STANDARD OPERATING PROCEDURE			
Department	Quality Assurance	**SOP Number**	
Title	**Standard Operating Procedure for SOP**	**Version**	
		Superseded SOP No.	
		Effective Date	
		Review Date	
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1. OBJECTIVE:

1.1 To provide written guidelines for preparation of new SOP's or revision to existing SOP's, review, approval, training, distribution, implementation, retrieval, control, discontinuation and destruction of Standard Operating Procedures (SOP's). It also ensures that concerned employees receive training pertaining to their areas of function.

2. SCOPE:

2.1 **This procedure is applicable to:**

2.1.1 All processes and procedures carried out in the plant that requires the preparation of written SOPs.

2.1.2 All new and existing SOP's prepared.

3. RESPONSIBILITY:

3.1 **Originating department shall be responsible** :

3.1.1 For preparation a list of all assigned numbers of the new SOP for their departments.

3.1.2 For initiating preparation, review and revision of the SOP's Originating from the department.

3.1.3 To provide the final draft copy to Quality Assurance.

3.2 **Head of Originating department shall be responsible for :**

3.2.1 Checking of the SOP for procedural, technical content, accuracy and cGMP compliance.

3.2.2 To get the SOP approval from Head Quality Assurance.

3.2.3 To impart the training of the SOP to the concerned personnel in-between Approval date and Effective date of the SOP.

3.2.4 After training user department Head or designee to ensure implementation of the SOP on effective date.

3.2.5 To maintain the controlled copies of the SOPs and display them at required location.

3.3 **Quality Assurance department shall be responsible for:**

3.3.1 Checking of the draft SOP for regulatory and cGMP compliance.

3.3.2 To maintain the approved master copy of the SOP of all departments for document control.

3.3.3 To issue the required number of controlled copies to the departments and document

the same.

3.3.4 To retrieve the earlier issued / superseded copies from the respective department(s) and to document the same.

3.3.5 Issuance of the change control form required for the SOP revision.

3.3.6 Destruction of earlier issued / superseded controlled copies of SOP in case of new SOP implementation as per procedure and document the same.

3.3.7 Destruction of earlier issued / superseded controlled copies of SOP by paper shredding machine.

3.4 Head - Quality Assurance shall be responsible for:

3.4.1 Review of the draft SOP for regulatory and cGMP compliance.

3.4.2 Final approval of the SOP by signing off as Approved By.

4.0 ACCOUNTABILTY

4.1 Head-QA shall be accountable for implementation of this SOP.

5.0 PROCEDURE

5.1 **Initiation & preparation of draft SOP:**

5.1.1 Head of the department shall identify the need for new SOP, and confirm with relevant personnel for finalizing the input.

5.1.2 Head of the department shall assign responsibility to department personnel for preparation of SOP.

5.1.3 The person who is having sufficient knowledge and experience shall prepare a draft SOP for review by concerned various departments.

5.1.4 The department performing the operation shall initiate the SOP. General SOP's can be initiated by any of the department.

5.1.5 The title and text shall be in English and clearly understood, so that everyone shall carry out the particular function in the same way and safely upon reading the SOP

5.1.6 An SOP shall be written afresh or revised under following circumstances:

5.1.6.1 When new practice is being adopted.

5.1.6.2 When new equipment is being used or there is change in operation of the existing equipment.

5.1.6.3 Whenever there is change in regulatory or statutory guidelines affecting pharmaceuticals products being manufactured.

5.1.6.4 There is need to eliminate any discrepancy in existing procedure.

5.1.6.5 There is need to comply audit observations.

5.1.6.6 Review of procedure due to market complaints, recalls or repeated rejections.

5.1.6.7 Need to review as per due date of review *i.e.* two years from effective date.

5.1.6.8 Any other reason found valid, but not listed above, prior to review date.

5.1.7 For critical SOPs there shall be a format to the SOP written in vernacular language which describes the procedure for easy understanding by employees, if required, or the observation for record purpose.

