TITLE: PROCEDURE FOR PREPARATION OF STANDARD OPERATING PROCEDURES

1.0 PURPOSE:

To lay down the Procedure for Preparation of Standard Operating Procedures.

2.0 SCOPE:

This procedure is applicable for Preparation, Review, Approval, and Revision of standard operating procedures of all departments at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 **Document Initiator:**

It is the responsibility of the author of the document (SOP and records/ formats) to follow the guidelines outlined in this SOP prior to forward to the Quality Assurance department for review.

3.2 **Initiating Department Head:**

3.2.1 It is the responsibility of concerned department head/designee to review the document.

3.2.2 It is the responsibility of user department head/designee to ensure that the current approved procedures and formats being followed.

3.3 **QA Department:**

3.3.1 It is the responsibility of QA to review each proposal for clarity, correct format, and spelling etc.

3.3.2 It is the responsibility of Head-QA/Designee to approve the document.

3.3.3 It is the responsibility of Quality Assurance department to distribute the current approved procedures and formats to all concerned departments.

4.0 DEFINITIONS:

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality

4.1 **Document:** Document provides guidelines of direction for performing work, making decisions of rendering judgments, which affect the quality of the product Ex: SOPs, Guidelines, Specifications, STPs, protocols and formats etc.

4.2 **Record:** Record is a proof of evidence that an action performed. The format which is a document after it is written, it becomes a record.

4.3 **SOP:** SOP is a document used for routine or repetitive administrative and technical activities to facilitate consistently in the quality and integrity of the product.

4.4 **Annexure(s):** Annexure is an attachment or supplementary document which is added at the end of the standard operating procedure.

4.5 **Signature / Signed:** The record of the individual who performed a particular action or review, this record can be initials, full had written signature, personnel seal or authenticated.

5.0 PROCEDURE :

5.1 Purpose of Standard Operating Procedures may be necessitated for the following reasons:

5.1.1 To provide clear, unambiguous instructions to personnel as to the accepted method of performing a particular operation in a systematic, consistent and safe manner.

5.1.2 Introduction of new facility/process/system/procedure/equipment.

5.1.3 Up gradation of an existing facility /process /system /procedure/equipment.

5.1.4 Review of SOP to give additional clarity / continual improvement while performing an operation or to introduce additional controls at any stage.

5.1.5 To comply with the regulatory requirements.

5.1.6 Each SOP will have the following:

Header

Footer

Body of the SOP

The above are explained clearly in the following sections.

5.2 Once the need for a new SOP has been determined, it is the responsibilities of the Head of the department to prepare the SOP. The Head of the department may delegate the writing responsibility to a member of department.

5.3 **HOD or Assigned Author:**

5.3.1 Shall carryout discussions to determine the practice involved in the performance of the operation.

5.3.2 Shall get the rough draft of SOP prepared, using the format outlines in this procedure.

5.4 **SOP Contents and Templates:**

S. No.	Parameter	Standards
1	Paper	White Paper
2	Paper size	A 4 (210 mm × 297 mm)
4	Header	Company logo on left side middle of box.
5	Heading	As name Standard Operating Procedure typed in bold capital letters with font size 12 Times New roman font.
6	Title	Title of the SOP typed in bold capital letters with font size 12 in Times New roman font.
7	Department, SOP No., Supersedes, Effective date, Next Review date & Page.	Font size 12 in Times new roman font.

S. No.	Parameter	Standards
8	Sub Headings	Bold and Sentence case, Font size 12 in Times New roman font.
9	Footer	Name, Department, Signature and date for prepared by, Reviewed by & Approved by with Times New Roman font and size 12.
10	Paragraph line spacing	Line spacing should be maintain 1.5 lines

5.4.1 The contents of the SOP are as per the following:

A) Header and Footer

B) Body: Body of the SOP contains the following.

1.0 Purpose

2.0 Scope

3.0 Responsibility

4.0 Definitions

5.0 Procedure

6.0 Formats / Annexure(s)

7.0 Change History

5.4.2 **Header and Footer:** The following Header and footer is self explanatory.

Header:

1	STANDARD OPERATING PROCEDURE[2]

	SOP No.: [3]	SOP-QA-001-06	Effective Date:[6]	05.03.2020
	Supersedes : [4]	SOP-QA-001-05	Next Review Date:[7]	04.03.2023
	Department:[5]	Quality Assurance	Page:[8]	5 of 13
TITLE:PROCEDURE FOR PREPARATION OF STANDARD OPERATING PROCEDURES [9]				

5.4.2.1 Cell 1: Company Logo given in header at left side top of the SOP.

5.4.2.2 Cell 2: The name of the document i.e. **'Standard Operating Procedure',** It shall be printed at center of the cell, having equal distance above and below in the cell.

5.4.2.3 Cell 3: SOP Number is the SOP number which is a unique number given to each SOP. SOP number assigned as per the following:

SOP-DD-NNN-XX

SOP indicates : Standard Operating Procedure

DD indicates : Department code

NNN indicates : Serial No. of SOP (like 001, 002, 003……..)

