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TITLE: TRAINING OF EMPLOYEES**1.0 PURPOSE :**

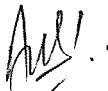

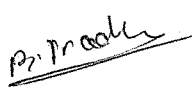


To lay down a procedure for Training of employees, with respect to Induction training, Behavioural training, cGMP training, Technical training, On the job Training and other as identified during Annual appraisal.


2.0 SCOPE:

This SOP is applicable to all the employees of manufacturing plant of Olive Healthcare, Unit II, Daman.

3.0 RESPONSIBILITY:

- 3.1. HOD Admin and Personal (A&P) : Providing Induction training to newly Joined or his / her designee employee.
- 3.2. HOD Quality Assurance or his / : Imparting knowledge of cGMP topic. her designee.
- 3.3. HOD Concern department or his / : Responsible to provide training on technical subjects, her designee. On the job & refresher training.
- 3.4. Training Co-ordinator of each : To prepare training need identification. To Co-ordinate the training of their department and to ensure that the employees of their department get trained according to session planned to evaluate questionnaire.
- 3.5. Training Co-ordinator of QA : To prepare training need identification. To Co-ordinate the training of their department and to ensure that the employees of their department get trained according to session planned. To review Training Calendar and

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Designation	SR. OFFICER	MANAGER	SR. OFFICER	HEAD-QA	HEAD-QUALITY
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TITLE: TRAINING OF EMPLOYEES

Refresher Training Need Identification of each department. To prepare Annual Training Calendar for cGMP refresher training topics each year. To prepare format for planner cum tracking for each cGMP training topics covered under Annual Training Calendar. To evaluate training questionnaire as evaluator.

3.6. Trainer : To conduct the training as per training plan.

3.7. Trainee : To attend the training program as per the schedule, to appear for the Training evaluation test and to maintain the Staff Training Card.

4.0 ACCOUNTABILITY

Head Quality shall be accountable for the overall implementation and adherence to of the Standard Operating Procedure.

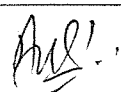
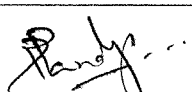
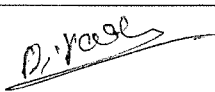
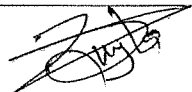
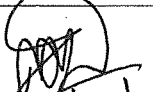
5.0 PROCEDURE:


5.1 All the employees shall be categorized as per following levels based on their work profiles.

5.1.1 Level-1 : Includes Executives and above.

5.1.2 Level-2 : Chemist; Officers and Skilled Operators and supervisors involved in the manufacturing and primary packing process.

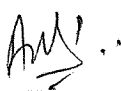
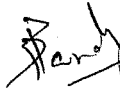



5.1.3 Level-3: Semi Skilled worker who are involved in secondary packing process and all house keeping staff..


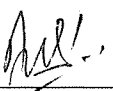

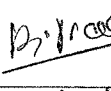
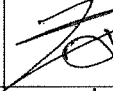

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TITLE: TRAINING OF EMPLOYEES

- 5.2** Every employee of the organisation shall be trained on his / her area of operation prior to start of the intended work. The training shall be imparted depending on the nature of job responsibilities. cGMP training is mandatory for each employee which shall be provided during induction as well as during refresher training.
- 5.3** Training activities of all department shall be coordinated by the training coordinator of the respective department. List of Training Coordinator shall be prepared as per Annexure XVI titled "List of Training Coordinators" and shall be updated as and when required.
- 5.4** Planning and execution of training for each new employee shall be carried out as mentioned in section 5.5.
- 5.5 Planning and Execution of Training**
- 5.5.1** On joining the Organization; each new employee shall undergo following trainings which shall be conducted within the organisation by the in house faculty only. It is divided into three main categories as mentioned below:
- 5.5.1.1 Induction Training
- 5.5.1.2 On the Job Training
- 5.5.1.3 cGMP Training
- 5.6 Induction Training**
- 5.6.1** A&P department shall prepare an induction schedule as well as co-ordinate for induction training for all new Level - 1 and Level - 2 employees. (As per Annexure -V titled "Induction Training Schedule").
- 5.6.2** Induction Training covers the overview of the company organisation and department.
- 5.6.3** After completion of joining formalities, A&P department shall update new employees on following topics:

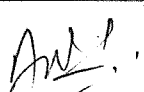
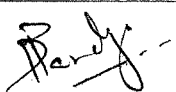
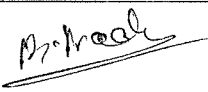
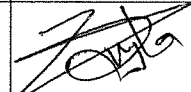

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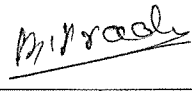
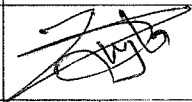