5.1.8 The language used shall be in directive form i.e. in the given step-wise instructions, the words like "shall", "must" are to be used rather than "should", "may" or "might".

5.1.9 The sufficient inputs shall be provided in detail so as to allow the procedure to be followed *e.g.* Inputs such as Information, Materials Requirement, Sequence of Operations, Limits, and action plan for non-occurrence of the event, Frequency and Checklist relevant to the process.

5.1.10 Where appropriate, there will be schematic diagram of critical steps of SOP.

5.1.11 In case of preparation of new SOP, draft SOP shall be circulated without allocating the SOP number. At the time of taking the final print, SOP number shall be assigned and list of SOP shall be updated. SOP No. shall be mentioned on all pages of SOP. All the SOPs shall be printed on one side of the page.

5.1.12 Concerned department found valid and justified reason for Preparation of New SOP then Initiating department shall send requisition for New SOP Initiation Form as per **Format No.: 001** along with SOP title to QA department for issuance of New SOP number.

5.1.13 QA executive shall enter the request with issuance of SOP initiation form (SIF No.) as per **Format No.: 005** and document the same in logbook of SOP initiation form with issuance of New SOP number.

5.1.14 Quality Assurance department shall be the only authorization for assigning new SOP number on the basis of New SOP initiation Form received from initiating department.

5.1.15 Numbering system of SOP initiation form describe in section 5.11 sub-section 5.11.1.

5.2 Checking and corrections of draft SOP:

5.2.1 SOP shall be checked with special reference to convenience of sequential operations, technical correctness.

5.2.2 In case if SOP is also related to the function of other department, discuss with the other departmental employee / Head and ensure agreement with those for proposed draft SOP.

5.3 Review of draft SOP:

5.3.1 After completion / drafting of the SOP, the initiator department then to be forwarded to Quality Assurance department for review and final approval.

5.3.2 Quality Assurance shall review the technical content of SOP for cGMP and regulatory compliance.

5.3.3 If any changes are required at any stage, then the SOP shall be returned to the Originating department for amendment and re-issue of corrected version of a draft SOP.

5.4 Approval of SOP:

5.4.1 After final approval on the draft is obtained from Head Quality Assurance, the Originating department shall forward the soft copy of the SOP to Quality Assurance for printing. Other soft copies prevailing elsewhere shall be deleted by the user department head or designee.

5.4.2 The draft copies shall be destroyed after correction.

5.4.3 Quality Assurance shall check the content and formatting of the SOP and final SOP shall be printed out on A-4 size pages with site name with company logo. Only master shall be made available to QA.

5.4.4 Quality Assurance shall forward to Originating department for obtaining the subsequent prepared by and checked by signatures at the designated place.

5.4.5 Approval of the SOP shall be done by Head - Quality Assurance by signing at the designated place.

5.5 Training of SOP:

5.5.1 After obtaining the approval signatures the training of the SOP shall be imparted to all concerned personnel before the effective date of the SOP, for executing the functions defined in the SOP. Training shall be imparted within 15 days from the approval date of SOP.

5.5.2 Approved SOP shall be **"MASTER"** stamped by quality assurance and provided to concerned department Head only for imparted training and after training SOP shall be return to QA department along with training record.

5.5.3 Quality Assurance shall put effective date and Review before date stamped on all pages of SOP.

5.5.4 The SOP shall be made effective after imparting training, to all concern, within a week.

5.5.5 Head of Originating Department shall be responsible for imparting the training to all concerned personnel before the effective date of SOP.

5.5.6 SOP training record shall be maintained by respective department as per **Format No.: 003.**

5.6 Control of the SOP:

5.6.1 The Originating department shall submit the approved SOP along with a copy of the training record to Quality Assurance for Master, control, issue and display of the SOP.

