation of planned changes and their approval prior to implementation taking into account regulatory notification and approval where required.
31.	To verify post change implementation to confirm the quality objectives were achieved and that there was no unintended deleterious impact on product quality.
32.	To review and authorization of critical documents like SMF, VMP, SOP, Specification, Validation Protocol/report, BPCR, Stability Protocol/report, etc.
33.	To review and approval of Change control, Deviation, MFR, Technology Transfer, Market Complaints, Failure Investigation, APQR.
34.	To help taking an appropriate level of root cause analysis applied during the investigation of deviations, suspected product defects and other problems.
35.	To handle & management of complaint / return of goods / product recall as per approved / mutually agreed procedure with contract giver / agency.
36.	To monitor and control outsourced service activities like calibration, laundry, pest/rodent control, housekeeping etc.

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	DEPARTMENT: QUALITY ASSURANCE	Page No. 3 of 15
	Job Responsibility of Key Personnel	

➤ PLANT HEAD:


Sr. No.	Area	Activities
1.	HR	Understanding all Policies Understanding all SOPs Leave/OT Manpower recruitment Salary Medical Check up AMC for Pest/Medical/GEPIL/Laundry/Scrap/Security & Labour PF
2.	Admin.	Understanding all Policies / Understanding all SOPs Purchases (Mumbai / Local) Working on quotes from vendors / follow ups for delivery schedules Purchase of Engg. / Chemicals / columns / RS Purchase of glasswares / microbiol media AMC for instruments / equipments/testing labs House- keeping contract / Stationery purchase Service personnel for QC/Engg/Utilities Purchase/Monitor stock of Diesel, FO, Scrap, electricity, GEPIL, Sewage, Power cuts, Fire and Safety. Factory Lic. / Pollution Control Board/Labour/Fire and Safety/Gram Panchayat Plant safety Address employee issues Ensure implementation of policies, discipline, GMP in plant Returnable/Non returnable registers monitoring Approvals for statutory chemical storages
3.	FDA (Daman FDA)	Application for renewal of lic. Application for new products Application for Test Lic. Checklists/Undertaking/List of documents/Pharmacopoeia ref./labels/packs Type of lic. Application Application for COPP Application/list of products for GMP approval Application of Free Sale Certificate Application for NOC/ Other regulatory certificates as applicable Technical staff updates/renewal Lic. Unit – I and II Attend Hearings / Document supports
4.	CDSCO/FDA	Application for WHO – GMP certification Application/list of products for GMP approval

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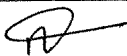
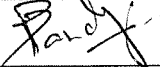

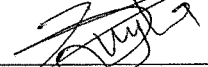

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	DEPARTMENT: QUALITY ASSURANCE	Page No. 4 of 15
	Job Responsibility of Key Personnel	

		Operation in Sugam Portal / Online applications/submission Application for NOC – Import/Export Co-ordinating with CRO / Approval of CRO protocol Approval of A/w
5.	CBN – Gwalior	Application on CBN portal Application for import certificate Application for export authorisation Return filings – Quarterly
6.	Ayurvedic Product lic.	Q&Q formula from HO Approval from HO – Management Application on on-line portal Customer copy of lic. Preparation of lic for submission Ayush details on lic.
7.	FSSAI Applications	Q&Q formula from HO Approval from HO – Management Application on on-line FSSAI portal Customer copy of lic. Procedure for Renewal of lic. Procedure for Modification of lic. Preparation of lic for submission Sending samples to Mumbai Labs for RDA/RDI calculations Reference of FSSAI rules/norms Schedule – IV / VI product category verification Preparation for Sch-IV audits Preparation for HACCP audits Update lic. For FoSCOS Coordinate with Food Consultant – Mr. Panda Coordinate with HO team for lic details
8.	Production Planning, Packing, Dispatch, Logistics, Documentation	Receive Factory Order from HO Inform details to Production Head Check with WH for availability of RM, PM Plan with HO for purchase of RM, PM Arrange to send PR for RM/PM to HO Monitor schedule for receipt of RM, PM Ensure for completion of testing with QC, External labs <ul style="list-style-type: none"> <li>• Intimation to production for planning</li> <li>• Intimation/follow up for packing</li> <li>• Sent packing list to HO</li> <li>• Ensure QC testing and release</li> <li>• Plan for dispatch,</li> <li>• Arrange for logistics</li> </ul>