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<p>5.6.3.1 Introduction to Olive Healthcare.</p> <p>5.6.3.2 Organisational Structure.</p> <p>5.6.3.3 Key personnel and organisation structure of various departments.</p> <p>5.6.3.4 Brief information about plant.</p> <p>5.6.3.5 A&P policies e.g. shift timing, leave policy and other employee benefit policies.</p> <p>5.6.3.6 All Policies of OHC Unit-II</p> <p>5.6.3.7 Code of conduct.</p> <p>5.6.3.8 Quality, Environment, Occupational Health and Safety (QEOHS) Policy.</p> <p>5.6.4 As per the induction training schedule, the new employee shall go to applicable departments for interaction with concerned HOD and staff members.</p> <p>5.6.5 HOD of various departments or his / her designee shall brief to the new employee about their departmental structure & functions.</p> <p>5.6.6 After successful completion of the induction training, employee shall be shifted to his/her department.</p> <p>5.6.7 Induction training shall not be provided to Level -III employee. Admin and Personal shall explain basic cGMP, Do & Don't, House keeping, Shift timing etc and they shall be directly shifted to concern department for on job training.</p> <p>5.7 On the Job Training</p> <p>5.7.1 On the job training shall be imparted to all new employee (Level-1, Level-2 and Level-3) by the concerned HOD or his / her designee related to the area of operation.</p> <p>5.7.2 Training need identification shall be determined for new employee based on the intended function/operation to be performed by the new joiner in that department.</p>					
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- 5.7.3 On the job training shall include the training in relevant SOP of his/her department and applicable cross functional department and topic of cGMP aspect.
- 5.7.4 This training program shall also include the training related to the specific aspects of an individual's role including use of equipment, unit operations, safety norms to be followed and adherence to cGMP.
- 5.7.5 During on job training cGMP training shall cover topics viz. principles of EU GMP Regulations, 21 CFR and Basic Health & Hygiene policy.
- 5.7.6 Format for allocation of On the Job Training shall be Prepared by concern Department Training Co-ordinator, Checked by Department Head; Reviewed by Head QA/designee and finally Approved by Head Quality.(Refer Annexure-VI titled "Format for on Job Training Record).
- 5.7.7 The mode of imparting training on identified topics during on job training shall either be "Practical" (By means of physical demonstration of that operation), "Theoretical" (By means of classroom training with explanation of the procedure on identified topic by the certified trainer) or "Self Reading" (By means of self reading of the procedure by the trainee) or combination of any and same shall be pre-defined in the On Job Training Record prepared by concern department co-ordinator.
- 5.7.8 Mode of training shall be identified by the Head of Department/Training Co-ordinator of that department based on criticality of work performed in future and previous exposure of the concern employee on identified topic/subject.
- 5.7.9 Self reading of SOPs is applicable to only Level 1 and Level 2 employees however academic qualification and previous relevant experience shall be considered for the self reading of the SOP.
- 5.7.10 After completion of the self reading; session shall be evaluated by written assessment.

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<p>5.7.11 Wherever applicable practical training shall be identified and provided by practical demonstration and same shall be followed by reviewer assessment.</p> <p>5.7.12 For Level 3 employees, theoretical understanding of required SOPs shall be imparted by the concerned HOD and same shall be evaluated by written questionnaires.</p> <p>5.7.13 Questionnaire Format for evaluation of training topics other than SOP training questionnaire shall be as per Annexure - VII titled "Training Evaluation Questionnaire".</p> <p>5.7.14 On Job Training shall be completed probably within a month from the date of joining of employee. However wherever practical demonstration and personnel qualification is required the training completion time shall be extended based on the requirement.</p> <p>5.7.15 After successful completion of On the Job Training; Trainees shall be certified regarding understanding of the trainee on relevant aspects with completed on - job training record duly signed by Concerned HOD followed by Plant Head and Quality Head. (Refer Annexure-VI titled "Format for On the Job Training Record").</p> <p>5.7.16 After completion of the On Job Training, Job responsibility of the employee shall be prepared as per SOP No.: OHC/II/SOP/QA/020.</p> <p>5.7.17 If any employee is transferred from one area of operation to other area of operation within the department, training on related SOP's shall be imparted to the employee and shall be certified to perform work only after successful completion of on the job training.</p> <p>5.7.18 Training Attendees group (Annexure - XII titled "Format for Training Attendees group") shall be prepared which shall include the level wise details of the employees viz. name of the employee, department and employee code for the ease of identification of the applicable trainee for future refresher training on SOP, cGMP and other relevant aspect.</p>					
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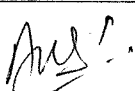
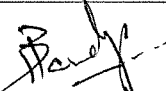
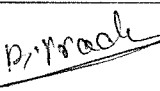
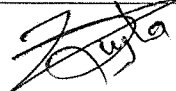
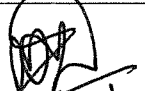
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- 5.7.19 Training Attendees group (Annexure - XII) shall be prepared by QA Training Coordinator; reviewed by Manager QA/designee and finally approved by Head Quality
- 5.7.20 After completion of the on job training, name of new employee shall be updated in the addendum format of the training attendees group Annexure- XII by training coordinator of QA department and same shall be mentioned in the remark column as "Addition".
- 5.7.21 In case any employees leaves the organization the name of the same shall be updated in the addendum format of the of the training attendees group Annexure- XII by training coordinator of QA department and same shall be mentioned in the remark column as "Deletion".
- 5.7.22 Annexure- XII "Training Attendees group" shall be updated at the frequency of every year or as and when required.