5.6.2 Quality Assurance shall put **"MASTER COPY"** stamp on all pages of the SOP on the Top right corner in **Green ink** inside square box. After this the SOP shall be considered as a Master Copy and shall be under Quality Assurance possession only.

5.6.3 Photocopies of Master SOP shall be made and one set of copy shall be stamped with following information in **Blue ink at** the bottom of right hand side of footer under the

heading 'STAMP' and duly signed by head QA or designee. The display copy shall be issued to the concerned department for display in area.

5.6.4 Issuance and retrieval record of SOP shall be maintained as per **Format No.: 004.**

5.6.5 If any additional copies are required by any department, the request shall be made in prescribed format as given in **Format No.: 006** to Quality Assurance and then these copies shall be issued.

5.6.6 Previous / superseded controlled copies shall be retrieved and destroyed by quality assurance while issuing the revised copy of new version number and shall be documented as per **Format No.: 004.** This shall be done on the effective date of the new SOP.

5.6.7 No further photocopy is allowed from controlled copy. Head of the Department to whom the controlled copies are issued shall ensure the same. However any photocopies found that of the controlled copy shall be treated as uncontrolled copy.

5.6.8 Display copies shall be stamp in **Blue ink** the bottom of right hand side of footer under the heading 'STAMP' and duly signed by head QA or designee. The display copy shall be issued to the concerned department for display in areas per **Format No.: 004.**

5.6.9 The old master copies shall be stamped as **"SUPERSEDED"** on all pages of the master copies at the center of page in **Red ink** and shall be archived by Quality Assurance. **"SUPERSEDED"** stamped shall be done on the old master copies on the same date of effective date of new version of SOP. The storage of SOP shall be access controlled and be with QA only.

5.6.10 Master list of SOP of all departments shall be prepared as per **Format No.: 007** and shall be maintained by concerned department.

5.7 Formatting of SOP:

5.7.1 The format of SOP shall be divided in following three parts:

5.7.1.1 Header

5.7.1.2 Text portion

5.7.1.3 Footer

5.7.2 SOP shall be prepared in **'Garamond',** with font size '12' and line spacing '1.0' in header –Footer and line spacing '1.5' in the text portion.

5.7.3 All main headings shall be in **CAPITAL BOLD** letters and sub headings shall be in **bold** letters. *e.g,* effective date, review before date, SOP number with Version number and page number (page number of total pages).

5.7.4 If Abbreviations shall be used then first time it shall in written in full form with short form in bracket and after that it shall be in short form wherever applicable .*e.g.* Standard Operating Procedure (SOP).

5.7.5 The standard format for SOP shall be as follows:

5.7.5.1 SOP shall be printed on 210 mm x 297 mm (A4 size) with Company Name and logo. The page setup margins shall be sufficient so the matter shall not to cut during printing.

5.7.5.2 The layout for header and footer of first page and remaining pages shall be as per **Format No.: 001.**

5.7.5.3 The layout for Format shall be as per **Format No.: 002.**

5.7.5.4 Any formatting parameters not defined herewith shall be as per the formatting of this SOP, which shall serve as a template.

5.7.5.5 Text portion shall be divided into logical sections numbered 1.0, 2.0, 3.0 *etc.* where 1.0 relates to Purpose; 2.0 relates to Scope, 3.0 relates to Responsibilities *etc.* These sections shall be sub-divided into logical sections. 1.1; 1.2; 2.1; 2.2; 2.3,.....so on. Where required, these sub-divisions shall further be sub divided, as 1.1.1; 1.1.2; 1.1.3, and so on for further sub division.