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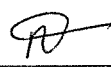
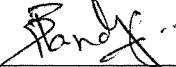



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	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 5 of 15
	<b>Job Responsibility of Key Personnel</b>	

		<ul style="list-style-type: none"> <li>• Arrange for CoA</li> <li>• Arrange for data loggers</li> <li>• Loading of trucks / monitoring cold chain</li> <li>• Documents for Customs clearance</li> <li>• Arranging samples for Customs</li> <li>• Ensure manufacturing of finished products as per desired/acceptable quality</li> <li>• Ensuring man power for production and packaging activities</li> <li>• Production output, product quality, shipping on time</li> </ul>
9.	Weekly Management Meeting	Preparation and updates for weekly meeting, every Thursday. Check for completed/pending/in-pipeline activities Check for updates – all department Updates / Progress / Shortfalls Information to Management for any observations/incidences
10.	Additional Activities/QMS	Support for Technology Transfers, Method Transfers and Validation activities Proposal for CAPA Organising execution of Regulatory & GMP / Compliance to GMP in the unit Man-power management for day to day operations Cost parameters To allocate resources effectively and utilise assets to produce optimal results. Implement strategies, initiate and provide a clear sense of direction Collect and analyse data to reduce waste or overtime Stay updated with latest legal / statutory requirements

➤ HEAD QUALITY ASSURANCE


Sr. No.	Description
1.	To ensure that batch has been produced and controlled in accordance with the requirement of marketing authorization & complies of internal SOP policy & cGMP norms.
2.	To inform and obtain approval from Manufacturing Authorization holder or Contract Giver in the event of any changes / deviations / Failure in the system or product, where applicable.
3.	To conduct review of periodic Product Quality Review report and to ensure compliance to regulatory standards and Manufacturing Authorization Holder's Specification and to identify OOT parameters to take necessary action to maintain process in control.
4.	To participate in the Management Review of product quality, QMS and continual improvement & to take follow-ups for timely action.
5.	To ensure that required, initial and Re-training is Provided and adapted according to need of factory personnel & to ensure they are updated with correct GMP norms.
6.	To monitor & approve microbial water analysis and environmental monitoring trend charts and to take action if any OOT observed.
7.	To implement and maintain cGMP work environment and Quality culture throughout the facility.

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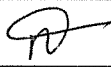


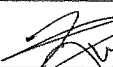



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	DEPARTMENT: QUALITY ASSURANCE	Page No. 6 of 15.
	Job Responsibility of Key Personnel	

Sr. No.	Description
8.	To implement and monitor compliance with the requirements of good distribution & good laboratory practices.
9.	Review and approved of CCP, CCT, Deviation, CAPA, Product Complaint, Internal Audit in eQMS system.
10.	To keep track of QMS activity and to ensure its timely closure & Periodic effectiveness verification.
11.	Trending of the QMS events as per SOP to evaluate required CAPA & to ensure its implementation
12.	To ensure adherence of the data governance requirement and to monitor the same.
13.	To verify all equipment /Instrument/ measuring & Monitoring components are in qualified and calibrated state.
14.	Monitoring of implemented software at site.
15.	To conduct Quality Risk Management, Failure Mode and Effective Analysis (FMEA) and to monitor effectiveness of mitigation plan to reduce the risk.
16.	Responsible for Quality Assurance Monthly Planning.
17.	To conduct investigation in lieu of any non conformity, OOS, incidence, deviation and implement resultant CAPA.
18.	Responsible for review and approval of Annual Product Quality Review.
19.	To examine market complaints and ensure the cause of quality defects investigated and measures are taken with respect of the defective products and to prevent reoccurrence.
20.	Responsible for hosting of regulatory /customer audit and to implement CAPA.
21.	To timely responded on audit responses/Complaints and customer query.
22.	Review and Approval of master documents e.g. BPCR, Specification/ STP/ Validation/ Qualification Protocols.
23.	To review, approve plant SOPs & to ensure SOPs are followed as written or to make the changes as & when required to comply with cGXP regulations.
24.	Design of process, system & equipment w.r.t. cGXP regulations to ensure intended Objectives are met & failures are avoided.
25.	To verify that only trained personnel are performing manufacturing /Packing, testing activity.
26.	To monitor the state of compliance at shop floor.
27.	Review of site master file (SMF) and Validation master plan (VMP), Quality Manual.
28.	Responsible for monitoring activities concerning to outside contract lab audit & management.
29.	Accountable for timely revision of master documents.
30.	Responsible for approval of Artwork related to new products.
31.	Responsible for ensuring the proper execution of Batch Numbering System.
32.	Approval of Quality Documents and GMP Records and to ensure data produced are authentic, traceable & accurate.