5.8 Refresher Training

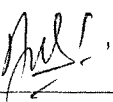
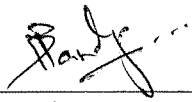
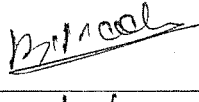
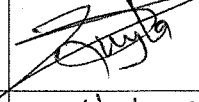

- 5.8.1 Refresher training shall be applicable to the existing employee of all level of all department who are with the organization from previous year.
- 5.8.2 The refresher training need identification for each employee shall be primarily based on the procedure of their departmental/cross functional departmental functions and cGMP aspect.
- 5.8.3 Training need identification for refresher training for each employee of that department shall be prepared to acquaint them on existing procedure and relevant current guidance as per annexure - XI titled "Refresher training need identification for individual person".


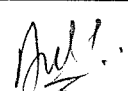
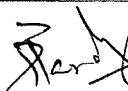
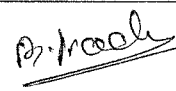
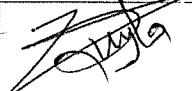
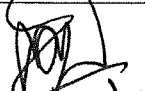
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- 5.8.4** Refresher training need identification form is prepared by training coordinator of that department; reviewed by department head; approved by QA Head / Designee and finally authorized by Head Quality.
- 5.8.5** Once Refresher training need identification form is authorized by Head QA, it shall be stamped as "MASTER COPY" and shall be issued to concern department for execution.
- 5.8.6** Based on the above Refresher training shall be categorized as below:
- 5.8.6.1** Refresher Training on relevant SOP
- 5.8.6.2** Refresher Training on cGMP guidance and other aspect.
- 5.8.7 Refresher Training on relevant SOP:**
- 5.8.7.1** According to the training need identification form of concern department each employee has to undergo refresher training on the identified SOP.
- 5.8.7.2** Mode of imparting training shall either be self reading or as theoretical (classroom) training which shall be defined in the training need identification form.
- 5.8.7.3** If it is classroom training than Training attendance sheet shall be filled as per Annexure - IV (Training Attendance Sheet cum Evaluation Sheet) for the trainee who attended that session.
- 5.8.7.4** After completion of the training session through both training modes viz. self reading and theoretical; understanding of the SOP by the trainee shall be assessed through filled questioner by Concern Department Head/Cross Functional Section Head.
- 5.8.7.5** Additionally concern Department Head shall assess the overall adequacy on understanding of the topic by concern person including complete review of deviation occurred in a previous year related to the concern operation

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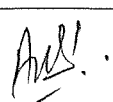
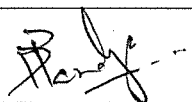
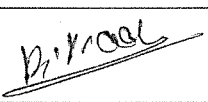
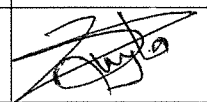

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TITLE: TRAINING OF EMPLOYEES					
<p>performed by individual in previous year and same shall be mentioned in the remark column of the attendance log.</p> <p>5.8.7.6 After successful completion of training on the identified topic, it shall be circled in Annexure-XI by training coordinator of that department for significance of the completion of the training of that individual person.</p> <p>5.8.7.7 If all the employees are not covered in scheduled SOP training or any Identified training topics then second session of such training shall be conducted.</p> <p>5.8.7.8 For second session of training, separate training attendance sheet as per Annexure-IV titled "Training Attendance Sheet cum Evaluation Sheet" shall be filled and same shall be maintained separately.</p> <p>5.8.8 Refresher Training on cGMP guidance:</p> <p>5.8.8.1 At the start of the calendar year, cGMP Training Calendar shall be prepared as per Annexure XIII titled "Format for cGMP Training Calendar"</p> <p>5.8.8.2 cGMP Training calendar shall be Prepared by QA Training Coordinator, Reviewed by QA Head and Approved by Head Quality.</p> <p>5.8.8.3 cGMP Training Calendar shall be stamped as "MASTER COPY" and shall be kept with QA training coordinator for reference purpose..</p> <p>5.8.8.4 Training on cGMP Annual topics i.e. EU GMP Regulations, 21 CFR shall be provided to Level 1 and Level 2 employees and training on Health and Hygiene shall be provided to Level 1, Level 2, and Level 3 employees on semi annual basis.</p> <p>5.8.8.5 cGMP Training Calendar shall be updated as and when required.</p> <p>5.8.8.6 Prior to execution of training, QA training coordinator shall identify the Name of Trainer, Training Topic, Document No. (if any), Date, Time and</p>					
	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
Name	ADARSH KASHYAP	PRATIK PANDYA	BIKASH PRADHAN	VIKASH JHA	RAJAN DESAI
Designation	SR. OFFICER	MANAGER	SR. OFFICER	HEAD-QA	HEAD QUALITY
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023


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TITLE: TRAINING OF EMPLOYEES

Trainee Group and communicate same to the cross functional department training coordinators either via verbal, telephonic or through email communication and record the same in Annexure XIV (Training Session Group Identification cum Attendance Sheet of cGMP training).