5.7.6 The SOP shall have 11 sections in all, specifically following the following order:

1.0 Objective

2.0 Scope

3.0 Responsibilities

4.0 Accountability

5.0 Procedure

6.0 Related Documents

8.0 List of Attachments

9.0 References

10.0 Abbreviations

11.0 Revision History

5.8 Filling of SOP Contents:

5.8.1 Header

5.8.1.1 **Heading:** This section shall contain the document heading *i.e.* **…….**in the top middle of header table in **Garamond font',** with font size '14 followed by **STANDARD OPERATING PROCEDURE** in **Garamond font',** with font size '12' in **CAPITAL BOLD** letter with line spacing'1.5'

5.8.1.2 **Department:** This shall be name of department from which SOP is originating. The content shall be in **Garamond font',** with font size '12' with line spacing '1.5'.

5.8.1.3 **Company Logo:** This shall be comes in left top of header table with preprinted letter. Logo shall be in JPEG image.

5.8.1.4 **Effective Date:** This shall be intended effective date of SOP. This shall be stamped in **blue ink** with DD MMM YYYY format, on which SOP is implemented and this shall be on middle right in header table. The effective date will be assigned within ten days after approval of the SOP. Effective date shall be stamped for e.g. 01 JAN 2016 i.e. there shall be one space between date, Month and Year.

5.8.1.5 In case for Logbooks Effective Date shall be preprinted (in Black ink) and follow same patterned i.e. 01 JAN 2024.

5.8.1.6 **Review Date:** This shall be review date of SOP on or before which SOP shall be reviewed *i.e.* 2 years from effective date. This shall be stamped in **blue ink** at right of header table in DD MMM YYYY format. However SOP's may be revised before the next review date if required. SOP shall be reviewed along with cross-references of other procedures, equipment, SOP's, utilities, changes in the references documents and /or current practices if changes are applicable to those SOP's also. *e.g.* If the SOP effective on dated 01 JAN 2024 then review date shall be 31 DEC 2025.

5.8.1.7 **Version:** This denotes the number of changes made to SOP. The first version will be denoted by two lettered numeral "00". Any change to SOP in subsequent versions will be identified by 01, 02 and so on…

5.8.1.8 **Superseded SOP No.:** This denotes superseded SOP number.

(**Note:** in case of new SOP, superseded SOP number shall be written as 'NIL'. If SOP is revised, superseded SOP number shall be given as SOP number of superseded SOP followed by revision number of the same, as described in header of the standard operating procedure).

5.8.1.9 **Title of SOP:** Title shall contain the representative caption of the SOP, which shall be short, concise and indicative of the procedure of the SOP. It shall be normal letters with line spacing '1.5' at the bottom middle of the header table. The title of the SOP shall be mentioned on all the pages of the SOP.

5.8.1.10 **Master Stamp:** Master Stamp shall be in right top corner of header table in **Green ink** inside square box. Master Stamp shall be affixed after approval of SOP.

5.8.1.11 **SOP Number:** This section shall contain SOP number along with version number as describe in section 5.11 sub-section 5.11.2. SOP number shall be mention in the right of header table. In case of preparation of new SOP, draft SOP shall be circulated without allocating the SOP number. At the time of taking the final print, SOP number shall be assigned and list of SOP shall be updated.SOP No. shall be mentioned on all pages of SOP. SOP number shall be used in all annexure as well as wherever applicable but without version number.

5.8.1.12 **Page No:** This section shall contain the page number exclusive of annexure in Page X of Y format, where X is the current page number and Y is the total number of pages, both the numbers should be represented without a prefix 'zero' mentioned as in **Format No. 001.** Page number shall be mention in the bottom right of header table. This shall be mentioned on all pages of the SOP.

5.8.2 Text portion:

5.8.2.1 **Objective:** This shall contain purpose of writing SOP. It should be framed in similar manner for all SOPs *e.g.* To describe procedure for…… in case of SOP.

5.8.2.2 **Scope:** This section shall define the applicability of SOP., *i.e.* particular

equipment, area or department *etc.*

5.8.2.3 **Responsibility:** This section defines the responsibilities of various personnel required to execute the SOP. Heading of the section shall mention the designee responsible for the activity whereas his/her responsibilities shall be mentioned in sub-sections *e.g.*

> **3.4 Head – Quality Assurance shall be responsible for:**
>
> 3.4.1 Review of the draft SOP for regulatory and cGMP compliance.
>
> 3.4.2 Final Approval of the SOP by signing off as approved by

5.8.2.4 **Accountability:** This section defines the accountability of respective department head for implement the Standard Operating Procedure.