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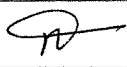


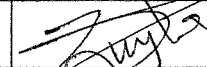
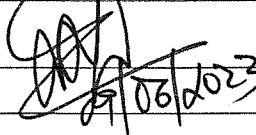
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	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 7 of 15
	<b>Job Responsibility of Key Personnel</b>	

Sr. No.	Description
33.	Responsible for Field Alert & Post Marketing.
34.	Co-ordination with internal / external customer regarding quality issues.
35.	Qualification & approval of manufacturer & supplier of starting & packing material.
36.	To ensure the availability of quality technical agreement with contract giver/acceptor
37.	To participate in management review meeting and escalate the issues pertaining to quality and EHS.
38.	To ensure Internal Audits schedule is followed as planned & appropriate CAPA is taken & compliance of the same.
39.	To ensure the appropriateness of document management & to ensure that current version are available with all stake holder.
40.	To ensure manufacturing, cleaning procedures are validated & remains in validated state to yield product of desire quantity throughout its life cycle.
41.	To plan, monitor and ensure process & cleaning Validation activity is done according to approved protocol.
42.	To timely compile and summarize validation results.
43.	Ensuring the correctness of Item code and product code allocation.
44.	To obtain monthly planning from all departments, its follow-ups for execution and to obtain status report.
45.	To ensure Validation / Qualification activities as per schedule are performed on time.
46.	To Implement, monitor and update EHS procedure.
47.	To Authorized for batch release in absence of Head Quality.
48.	To establish and ensure procedures to be followed when the actions to be taken if data review identifies an error or omission and its correction / clarification to be made in a GMP compliant manner.
49.	Any other additional Responsibility allotted by management.

➤ **HEAD QUALITY CONTROL**


Sr. No.	Description
1.	Responsible for overall management of Quality Control laboratory and compliance to applicable standards.
2.	To approve or reject, as he sees fit, raw materials, packaging materials, semifinished product and finished products as per agreed/approved Specifications.
3.	To review and approve analytical reports, validation protocols, calibration reports, environmental monitoring planner and other documents of microbiology laboratory.
4.	Preparation and review of departmental SOP's related to Quality control and microbiology laboratories.
5.	To ensure instruments are calibrated timely and approval of relevant records.
6.	To ensure analyst are validated for required testing.
7.	Procurement and Management of Reference and working standards.

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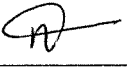
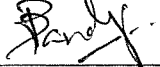

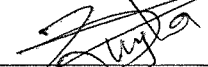

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	DEPARTMENT: QUALITY ASSURANCE	Page No. 8 of 15
	Job Responsibility of Key Personnel	