- 5.8.8.7 Concern department coordinator shall identify personnel in consultation with department head.
- 5.8.8.8 HODs of concern department shall plan work accordingly to ensure that all concern employees get trained as per session planned.
- 5.8.8.9 During training session; identified trainee shall record their detail along with sign/date in the training session group identification cum attendance sheet for cGMP training (Refer Annexure XIV)
- 5.8.8.10 QA training coordinator shall plan the Next training session in consultation with Trainer and department head at the end of the training session to ensure all remaining employees get trained.
- 5.8.8.11 The training topic shall be specific for each level.
- 5.8.8.12 For effective tracking of cGMP training of applicable employees of all departments for identified cGMP session "Planner cum tracking sheet for cGMP session" shall be prepared as per Annexure - XV (Format for Planner cum Tracking of cGMP Session) which shall be prepared by Training coordinator of QA department; approved by Head QA and authorized by Head Quality.
- 5.8.8.13 At the start of the year, Planner cum tracking sheet for cGMP session for each training topic shall be prepared.
- 5.8.8.14 The same shall be stamped with "MASTER COPY" stamp and issued to QA training coordinator for execution.

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TITLE: TRAINING OF EMPLOYEES

5.8.8.15 After completion of successful training on cGMP training session; Training coordinator of the QA department shall mark in the column for execution in "Planner cum tracking sheet for cGMP session" for completion of the training by the individual.

5.8.8.16 On the identified training topic, trainer shall prepare the presentation available from the official guidance website for effective training and questionnaires for evaluation of its effectiveness.

5.8.9 Staff Training card of each employee shall be maintained by respective user after completion of training. (Refer Annexure-VIII, Staff Training Card)

5.8.10 Refresher training shall be carried out as per on going training calendar, and whenever there is a procedural change or revision in the SOP.

NOTE:

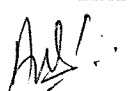
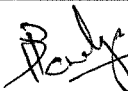
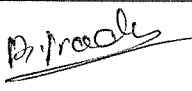
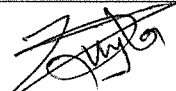

- If an employee resumes after a long leave of more than 6 months, a complete refresher training shall be provided to him/her.


- If an employee resumes after a long leave of less than 6 months, then the pending training as per the schedule applicable to him / her shall be completed first prior to commencing of any job activity. If there is any core changes in procedure of any SOP, same shall be imparted to the employee. Additionally, the respective HOD & Head QA shall conduct a personal interview with the employee to assess him / her present awareness about the procedure and identify if any specific trainings are to be provided to him / her.

5.9 Apart from above specified training following training to be given to identified employees to explore their functions as and when required.

5.9.1 Technical Training

5.9.1.1 Technical training is the training which is designed to develop specific and cross functional skill and to update the technical knowledge.

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TITLE: TRAINING OF EMPLOYEES

5.9.1.2 Technical training shall be conducted as per Calendar or whenever needs identified.

5.9.2 Specific Training

5.9.2.1 This shall be identified by the concerned HOD on the basis of Market Complaints received; any Non Conformance observed during Internal Audits or routine operation or Performance review or feed back received from the concern employee during audit is not satisfactory.

5.9.3 Behavioural Training

5.9.3.1 Admin and Personal department in consultation with HOD identifies the Behavioural Training needs for employees if required.

5.9.4 External Training

5.9.4.1 The External Training shall be conducted as and when required.

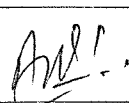

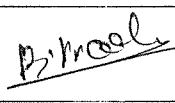
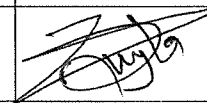
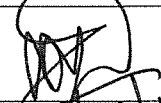
5.9.4.2 The selection of External Trainer for in house training shall be done with the consent of concerned HOD and HOD Quality Assurance. The selection of trainer shall be primarily based on his Experience, Qualification, Skills and Expertise on the training topics.


5.9.4.3 The external training program shall be identified by the concerned HOD and information shall be sent to Admin and Personal or his / her designee.

5.9.4.4 Selection of outside training program and identification of the employees for training shall be done by concerned HOD.

5.9.4.5 Feedback form shall be taken from each participant for the outside training program. (Refer Annexure X, General Feed back Form).

5.9.4.6 After attending the training program at outside it shall be recorded in the staff training record (Refer Annexure-VIII, Staff Training Card).

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5.9.4.7 If required the training material used by the trainer shall be distributed, after the training, to the employees attending the training programme.

5.10 Selection of Trainer

5.10.1 Refer SOP No.OHC/II/SOP/QA/059 for trainer selection & Approval.

5.10.2 QA shall prepare list of trainers, which shall be approved by Head- Quality Assurance (Refer OHC/II/FM/003-SOP/QA/059).