XX indicates : Revision Number. In two numerical - indicates the SOP whenever revised after change control procedure. It will be 01, 02, 03 and so on. New SOP will have the version number as "**00**". Training should be completed in between Approval and Effective date.

Ex: SOP-QA-001-00

S. No.	Name of the Department	Department code
1.	Quality Assurance	QA
2.	Quality Control	QC
3.	Engineering	ED
4.	Production	PD
5.	Warehouse	WH
6.	Human Resource	HR
7.	Research & Development	RD
8.	Environment, Health & Safety	EHS

5.4.2.4 Cell 4: Supersedes is the reference of earlier effective standard operating procedure with its revision number and shall be written under this heading. For any new SOP, 'NIL' shall be written against supersede.

5.4.2.5 Cell 5: Department is the name of the originating department of standard operating procedure. It shall be written in capital letters with font size 12.

5.4.2.6 Cell 6: Effective date is the date on which the particular standard operating procedure shall be effective for implementation. The alignment shall be done at the top of the cell, on right side.

5.4.2.7 Cell 7: Review date Every SOP should be reviewed once in three years or whenever required, ± two months tolerance is acceptable to revise the SOP.

5.4.2.8 All the dates (Effective Date and Review Date) in the SOP shall be pre-printed as DD/MM/YYYY / DD.MM.YYYY / DD-MM-YYYY / DD/MM/YY / DD.MM.YY / DD-MM-YY.

5.4.2.9 DD represents the Date, MM represents the Moth, YY or YYYY represents the Calendar year.

Ex.: 05-03-2020 or 05-03-20.

5.4.2.10 Cell 8: Page Number shall be followed as X of Y format, where, X is page number Y is total number of pages of the standard operating procedure.

5.4.2.11 Cell 9: Title of the procedure shall be precise, concise and shall be given brief related to the subject of the SOP. All characters shall be bold & capital letters with font size 12 in Times New Roman fornt.

5.4.3 **Footer:** Following particulars shall be described at the bottom portion (Footer) of first page of the standard operating procedure as given below.

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality

Name			
Department			

5.4.4 **Contents of the Standard Operating Procedure:**

5.4.4.1 **Purpose:** The purpose of the procedure shall be given in specific details.

5.4.4.2 **Scope:** The scope of shall cover the Activities/ Areas/ Equipments/ Instruments/ Subsections to which the procedure shall be applicable.

5.4.4.3 **Responsibility:** The personnel responsible for performing, monitoring, supervising and recording the activity and directly associated with the implementation of the procedure shall be identified in this section.

5.4.4.4 **Definition:** It required, provide definitions to the critical term(s), when specified in the SOP. Skip this section if not applicable.

5.4.4.5 **Procedure:** The procedure shall be written in the following manner.

5.4.4.5.1 Describe the procedure in accordance with stepwise, sequential and chronological flow of operations. Each step being indentified by a number indicating the subgroups.

5.4.4.5.2 The subheading shall be numbered sequentially and subsequent numbering is done by giving the main point number and sub point number and sequentially.

5.4.4.5.3 Elaborate the procedure simple and small steps.

5.4.4.5.4 Write the procedure in an unambiguous manner

5.4.4.5.5 Write the procedure in the instructive language.

5.4.4.5.6 Provide examples, flow chart for more clarity, wherever required.

5.4.4.5.7 Give cross references of the other SOP/Document/Form wherever required.

5.4.4.5.7.1 If the SOP has reference of another SOP, then SOP title and number of the SOP shall be written without revision number.

5.4.4.5.7.2 If the SOP has a reference of a form then form title and number shall be written without revision number.

5.4.4.6 **Formats / Annexure(s):** All forms identified during the SOP preparation shall be listed with form No. and form title in this section. The numbering and layout of the forms shall be done as per SOP titled layout and numbering as follows:

XXYYY- FMNNN-ZZ

XX indicates – Department code

YYY indicates – Serial number of the SOP.

FM indicates – Format

NNN indicates – Format Number

ZZ indicates – Version/Revision number of the format (starts from 00)

Ex. QA001-FM001-00

AA-BB-CCCC indicates – Effective date

AA indicates – Specific day of the month

BB indicates – Month

CCCC indicates – Calendar Year

For Ex. QA001-FM001-00-05.03.2020

5.4.4.6.1 Continue serial numbering shall be maintained for formats irrespective of SOP. If any format removed that number shall be obsolete and the same number shall be not be assigned for new formats.

5.4.4.6.2 Operational convenience formats can be revised without SOP revision, through change control.

5.4.4.6.3 If the format content is related to SOP (i.e. Format Title, Body of the matter etc.,), then format shall also be revised along with SOP.

5.4.4.6.4 'Discovery' logo shall appear on the left side top corner and format number shall appear on the left side bottom corner and also effective date. Format preparation, review & approval sign & date details shall be printed back side of the format.