Sr. No.	Description
8.	To ensure compliance of laboratory instruments and procedure as per 21CFR part 210,211, EU GMP and other applicable GLP regulations.
9.	To participate in the Investigation of complaints related to Quality of Product.
10.	To participate in the Management review of Product Quality, QMS and continue improvement.
11.	To ensure timely and effective communication with the management to raise Quality issue.
12.	Review of analytical data.
13.	To carry out investigation in case of any OOS, deviation.
14.	To involve and to participate in "Internal audit" activities.
15.	To ensure data back up procedure is followed as per SOP.
16.	To involve and to participate in cleaning validation, method validation and process validation activities.
17.	To monitor & approve water analysis trend charts.
18.	To ensure disposal of test over samples as per approved procedure.
19.	To ensure Analytical method transfers are executed as per the protocols.
20.	To ensure Proper documentation of all the QC records are maintained in a proper manner.
21.	To ensure laboratory equipments are covered under Annual Maintenance Contract (AMC) and schedule is followed.
22.	To Encourage staff to follow GDP/GLP/QMS.
23.	To ensure/maintain GLP environment in QC laboratory.
24.	To ensure compliance related to applicable EHS procedure.
25.	To ensure all necessary testing is carried out against current approved specification and test procedure and the associated records are evaluated.
26.	To review specification, sampling instruction, test methods and other quality control procedure.
27.	To monitor contract analysis activity.
28.	To ensure the qualification and maintenance of the department, premises and equipment.
29.	To ensure that required, initial and Re-training is Provided and adapted according to need of his department personnel.
30.	To participate in Vendor audit programme.
31.	To conduct audit of contract laboratories.
32.	Handling and monitoring of reference sample of raw materials/packaging materials.
33.	Inspection, investigation and taking of samples in order to monitor the factors which may effect product quality.

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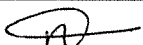




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	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 9 of 15
	<b>Job Responsibility of Key Personnel</b>	

Sr. No.	Description
34.	To ensure necessary stability studies are performed timely and review of the analytical data and to document any OOT value.
35.	To review and approve change controls, deviations, CAPA as per the requirement.
36.	To ensure that the analytical methods are validated for intended use.
37.	To perform any other task from time to time as assigned by superior.
38.	To ensure data generated in QC laboratory is ALCOA+ (Attributable, Legible, Contemporaneously recorded, Original and Accurate, Complete, Consistent, Enduring, Available).
39.	To Review/Approve QAMS related Activities.
40.	To impart training on EUGMP and 21CFR guidelines.
41.	To perform assesment of Dissolution Profiles of batches Manufactured at Olive vs RLD samples and evaluate against EMA guidance.
42.	To participate and provide resolution to regulatory eurries.

➤ **HEAD PRODUCTION**


Sr. No.	Description
1.	Reporting to Plant Head.
2.	Execution of production and packing activity as per production plan.
3.	To allocate work to workforce and perform the critical checks and ensure line clearance at all stages of production to ensure Current good manufacturing practice is followed.
4.	To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality.
5.	To co-ordinate with maintenance department in order to implement preventive maintenance as per schedule for minimizing the breakdown of machines.
6.	To ensure maintenance of records related to the respective departments, like machine log, cleaning record, batch record at right time.
7.	To ensure that the required initial and continual training of his department personnel is carried out and adapted according to need.
8.	To bring to the notice of higher management any process change to improve productivity and quality of the products.
9.	To bring to the notice of higher management any accident or injuries, if any.
10.	To initiate change control related to production department.
11.	To monitor that shop floor SOPs are being followed.
12.	Being a member of cross functional investigation for market complaints, investigation and out of specification investigation.
13.	To co-ordinate and control all activities of different departments for orderly production, packing and delivery of quality products according to priority and schedule.
14.	To co-ordinate with QC department for obtaining timely analysis results and QA department for timely release so as to have minimum lead-time for the products.

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	07/06/2023



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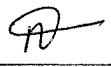


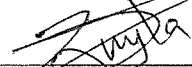

OHC/II/FM/4/02-SOP/QA/020

	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 10 of 15
	<b>Job Responsibility of Key Personnel</b>	


15.	To implement discipline and related functions among the workmen in the factory under the certified standing orders.
16.	To prepare and review of departmental SOPs
17.	To ensure the cleanliness of the production department.
18.	To approve the instructions relating to production operations and to ensure their Implementation.
19.	To ensure that the production records are timely evaluated and authorized.
20.	To ensure the maintenance of his department and premises and qualification of equipment and machines.
21.	To ensure that the production records are evaluated and signed by an authorized Person.
22.	To ensure that the appropriate validations are done.
23.	The monitoring and control of the manufacturing environment.
24.	To Participation in management reviews of process performance, product quality and of the quality management system and advocating continual improvement.
25.	Ensuring that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management.
26.	To review of BPCR.
27.	To ensure data generated in department is ALCOA (Attributable, legible, contemporaneous, original and accurate).