5.11 Evaluation of Training

5.11.1 The evaluation shall be conducted for classroom training where possible by Questionnaire on need basis to check the effectiveness of training program (Refer Annexure-VII, Training Evaluation Questionnaire).

5.11.2 The questionnaire shall include questions related to training topic and the questions can be of descriptive types as well as objective types.

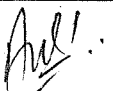
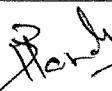
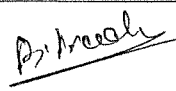


5.11.3 If the scored marks are less than 80%, then the employee shall be retrained & re-evaluated within one week. All the on job questions shall be answered 100% failing which the employee shall be deemed to be re-evaluated & explained the correct answers.

5.11.4 Trainer shall prepare a model answer sheet for evaluation of answer paper.

5.11.5 Oral feedback shall be taken for each type of training to check the effectiveness of training.

5.12 Documentation


5.12.1 The documentation of different types of training shall be done by the departments as mentioned below:

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Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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TITLE: TRAINING OF EMPLOYEES

- Induction / Behavioural Training : Admin and Personal Department
- On the Job Training : Concerned Department
- cGMP Training : Quality Assurance Department
- Technical Training : Concerned Department
- External Training : A&P Department / QA Dept.
- SOP Training : Concerned Department

5.12.2 After approval of any new / revised SOP the training shall be imparted by the concerned user department Head or Reviewer of the SOP to concerned persons before implementation of the SOP.

5.12.3 Training Co-ordinator from respective department shall coordinate with QA dept. for conducting any training and maintaining the record of the same. All the training relevant documents (Evaluation sheet, Attendance sheet, Model answer sheet, Presentation) shall be submitted to QA Dept for final storage.



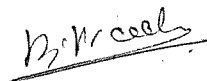
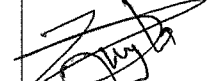

5.12.4 Concern person shall update staff Training card at the time of training.

5.12.5 Refer SOP for Retention Period And Destruction Of Documents (OHC/II/SOP/QA/006) for retention period of training records. Subsequently the records shall be destroyed and recorded (Refer Annexure-IX, Training Record Destruction).

6.0 TRAINING:

Trainer -- Head – Quality Assurance


Trainees -- All Departmental HODs / Sectional Heads / All Department Training Co-ordinators

	Prepared By-QA	Reviewed By-QA	Reviewed By-QA	Approved By	Authorized By
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


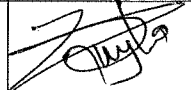

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TITLE: TRAINING OF EMPLOYEES**7.0 DISTRIBUTION:**

- 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

8.0 ATTACHMENTS:

- Annexure-I : Discontinued (OHC/II/FM/1/02- SOP/QA/028)
 Annexure-II : Discontinued (OHC/II/FM/2/00-SOP/QA/028)
 Annexure-III : Discontinued (OHC/II/FM/3/00-SOP/QA/028)
 Annexure-IV : Training Attendance Sheet cum Evaluation Sheet
 (OHC/II/FM/4/00-SOP/QA/028)
 Annexure-V : Induction Training Schedule (OHC/II/FM/5/01-SOP/QA/028)
 Annexure-VI : On Job Training Record (OHC/II/FM/6/01-SOP/QA/028)
 Annexure-VII : Training Evaluation Questionnaire (OHC/II/FM/7/00-SOP/QA/028)
 Annexure-VIII : Staff Training Card (OHC/II/FM/8/01-SOP/QA/028)
 Annexure-IX : Training Record Destruction (OHC/II/FM/9/00-SOP/QA/028)
 Annexure-X : General feedback form (OHC/II/FM/10/02-SOP/QA/028)
 Annexure-XI : Refresher Training needs Identification for Individual Person
 (OHC/II/FM/11/02-SOP/QA/028)
 Annexure-XII : Training Attendees Group (OHC/II/FM/12/01-SOP/QA/028)
 Annexure-XIII : cGMP Training Calendar (OHC/II/FM/13/01-SOP/QA/028)

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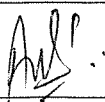
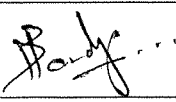

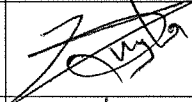
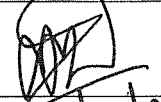
- Annexure-XIV : Training Session Group Identification cum Attendance sheet of cGMP Training (OHC/II/FM/14/01-SOP/QA/028)
- Annexure-XV : Format for Planner cum tracking of cGMP Session (OHC/II/FM/15/01-SOP/QA/028)
- Annexure-XVI : List of Training Co-ordinators (OHC/II/FM/16/00-SOP/QA/028)