5.8.2.5 **Procedure:** This is the main content of the SOP. This shall be an elaborative section defining the details of operation. This section also shall include the details about the recording & documentation involved in the procedure.

5.8.2.6 **Related Documents:** This section shall include the list of documents (with document no.)/ SOP's references (mentioned SOP No. without Version no.) related to the procedure defined in the SOP. Document no. shall be without its version no. which shall refer to current version no. of SOP/documents.

5.8.2.7 **List of Attachments:** This section shall contain the list of annexure, check-lists, formats, label *etc.*

- Formats that are used for record purpose shall be numbered as per numbering System described in section 5.11 sub sections 5.11.3. If attachment is of two pages then pages should be numbered as page 1 of 2 and page 2 of 2.
- In case there is updation of format and no change in the SOP contents then along with the change in the Format no., the version no. of the SOP shall also be changed. In cases where there is no change in format even with revision of SOP, the format number shall also be revised with revised format number. Where the formats are used as Logbooks, the same shall be issued by the quality assurance. When the formats are updated, then previous version logbooks should be discontinued from the effective date of the new SOP.

5.8.2.8 **Reference:** This section shall contain the official publication, guideline,

instruction manuals, other document details which are referred for preparation of the SOP. In case of no references, 'NA' shall be mentioned in this column.

5.8.2.9 **Abbreviations**: This section shall full form of Abbreviations used in the SOP. Abbreviations shall be explained in full wherever they are used for the first time and shall be used as such thereafter.

5.8.2.10 **Revision History:** This section shall contain compilation of the changes made from first version to the current version. Mention 'New SOP prepared for first time' in this column if the SOP is prepared first time. Effective Date in revision history shall be pre-Printed in Black ink except current revision which shall be stamp in blue ink.

5.8.3 All the SOPs prepared or revised after the effective date of this SOP shall be as per this SOP. All existing SOPs shall remain effective in the previous format until their next revision.

5.8.4 The revision history section of the SOP shall contain the compilation of the changes from all previous versions.

5.9 Footer:

5.9.1 The names and designations with date of the prepared by, checked by and approved by shall appear on the footer pages shall contain name, designation, signatures and dates of personnel responsible for preparation, checking and approval of the SOP in **blue ink.**

5.9.1.1 **Prepared by:** The personnel, who have prepared the SOP shall put his/her name, designation, signature and date in **blue ink.**

5.9.1.2 **Checked by:** The personnel (HOD) of origination departments, who have checked the SOP, shall put his/her name, designation, signature and date in **blue ink.**

5.9.1.3 **Approved by:** Head-QA shall review and approve the SOP by putting his/her name, designation, signature and date in this section in **blue Ink.**

5.10 **Numbering System:**

5.10.1 **Numbering system for New SOP initiation form**

Numbering system for New SOP initiation form shall be as follow:

SIF/YY/XXX

Where, 'SIF' Indicate SOP Initiation Form

'YY' Indicate last two digits of current year

'XXX' Indicate the sequential serial number of the SOP initiation form *e.g* 001, 002 etc.

5.10.2 **Numbering system for SOP**:

Each SOP shall be allocated unique SOP number. *e.g.***"XXX/DC/NNN/VV"**

'**XXX**' indicates "SOP" *e.g* '**Standard Operating Procedure.**

'DC' indicates Department Code (Mentioned below in section 5.12)

'**NNN**' indicates sequential SOP number *e.g.*001, 002 *etc.*,

'**VV**' indicates two digit version numbers starting from 00, superseding the previous revision number of SOP

5.10.3 **Numbering system for Formats** :

5.10.3.1 **Formats Numbering system**:

DCXYYY/F/ZZ//VV

'**DC**' indicates for Departmental code refers in section 5.12.