➤ **HEAD WAREHOUSE**

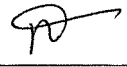
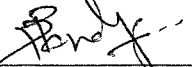



Sr. No.	Description
1.	Overall responsible for starting material, packing material and finished goods in warehouse.
2.	To Prepare shortages of RM/PM and to send indent to purchase department.
3.	To ensure adequate measure are in place for safety of people working in the area.
4.	To ensure MSDS is available & staff is aware about any hazard associated with the material.
5.	To ensure material purchased & received from Approved Manufacturer/Supplier.
6.	To ensure integrity of packages & seal at the time of receipt.
7.	To check containers for damage/spillage, complete document and to inform QA incase of discrepancy by raising incidence.
8.	To Verify physical reconciliation of material and intimate to QA if any discrepancy observed.
9.	To ensure compliance of all warehousing SOPs and relevant records are maintained.
10.	To check the data of temperature of cold chamber on daily basis.
11.	Verify the Record for Minimum & maximum Temperature & RH.
12.	To ensure raw material, packing material and finished product are stored according to defined storage condition.
13.	To ensure stock rotation system is followed.
14.	To ensure materials received as per production plan and to ensure timely delivery.

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	07/06/2023

**Annexure – IV**
**OHC/II/FM/4/02-SOP/QA/020**


	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 11 of 15
	<b>Job Responsibility of Key Personnel</b>	

15.	To ensure correct materials is issued for manufacturing and packing as per BPCR.
16.	To ensure materials and finished product in stored in appropriate area according to its status.
17.	To ensure all material containers have appropriate and legible status label all the time.
18.	To ensure adequate measure are in place for prevention of contamination and cross contamination
19.	To impart initial and continual training to departmental personnel for related quality, environmental health and safety requirement.
20.	To ensure all departmental equipment/instrument are calibrated and qualified on time.
21.	To maintain cleanliness, orderliness & hygiene in warehousing area.
22.	To ensure only released materials within the shelf life is issued to production as mentioned in BPCR.
23.	To prepare/circulate monthly retest note and to ensure compliance of retest procedure.
24.	To ensure dispensing operation is follow as per SOP and performed in presence of QA
25.	To take follow-ups with QC for timely release of materials.
26.	To ensure bin card are updated and monthly physical stock checking.
27.	To ensure only authorized persons entered in warehouse area.
28.	Responsible for handling of Narcotic and Psychotropic substances.
29.	Responsible for monitoring the compliance with the requirement of good manufacturing practice.
30.	To ensure safe disposal of expired/ obsolete / rejected / non-moving RM, PM and FG complying internal SOPs and statutory requirement.
31.	To implementation and the monitoring of compliance with the requirements of Good Distribution Practices.
32.	Review and implantation of departmental SOP.
33.	Review of Annual product review.
34.	To handle returned/rejected/recall products as per SOP.
35.	To ensure products are dispatched according to marketing authorization.
36.	To ensue implementing of QMS in the department.
37.	To participate in OOS, incidence, market complaint investigation and fill CAPA.
38.	Ensuring that timely and effective communication and escalation process exist to raise quality issues to the appropriate levels of management.
39.	Responsible to ensure the maintenance of data integrity in documents.
40.	To attain and participate in internal audit.
41.	Initiate and review of any change in department and procedure and initiate to QA through change control in Caliber QAMS software.

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

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	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 12 of 15
	<b>Job Responsibility of Key Personnel</b>	

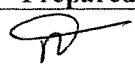
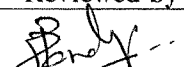
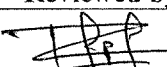
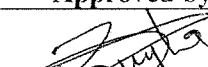
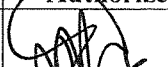
42.	To participate in the management review meeting and to raise any issues pertaining of quality, environment, occupational health & safety.
43.	Review the CAPA, Temporary change control and Deviation in Caliber QAMS software.
44.	To Ensure Batch are released and shipment completed in IT system prior to Dispatch.
45.	To perform and other duties assigned by supervisor.