9.0 REFERENCES:

In-house

10.0 REVISION HISTORY:

Revision No.	Reason for Revision	Effective Date
00	• New SOP	02/04/2012
01	• Change Control No.: D/14/04/001	25/04/2014
02	• Reference DCR No.: DCR/QA/14/014 • Reference CCF No.: D/14/08/003	20/11/2014
03	• Reference CCF No.: D/17/07/006	30/12/2017
04	• Reference Change Control No.: CCP-U2-QA-21-0001	05/02/2021
05	• SOP revised for incorporation of Training procedure for long absent employees. • SOP updated as per current format for SOP i.e. OHC/II/FM/1/02-SOP/QA/001. • Editorial changes done. • Reference Change Control No.: CCP-U2-QA-23-0051	29 DEC 2023

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Annexure - I



DEPARTMENT: QUALITY ASSURANCE

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SOP Training Calendar


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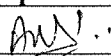
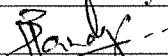
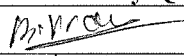
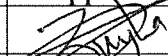

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Annexure – II

OHC/II/FM/2/00-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	Trainer Evaluation Record	


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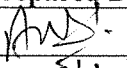
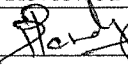
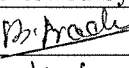
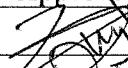
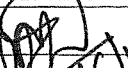
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Annexure – III

OHC/II/FM/3/00-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	Certified Trainer List	


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Annexure – IV

OHC/II/FM/4/00-SOP/QA/028

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	Training Attendance Sheet cum Evaluation sheet	

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

Training Topic:

Training session:

Name of Trainer:

From _____ hrs. to _____ hrs.

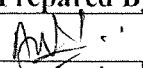
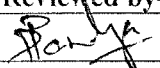
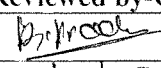
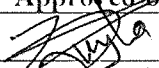
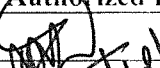
Venue:

Training Date: _____

Sr. No.	Name of Trainee	Designation	Department	Signature of Trainee	Remarks

(Use additional sheet if required)

Sign. of Trainer:


	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure - V

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 3
	Induction Training Schedule	

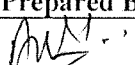
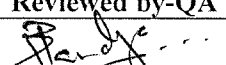
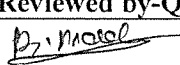
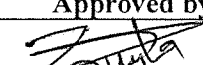
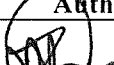
Name of New Employee: _____

Department : _____

Date of Joining : _____

Designation : _____ Level : _____

DAY 1 :				Date :
Time	Department	Subject to be Covered	Responsibility	Sign
	Admin and Personal	<ul style="list-style-type: none"> Brief about Olive Healthcare, Unit II, Daman Brief about Organization Structure Product range Basic HR Policies Joining formalities Welcome & Introduction by respective HODs May I help you? (Phone Connection & Bank A/C opening) Security House keeping Shift Schedule, timings for Tea, Lunch, Vehicle etc. All Policies of OHC Unit-II Code of Conduct Quality, Environment, Occupational Health & Safety (QEOHS) Policy. 		
	QA	<ul style="list-style-type: none"> Introduction to all staffs Role & Responsibility of QA Dept Concept of GMP SOP & other Documentation & Validation Processes 		
Lunch Break				
	QC	<ul style="list-style-type: none"> Introduction to all staff Role & Responsibility of QC Dept Concept & Significance of GLP 		

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure - V

DEPARTMENT: QUALITY ASSURANCE



Page No. 2 of 3

Induction Training Schedule**DAY 2 :****Date :**

Time	Department	Subject to be Covered	Responsibility	Sign
	Production	<ul style="list-style-type: none"> ▪ Role & Responsibility of Production Dept ▪ Brief about the Site Plan ▪ Documentation in Production Dept. ▪ Process flow of Dosage forms ▪ Brief about Mfg of various dosage forms 		
	Warehouse	<ul style="list-style-type: none"> ▪ Role & Responsibility of Warehouse Dept ▪ Concept of Engineering Stores, RM Stores, PM Stores ▪ Finished Goods Dispatch ▪ Material Handling 		
Lunch Break				
	Engineering/ HSE	<ul style="list-style-type: none"> ▪ Introduction to staffs ▪ Role & Responsibility of Engineering. Dept. ▪ Concept of GEP ▪ General Safety ▪ Type of utilities 		
	IT	<ul style="list-style-type: none"> ▪ Role & Responsibility of IT ▪ Computer Management ▪ Mail ID 		
	Head Quality	<ul style="list-style-type: none"> ▪ Discussion & Feedback ▪ Summing up 		

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure - V

OHC/II/FM/5/01-SOP/QA/028



DEPARTMENT: QUALITY ASSURANCE

Page No. 3 of 3

Induction Training Schedule

DAY 3 :	Date :
Handing over to the Departmental HOD by Admin and Personnel.	
Report Writing on Inductions : (To be submitted by the candidate)	
	Sign. / Date :
Evaluation of induction Report by Dept Head :	
	Sign. / Date :
Evaluation of induction Report by Admin. And Personnel :	
	Sign. / Date : _____


Prepared by:
A&P Dept.
(Sign. / Date:)

Approved by:
Manager-QA
(Sign. / Date:)