'**X**' Standard Operating Procedure

'YYY' Stands for SOP number

'**F**' indicates format

'ZZ' indicates serial number of format of respective SOP

'VV' indicates two Version numbers starting from 00.

5.11 Departmental Codes:

5.11.1 The department codes (DC) shall be as follows:

Originating department	Controlled copy reference	Department/ prefix
Quality Assurance	01	QA
Quality Control	02	QC
Production General	03	PG
Production Tablet	04	PT
Production Capsule	05	PC
Production Liquid	06	PL
Cephalosporin General	07	CG
Cephalosporin Tablet	08	CO
Cephalosporin Capsule	09	CP
Cephalosporin Dry syrup Powder	10	CD
Cephalosporin Block (Injection)	11	CI
Warehouse (General)	12	WH
Warehouse (Cepha)	13	CW
Maintenance (General)	14	MS
Maintenance (Cepha)	15	CM
Human Resource	16	HR
Environment, Health and safety	17	ES

Formulation & Development	18	FD
Analytical Research and Development	19	AD

5.12 Revision of SOPs:

5.12.1 All SOPs shall be reviewed within 24 months from effective date as a part of scheduled revision or early if required in case of any other reason like recommendation of change control, Gap analysis etc.

5.12.2 Revision of SOP for any technical and/or procedural changes shall follow the formal SOP change initiation form procedure.

5.12.3 In case of scheduled revision, if there are no technical changes (which affects quality, safety or efficacy of product) then it is not required to follow formal change control procedure.

5.12.4 Revision shall be initiated by the Originating department.

5.12.5 In case during periodic review, if there are no changes suggested by the reviewer, the SOP shall be reprinted with new Revision No. and Effective Date & Review Before.

5.12.6 At no case this period shall be extended, SOP has to be revised before completion of this period.

5.12.7 This review in the case of no change shall be documented in the prescribed form of scheduled revision of documents.

5.12.8 Wherever SOP number shall be used. It shall be current version of that SOP without revision number and the format number used for reference is also without version number. Current version shall be specified in point no. 8.0 List of Attachment.

5.13 Discontinuation of SOP:

5.13.1 When an SOP has to be discontinued, the request shall be made by Head of the originating department to Quality Assurance.

5.13.2 The impact of the discontinuation shall be evaluated like if the SOP has been cross referenced where and /or the procedure needs to be addressed somewhere and only after that the SOP shall be discontinued.

5.13.3 The issued controlled copies of the discontinued SOP shall be retrieved and destroy by Quality Assurance and the master copy shall be made obsolete and archived.

5.13.4 The SOP number of deleted SOP cannot be reassigned to any other SOP.

5.13.5 QA person shall put the **'VOID'** stamp in **red color** on the top of the middle side of each header page on the original copies of the discontinued SOP with signed & date.

5.13.6 Discontinued SOP along with the **'VOID'** stamp shall be filed along with the format for 'Authorization for Discontinuation of SOP' as per **Format No. 008.**

5.14 Merger of the SOP's:

5.14.1 In case of merger of two or more SOP's is required, apart from following normal procedure for revision of the SOP, mention SOP no's of all the superseded SOP in the column of the superseded in revision history. The same should be mentioned in the history of the revised SOP.

5.14.2 Refer Flow chart for preparation of SOP as in Annexure-01.

6.0 RELATED DOCUMENTS:

7.0 LIST OF ATTACHMENTS:

7.1	QAS001/F/001	:	SOP Format
7.2	QAS001/F/002	:	Format Title
7.3	QAS001/F/003	:	Training Attendance sheet
7.4	QAS001/F/004	:	SOP Distribution, Retrieval and Destruction Record
7.5	QAS001/F/005	:	Log Book for New SOP Initiation Form
7.6	QAS001/F/006	:	Request of Additional Copy/Copies of SOP
7.7	QAS001/F/007	:	Master List of Standard Operating Procedure
7.8	QAS001/F/008	:	Authorization for Discontinuation of SOP
7.9	QAS001/F/009	:	New SOP Initiation Form

8.0 REFERENCES:

Schedule M - Part I, Section 12.