➤ **HEAD PACKING**

Sr. No.	Description
1	To finalize Packing plan for weekly and monthly.
2	To allocate work to workforce and perform the critical checks and ensure line clearance at all stages of Packing to implement Current good manufacturing practice.
3	Preparation and review of SOPs.
4	To review the BPCR compliance.
5	To conduct monthly training for staff and worker.
6	To carry out the equipment qualification and change part suitability.
7	To ensure maintenance of records related to the respective departments, like machine log, cleaning record, batch record at right time.
8	To impart training on safety, hygiene, cleaning and cGMP.
9	To bring to the notice of higher management any process change to improve productivity and quality of the products.
10	To bring to the notice of higher management any accident or injuries.
11	To train for strict implementation of SOP's and safe working environment.
12	To investigate all market complaints and reports along with QA.
13	To co-ordinate and control all activities for order delivery of quality products according to priority and schedule.
14	P.M. Shortages and follow up of packing materials.
15	Ensuring that all process complies with cGMP.
16	To ensure the cleanliness of the packing department.
17	To implement discipline and related functions among the workmen in the factory under the certified standing orders.
18	Party Communication & Follow up as per Party Requirement.
19	Procurement, Approval of change part.
20	Preparation and review of BPCR.

➤ **HEAD ENGINEERING**


Sr. No.	Description
1.	Reporting to Plant Head
2.	To define and authorize the job responsibility of engineering department.
3.	To assure that the objective of Quality Policy is followed within the department.

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	05/06/2023	09/06/2023

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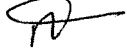




OHC/II/FM/4/02-SOP/QA/020

	<b>DEPARTMENT: QUALITY ASSURANCE</b>  <b>Job Responsibility of Key Personnel</b>	Page No. 13 of 15
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Sr. No.	Description
4.	To co-ordinate with other departments for timely execution of the activities in the department.
5.	To review and authorization of departmental Standard Operating Procedure (SOP).
6.	To review qualification protocol and reports of equipments and area.
7.	To ensure Quality System and applicable Standard Operating Procedures are followed.
8.	To ensure the availability of required number of skilled manpower and desired equipments in the department.
9.	To ensure that the personnel working in the department have necessary qualification, experience and are trained adequately.
10.	To maintain facility, equipment and utilities in good state of operational conditions.
11.	To maintain the equipment's, utilities in qualified and validated state of condition.
12.	To ensure that the utilities and applicable resources are provided to the user department.
13.	Adherence to planned preventive maintenance to minimize breakdown.
14.	To ensure the timely calibration of the various components.
15.	To ensure that safety norms and good engineering practices are followed.
16.	To contribute for improvement in systems and practices to ensure adequate care for various machines with respect to safety, cost saving & energy conservation.
17.	To be accountable for inventory of a required stock level of spare parts of equipment to minimize the total breakdown time.
18.	To co-ordinate with contractors in the preparation and execution for service contracts.
19.	To ensure compliance to cGMP requirements within the factory premises

➤ **HEAD IT**


Sr. No.	Description
1.	Responsible to Manage information technology and computer systems.
2.	Responsible to Plan, organize, direct, control and evaluate the operations of information systems and electronic data processing (EDP).
3.	Responsible to Develop and implement policies and procedures for electronic data processing and computers systems operations & development.
4.	Responsible for Troubleshooting hardware, Software, network and telecommunication system operating system.
5.	Responsible to ensure the procedure are timely updated as per the regulatory requirement.
6.	Responsible for taking backup data and backup of backup data and restore data as per the procedure.
7.	Responsible to ensure safety and security of backup data.
8.	Responsible to Maintain data security.
9.	Responsible to Full Administrator Privilege Access.
10.	To ensure password policy is followed.

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023


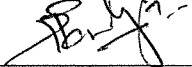

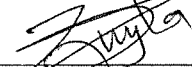



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OHC/II/FM/4/02-SOP/QA/020


	DEPARTMENT: QUALITY ASSURANCE	Page No..14 of 15
	Job Responsibility of Key Personnel	

11.	Responsible for timely validation of computer system.
12.	Responsible to Meet with managers to discuss system requirements, specifications, costs and timelines.
13.	Responsible to Hire and manage information systems personnel and contractors to design, develop, implement, operate and administer computer and telecommunications software, networks and information systems.
14.	Responsible to Control the computer systems budgets and expenditures.
15.	Responsible to troubleshoot hardware, software and network operating system.
16.	Responsible to provide training to new users of existing technology.
17.	Responsible to provide training to employees as an when required.
18.	Responsible to provide recommendations about accessing information and support.
19.	Responsible to maintain current and accurate inventory of technology hardware, software and resources.
20.	Responsible to take all system backup as per backup planner and periodic verified as per the procedure.
21.	Responsible to monitor and maintain technology to ensure maximum access.
22.	Responsible to troubleshoot all technology issues.
23.	Responsible to maintain log and/or list of required repairs and maintenance.
24.	Responsible to make recommendations about purchase of technology resources.
25.	Responsible to research current and potential resources and services.
26.	Responsible to provide network access to all staff.
27.	Responsible to install work stations.
28.	Responsible to connect and set up hardware.
29.	Responsible to load all required software.
30.	Responsible to provide network accounts and passwords as required.
31.	Responsible to monitor security of all technology.
32.	Responsible to install and maintain full proof passwords.
33.	Responsible to input and maintain IP addresses.
34.	Responsible to Advise staff of security breach and/or change in password or security status
35.	Responsible to ensure installation of lock out programs.
36.	Responsible to identify and prepare hardware for disposal when appropriate.
37.	Review of Daily Auto backup activity and take Archive of Email Data and LAB Data as per the planner.
38.	To perform in-house Computer system hardware qualification as per defined protocol.
39.	To ensure Computer system hardware qualification is completed as per defined protocol.

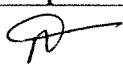
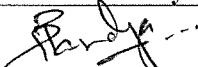
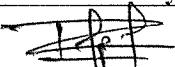
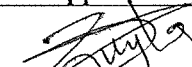
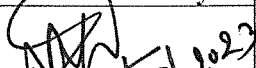
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Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	07/06/2023

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	DEPARTMENT: QUALITY ASSURANCE	Page No. 15 of 15
	Job Responsibility of Key Personnel	

40.	To perform PC hardware qualification and software validation as per CSVMP.
41.	To perform software validation of new instruments.
42.	To implement system and software control policies as defined in individual Instrument SOP's.
43.	To perform the IT Related activities of QC department as defined in individual Instrument/Equipment SOP's.
44.	To maintain and secure 21 CFR part 11 compliance of instrument / Equipment available in Quality control.
45.	Responsible as Administrative rights holder for instrument / Equipment available in Quality Control.
46.	Responsible for securing the Login/ Passwords as "Administrator" of instrument/ Equipment available in Quality Control.
47.	To coordinate with IT department for implementation of laboratory instrument control policy to ensure 21 CFR part 11 Compliance.
48.	Responsible to prepare SOP's related to Backup of Electronic data generated by laboratory Instrument/ Equipment Software's
49.	Training to new QC employee as per procedure and IT QC Server based and Stand-Alone based Instrument Software.
50.	Responsible to coordinate with IT department for implementation of backup policy in line with 21 CFR part 11 requirements
51.	To prepare SOP related to instrument operating procedure for new instruments as per Guideline.
52.	To maintain software inventory
53.	Ensure the laboratory Instrument/ Equipment IT systems are compliant and in a constant state of readiness for regulatory inspections.
54.	To maintain software inventory
55.	Support audits and other departments to assure adequacy of and compliance with established Quality Systems.
56.	Training to new QC employee as per procedure and IT QC Server based and Stand-Alone based Instrument Software.

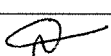
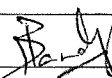

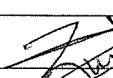

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Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/16/2023

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OHC/II/FM/5/01-SOP/QA/020


	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 1 of 2
	<b>Request form for Change in Specimen Signature</b>	

Name of Employee :		Department :
Designation :		Date of Request :
Request Raised By:		
SPECIMEN SIGNATURE OF EMPLOYEE:		
Initial	Full	With Effective From
ALTER SPECIMEN SIGNATURE		
Initial	Full	Required to be Effective From
Reason /Justification for Change in specimen signature:		
Employee Sign.&Date		
Comments of Concerned Department HOD:		
Concerned Department HOD Sign./Date		
Manager –QA Comments		Head Quality Comments & Approval :
Manager-QA Sign/Date		Head Quality Sign/Date