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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OHC/II/FM/4/00-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 2 of 2
	Training Attendance Sheet cum Evaluation sheet	

TRAINING EVALUATION

Reference SOP No.:

Version No.:

Oral feed back taken: Satisfactory /Not Satisfactory

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

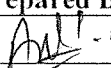

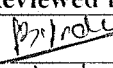
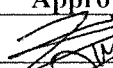

If not satisfactory:

Retraining identified for:

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

Retraining performed on:

Trainer Signature / Date:


	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure – VI

OHC/II/FM/6/01-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 2 of 2
	On-Job Training Record	

Sr. No.	Subjects	*Training required	Responsibility	Date		No. of Days	Training Mode (Practical/ Theoretical/ Self reading)	Trainer signature	Remark
				From	To				
3	Equipments (Specify)								
4	Utilities and Services (specify)								
5	Departmental SOPs (Specify SOP Name and Number)								
6	Cross functional SOPs (Other dept.) – (Specify SOP series)								
7	cGMP Training								

*Tick ✓ whichever is required.

This is to certify that _____ has successfully completed On the Job Training from dated _____ to _____ to _____.

His / Her Training evaluation was found satisfactory.

HOD
Signature

Plant Head
Signature

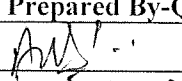
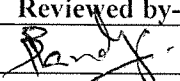
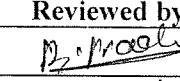
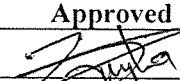

Quality Head
Signature

Comment: _____

Comment: _____

Comment: _____


	Prepared By (Concern Department Training coordinator)	Checked by (Concern HOD)	Reviewed By (Head QA/Designee)	Approved By (Head Quality)
Name				
Sign/Date				
Designation				

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure – VII

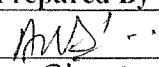
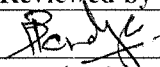
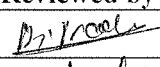
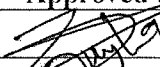
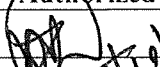
OHC/II/FM/7/00-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	Training Evaluation Questionnaire	

Topic of Training :	Document No. : (In case of Document Training)
Type of Training :	Revision No. :
Name of the Employee:	Department :
Total Marks : (All questions to be answered, Qualification mark is NLT 80% of Total Marks, On the job questions shall be answered 100 %)	Time: _____ Minutes

Q.1 Write questionnaires.....?

Employee Code No. :	Trainee Sign. / Date
Marks Scored :	Evaluation: Qualified / Retraining Required
Trainer Name :	Trainer Sign. / Date
Remarks :	

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

OHC/II/FM/8/01-SOP/QA/028

Annexure – VIII

Annexure – VIII



DEPARTMENT: QUALITY ASSURANCE

Staff Training Card

Page No. 1 of 1






Name:

Department:

Designation:






Date of Joining:

[illegible]

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023


Training Record Destruction

[illegible]

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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OHC/II/FM/10/02-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	General Feedback Form	

Topic:

Trainer Name

Venue:

Date:

Your feedback will help us to improve the future training programme so please try to be objective and frank in your statements.

1. How do you rate the programme as a learning experience? (indicate by tick mark)

☐

Very thought-Provoking

☐

Good learning experience

☐

Partially gainful

☐

Not clear at all

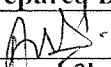
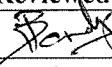
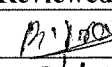
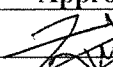
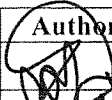
2. Which part of the program appealed you the most?

3. Which part of the programme was not clear to you?

4. What important points have you gained from the programme?

5. Write down the points most relevant to your day to day work?


6. Give your suggestions as to how the programme could be improved?

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/11/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure – XI

OHC/II/FM/11/02-SOP/QA/028

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	Refresher Training Need Identification For Individual Person	

Department: _____

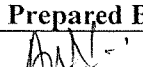
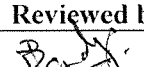
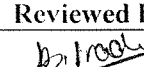
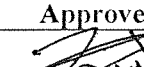
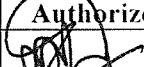
Year : _____

Note : "Y" indicates - Training Need;											
NAME OF STAFF →											
Sr. No.	SOP No./ Document No	SOP TITLE / Training topic	Mode of Imparting Training (Self Reading/ Classroom)	1	2	3	4	5	6	7	8
				Y							

	Prepared By (Concern Department Training coordinator)	Checked by (Concern HOD)	Reviewed By (QA Head / Designee)	Approved By (Head Quality)
Name				
Sign/Date				
Designation				

☐ Circle the 'Y', Indicates person is trained.

Note: Trainer shall be considered as trained and "Y" shall be circled.