A WHO guide to good manufacturing practice (GMP) requirements

9. ABBREVIATIONS:

9.1	SOP	:	Standard Operating Procedure
9.2	QA	:	Quality Assurance
9.3	QC	:	Quality Control
9.4	HR	:	Human Resource& General Safety
9.5	IT	:	Information Technology
9.6	MS	:	Maintenance
9.7	WH	:	Warehouse
9.8	PG	:	Production General
9.9	PT	:	Production Tablets
9.10	PC	:	Production Capsules
9.11	PL	:	Production Liquid

10. REVISION RECORD:

Version	Reason for Revision	Effective Date
00	New SOP	

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SOP FORMAT

1. **Purpose**
2. **Scope**
3. **Responsibility**
4. **Accountability**
5. **Procedure**
6. **Related Documents**
7. **List of Attachments**
8. **References**
9. **Abbreviations**
10. **Revision History**

	Name	Designation	Signature	Date	Stamp
Prepared by					
Checked by					
Approved by					

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Format No.:	Reference SOP No.:
FORMAT TITLE	
Effective Date:	**Page 14 of 21**

	Name	Designation	Signature	Date	Stamp
Prepared by					
Checked by					
Approved by					

STANDARD OPERATING PROCEDURE			
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TRAINING ATTENDANCE SHEET

Date		Time	
Type		Duration	
Trainer		Venue	
Topic			

Training Method:
☐ Verbal ☐ Video/movie ☐ Presentation ☐ Print based
☐ other, if any specify _____

S. No.	Employee Name	Employee Code	Department	Signature

Effectiveness of the training measured by
☐ Quiz, ☐ Questionnaire, ☐ Demonstration, ☐ Discussion, ☐ Other_____

Comments by trainer:

Trainer Signature / date:

STANDARD OPERATING PROCEDURE

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SOP DISTRIBUTION, RETRIEVAL AND DESTRUCTION RECORD

SOP Title:		
SOP No.:	Version No.:	Effective Date:

SOP Distribution Record					**SOP Retrieval Record**		**SOP Destruction Record**
S. No.	**Copy Details**	**Distributed to Dept.**	**Distributed By/Date**	**Received By/Date**	**Returned by/Date**	**Received By/Date**	**Destroyed by/date**

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LOG BOOK FOR NEW SOP INITIATION FORM

S.No.	Date	SIF No.	Title of SOP	New SOP No. Allotted	New SOP Effective Date	Originating Department	Justification for Preparation of New SOP	Approved By QA (Sign/date)

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REQUEST OF ADDITIONAL COPY/COPIES OF SOP

To,

Head-QA

Kindly issue following additional copy /copies of SOP:

S.No.	Title of SOP	SOP Number	Number of Copies Requested	Reasons for addition copy

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STANDARD OPERATING PROCEDURE			
Department	Quality Assurance	**SOP Number**	
Title	**Standard Operating Procedure for SOP**	**Version**	
		Superseded SOP No.	
		Effective Date	
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MASTER LIST OF STANDARD OPERATING PROCEDURE

Department:	**Section:**
Effective Date:	**Review Date:**
Version:	**Page Number:**

S.No.	SOP Title	SOP No.	Version	Effective Date	Review Date

STANDARD OPERATING PROCEDURE			
Department	Quality Assurance	**SOP Number**	
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		Superseded SOP No.	
		Effective Date	
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AUTHORIZATION FOR DISCONTINUATION OF SOP

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STANDARD OPERATING PROCEDURE

Department	Quality Assurance	**SOP Number**	
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		Review Date	
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