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	09/06/2023

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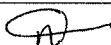
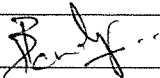

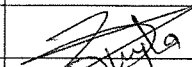
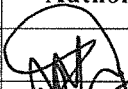
	DEPARTMENT: QUALITY ASSURANCE	Page No. 2 of 2
	Request form for Change in Specimen Signature	

For Information to the cross functional Department.(If applicable)


Department	Other Cross functioning Department HODs Name	Sign./Date
QA		
QC		
QM		
EN		
WH		
PR		
PK		
AP		
IT		
RA		

This is to confirm that Mr. / Ms. \_\_\_\_\_,  
working in department: \_\_\_\_\_ has changed his/her specimen signature, which is effective  
from: \_\_\_\_\_.

**Head –Quality**  
**Sign/date**

	Prepared By	Reviewed by	Reviewed by	Approved by	Authorized By
Signature					
Date	07/06/2023	07/06/2023	07/06/2023	09/06/2023	05/06/2023



 <b>Olive</b> HEALTHCARE	<b>DEPARTMENT: QUALITY ASSURANCE</b>	Page No. 1 of 1
	<b>Training Attendance Sheet cum Evaluation sheet</b>	<b>043</b>

**Type of Training:** *cGMP / Technical / On the Job / Specific / Refresher / Re-training / Behavioral*  
(Tick whichever is applicable)

**Training Topic:** \*A

### Training session:

Name of Trainer: Pratik Pandya

From 15:43 hrs. to 16:05 hrs.

Venue: Conference Hall

Training Date: 27/06/2023

Sr. No.	Name of Trainee	Designation	Department	Signature of Trainee	Remarks
01	Munish Patel.	Asst. Manager	PK	<i>[Signature]</i> 27/06/2023	-
02	Ramdev Sharma	Asst.	QC	<i>[Signature]</i> 27/06/2023	-
03	Mamta Chaudhary	Asst.	EN	<i>[Signature]</i> 27/06/2023	-
04	Amol D. Shelke	Executive	QC	<i>[Signature]</i> 27/06/2023	-
05	Satish Tiwari	Manager	PK	<i>[Signature]</i> 27/06/2023	-
06	Kunal Rajput	Sr. officer	QA	<i>[Signature]</i> 27/06/2023	-
07	Anand Singh	Officer	IT	<i>[Signature]</i> 27/06/2023	-
08	Abhinav Kashyap	Sr. officer	QA	<i>[Signature]</i> 27/06/2023	-
09	Hitesh M. Patel	Head-DIP	QC	<i>[Signature]</i> 27/06/2023	-
10	Abhinav Mishra	Sr. officer	WH	<i>[Signature]</i> 27/06/2023	-
11	Ashok Anand	Manager	WH	<i>[Signature]</i> 27/06/2023	-
12	Mahesh Bhatti	HR-officer	Admin	<i>[Signature]</i> 27/06/2023	-
13	Sanjay Patel	Asst. Manager	QC	<i>[Signature]</i> 27/06/2023	-
14	Abhinav Sharma	Executive	PK	<i>[Signature]</i> 27/06/2023	-
15	Chetan Ramdas	Asst. Manager	QA	<i>[Signature]</i> 27/06/2023	-
16	Anurag Kumar	Asst. Manager	PR	<i>[Signature]</i> 27/06/2023	-
		NA			

(Use additional sheet if required)

**Sign of Trainer:**

## TRAINING EVALUATION

Reference SOP No.: OHC / II / SOP / QA / 020-07      Version No.: 07

**Oral feed back taken:** Satisfactory /Not Satisfactory

Evaluated by questionnaires: Yes/No (If Yes: Satisfactory / Not Satisfactory)

If not satisfactory: NA

\* Allocation of Job responsibility & maintenance of specimen signature.

Retraining identified for: NA

A Reprocessing, Redressing & Rework Policy.

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

Retraining performed on:  $\mathcal{N}^A$ 

**Trainer Signature / Date:** NA