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure – VI

OHC/II/FM/6/01-SOP/QA/028



DEPARTMENT: QUALITY ASSURANCE

Page No. 1 of 2

On-Job Training Record

Name of Trainee : _____

Department : _____

Date of Joining : _____

Designation : _____

Sr. No.	Subjects	*Training required	Responsibility	Date		No. of Days	Training Mode (Practical/ Theoretical/ Self reading)	Trainer signature	Remark
				From	To				
1	Sanitization & Hygiene General Housekeeping Procedure (specify the SOP No.)								
2	General <ul style="list-style-type: none"> Gowning / degowning Different section in the department Man & Material Movement Process Flow and Briefing Safety in the department Briefing on the Departmental procedures In-Process checks (if applicable) Instruments used for In-Process checks Others (Specify) 								

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure – XII

DEPARTMENT: QUALITY ASSURANCE



Training Attendees Group

Page No. 1 of 1

Updation No: _____

Date of Updation: _____

Sr.No.	Level –I			Level –II			Level –III		
	Name of Employee	Department	Employee Code	Name of Employee	Department	Employee Code	Name of Employee	Department	Employee Code

Addendum :

Sr. No.	Name of Employee	Employee Code	Department	Level	Remark

A : Addition

D : Deletion


	Prepared By (QA Training coordinator)	Reviewed By (QA Head)	Approved By (Quality Head)
Name			
Sign/Date			
Designation			

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure - XIII
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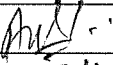
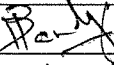
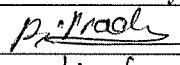

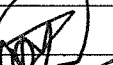
	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	cGMP Training Calendar	

For the Year: _____

Date of Preparation: _____

Sr. No.	Topics	Faculty	Applicable Level	Frequency	Planned Month

	Prepared By (QA Training coordinator)	Reviewed By (QA Head)	Approved By (Quality Head)
Name			
Sign/Date			
Designation			

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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OHC/II/FM/14/01-SOP/QA/028

**DEPARTMENT: QUALITY ASSURANCE**

Page No. 1 of 2

**Training Session Group Identification cum Attendance Sheet
for cGMP Training**

Name of Trainer :

Document No:-

Training Topic :

Date:- _____

Time:- _____ to _____

Identified Group :-

Quality Assurance Department	Quality Control Department	Production Department	Packing Department
<input type="checkbox"/> Documentation <input type="checkbox"/> QMS <input type="checkbox"/> Qualification & Validation <input type="checkbox"/> IPQA	<input type="checkbox"/> Raw Material <input type="checkbox"/> Finished Product <input type="checkbox"/> GLP <input type="checkbox"/> Stability <input type="checkbox"/> Microbiology	<input type="checkbox"/> Gelatin <input type="checkbox"/> Medicament <input type="checkbox"/> Encapsulation <input type="checkbox"/> Documentation	<input type="checkbox"/> Primar Packing <input type="checkbox"/> Secondary Packing <input type="checkbox"/> Documentation
Warehouse Department	Engineering Department	Regulatory Affairs Department	IT Department
<input type="checkbox"/> Warehouse	<input type="checkbox"/> Engineering	<input type="checkbox"/> RA	<input type="checkbox"/> IT
Admin			
<input type="checkbox"/> Admin			

List of Training Coordinator Communicated

Sr. No.	Department	Name of Training Coordinator
1.		
2.		
3.		
4.		
5.		
6.		
7.		






Prepared By (Sign/Date):- _____

(QA Training Coordinator)

Training Attendees

Sr. No.	Name of Trainee	Designation	Department	Trainee Sign/Date	Remark

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	21/12/2023	26/12/2023



For the Year:

Department:

Applicable for:

Date of Preparation:

Training Topics:

Sr. No.	Department	Employee	Employee Code	Level	Planned Month		
					Training Type (C/S)	Training Date	Status Updated by

Note: "C" Indicates as Classroom Training.

"S" Indicates as Self reading Training.

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023








Addendum:

Note:

➤ For every new joined employee, GMP training is conducted at the time of joining as per on-job training.

Department:

[illegible]

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

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Annexure -XV
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DEPARTMENT: QUALITY ASSURANCE

Page No. 3 of 3


Specimen Format for Planner cum Tracking of cGMP Session

Comment by QA HOD:

QA HOD
(Sign/Date)

	Prepared By (QA Training coordinator)	Reviewed by (Head QA)	Approved By (Head Quality)
Name			
Sign/Date			
Designation			

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023

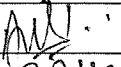
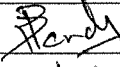
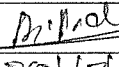
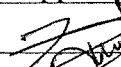

	DEPARTMENT: QUALITY ASSURANCE	Page No. 1 of 1
	List of Training Co-ordinators	

Updation No.: _____

Date of Preparation: _____

Sr. No.	Department	Name of Training Coordinator	Designation	Training Coordinator (Sign/Date)	Department Head (Sign/Date)

	Prepared By (QA Training Coordinator)	Reviewed by (Head QA/Designee)	Approved By (Head Quality)
Name			
Sign/Date			
Designation			

	Prepared By-QA	Reviewed by-QA	Reviewed by-QA	Approved by	Authorized By
Signature					
Date	20/12/2023	20/12/2023	20/12/2023	26/12/2023	26/12/2023