5.4.4.6.5 **Annexure(s):** A list of Annexure(s) described in the SOP shall be listed along with annexure number and annexure title in this section. The annexure(s) shall include documents for reference purpose only including flowcharts. All annexure(s) shall be signed by the person responsible for the approval of the SOP. The company logo shall be printed on the top left hand corner of all pages of annexure(s). The annexure(s) shall be numbered sequentially for the particular SOP and shall be include the document reference No. and Page No. along with annexure title in the header.

5.4.4.7 **Change History:** Contents as Revision No., Effective date, Details of Revision and Remarks.

5.4.4.7.1 Revision Number status shall denote the revision number of the SOP.

5.4.4.7.2 Effective date shall be provide current SOP effective date.

5.4.4.7.3 Details of revision shall give information on the change adopted in each revision of standard operating procedure.

5.4.4.7.4 Reference Change control number shall be provided.

5.4.4.7.5 Remarks shall be including any special comments pertaining to the respective revision.

Revision No.	Effective Date	Details of Revision	Ref. CCF No.

5.5 **Addition / Deletion /Addendum and Merging of SOPs.**

5.5.1 Addition of the new SOP shall be done in sequence manner.

5.5.2 If the activity is discontinued, then the related available SOP(s) are shall be obsolete and such superseded copy maintained by QA.

5.5.3 For operation convince two or more SOP(s) merged by one SOP, remaining SOP(s) shall be superseded.

5.5.4 Addendum procedure required for any regulatory / Audit query, user department shall be prepared separate annexure through change control. The addendum procedure shall be included whenever mother SOP revised.

Addendum procedure numbering system;

AA-BBB001-AD01

AA indicates: Quality Assurance

BBB indicates: Standard operating procedure

001 indicates: SOP number

AD01 indicates: Addendum procedure 01

Ex: QA-SOP001-AD01

5.6 **Document Preparation, Review & Approval:**

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality

5.6.1 User department shall make draft copy and submit to QA for review through Initiation form.

5.6.2 In case of SOP revision user department shall make draft copy and submit to QA for review through change control.

5.6.3 QA shall review and return to user department for final copy preparation. User department shall do the corrections if given by QA/others and prepare the final copy of document and submit to QA with prepared & reviewed signatures.

5.6.4 Head-QA/Designee shall review and approve the document.

5.6.5 After document approval by QA, put the "MASTER COPY" stamp on top of each page with blue color.

5.6.6 Master SOPs shall be kept in lock & key at Quality Assurance Department.

5.6.7 Quality Assurance department is authorized to take the photocopies of the Master document.

5.6.8 Whenever document is revised supersede copy shall be stamped as "OBSOLETE COPY" with red color on every page.

5.6.9 If observed any typographical error in approved master document during execution Head-QA is authorized for correct the document.

5.6.10 SOP index shall be prepared whenever SOP revised by QA department.

5.7 **Periodical Review:**

5.7.1 If changes are made during periodical review, user department shall prepare a draft copy of SOP, forward to QA for review through change control. Follow the procedure 5.6.2 to 5.6.10.

5.7.2 **In case no change in the SOP/STP:**

5.7.2.1 If there is no change in the procedure / specification, during the periodical review, user department shall inform to QA, change control is not required.

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality

5.7.2.2 QA personnel shall put the stamp as **Reviewed-No Changes required**" with black color on every page.

5.7.2.3 This shall be done on Master Copy and Controlled Copies; same shall be mentioned in the distribution record.

5.8 **Model stamps:**

MASTER COPY

Reviewed – No Change Required
Next Review date:
Reviewed by:
Date:

OBSOLETE COPY

6.0 FORMATS / ANNEXURE(S):

6.1 Standard Operating Procedure : QA001-FM139

6.2 New Document Initiation Form : QA001-FM140

6.3 Annexure : QA001-FM141

6.4 Addendum procedure : QA001-FM142

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01-06-2007	New SOP	---
01	01-07-2009	SOP format changed and reviewed for more clarity.	---
02	15.06.2014	Revised as per current SOP & more clear and clarity.	---
03	02-03-2016	Revised new format and more clarity.	---
04	01-11-2016	1. SOP format has been changed.	QA-CRF-012/16

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
		2. Reference" has been removed from SOP 3. New document initiation form has been included. 4. SOP next review date ±2 month's frequency incorporated. 5. Point no. 7 Change history contents were changed to Version No. Effective date, Details of Change &Ref. CCF Number. 6. Header contents have been modified. 7. Footer content has been modified. 8. Confidential copy stamp removed. 9. Document references content removed. 10. Addition / Deletion /Addendum and Merging of SOPs procedure included. 11. Engineering department code changed from MT to ED. 12. Periodical Review procedure included. 13. Altogether procedure has been rephrased for better clarity.	
05	01.04.2017	14. Company name changed from Discovery Intermediates Pvt. Ltd to Discovery Laboratories Pvt. Ltd. 15. Company Logo has been changed.	CCF-GEN-17005
06		Addendum procedure numbering system described clearly at 5.5.4 column	CCF/GEN/ 20004

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	V. Sathish	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality