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1.0 PURPOSE:

To lay down the procedure for initiation, Approval, Distribution, Retrieval, review and Retention of documents

2.0 SCOPE:

This procedure shall be applicable for the all new/ revised documents which documents prepared at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of the user department to follow the procedure and control the documents at their respective department.

3.2 Head -QA / Designee is responsible for implementing the procedure.

4.0 DEFINITIONS:

Document: Document provides guidance or direction for performing work, making decisions, or rendering judgments, which affect the quality of the products. Examples: SOPs, Specification and MOA, Protocol, Forms etc.

Record: Record is evidence that a quality system action is performed. Examples: Registers, records, reports, forms etc. The form when filled during operation / activity becomes a record.

5.0 PROCEDURE :


5.1 General guidance for writing document:

5.1.1 Use the industry specific guidelines like ICH Q7 and regulatory guidelines as a basis for preparing procedures.

5.1.2 All GMP documents shall be prepared, reviewed, approved and distributed according to respective approved procedures.


5.1.3 The issuance, revision, superseding and withdrawal of all documents shall be controlled with maintenance of revision histories.

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- 5.1.4 The content of the document shall be clear, unambiguous, specific and complete with all the necessary inputs.
- 5.1.5 The procedure shall be sufficiently detailed such that it can be readily understood and implemented.
- 5.1.6 Discovery logo shall appear on the top of page. All documents shall have identification number along with revision number.
- 5.1.7 The sequential number shall be tracked and the last number shall be allotted to the document, which shall be issued by QA during preparation of document.
- 5.1.8 Each section of record shall have column to record the details of performer like sign& date.
- 5.1.9 During preparation of formats / logs / register, the document shall be provided with required number of columns / tables to record the data and also provision shall be given to have information of operator / analyst like sign, date at each section of document.
- 5.1.10 The content of document shall be text / table / process flow / image etc..
- 5.1.11 Preferably, the font shall be in Times New Roman style.
- 5.1.12 Wherever necessary, the title and sections shall be in bold letters to have better clarity
- 5.1.13 Space between two lines shall be a minimum of 1.5 lines.
- 5.1.14 The side heading like Purpose, Scope, and Responsibility and so on shall be numbered
- 5.1.15 Use A4 Size paper to print the documents except forms. Forms can be in different sizes based on requirement for easy recording the data.
- 5.1.16 Abbreviations/short forms shall be elaborated at the first instance where it is used and short form can be used in subsequent sections.

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- 5.1.17 Any tables or figures used in procedure shall be identified with chronological sequential order. E.g.: Table-01; Figure-01.
- 5.1.18 Any templates/ process flow sheets shall be attached to specific document as attachments and which shall be identified with chronological sequential order.
- 5.1.19 In case there is a minor change/ correction in the document, the same shall be changed/ corrected by HOD-QA on original document. Strike old value/ matter/ figure with a single line and the new/ correct value/ matter/ figure shall be written with signature & date.
- 5.1.20 Wherever the operating personnel are not conversant with English language, SOP may be translated into local language and such documents shall be approved, controlled and distributed.

5.2 Initiation & Approval of document:

- 5.2.1 The person, who initiates the document shall inform and discuss with HOD or designee about the document to be initiated.
- 5.2.2 The initiator shall discuss with the concerned personnel and prepare a draft document. The draft version shall clearly be identified as 'DRAFT' before it is sent for review and comments.
- 5.2.3 The initiator of new or revised document shall submit the draft copy of document for approval by filling in change control form (CCF) to the concerned HOD or designee.
- 5.2.4 The initiator shall follow the current version of change control procedure, while filling the CCF.

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- 5.2.5 The HOD or designee shall go through the proposed document and evaluate the impact of the new / revised document on the established quality system. Review the CCF to ensure all the required information is complete and accurate. Review the document for clarity, correct format and correct spelling.
- 5.2.6 Upon satisfactory review, HOD or designee shall then forward the rough draft of document and CCF to QA for review & approval.
- 5.2.7 Upon review & approval of CCF along with draft document by identified departments and QA, requester shall modify the documents with the corrections recommended, if any. Requester shall sign the final document and obtain the signatures from all concerned.
- 5.2.8 Upon approval of document, the rough drafts of document shall be destroyed.
- 5.2.9 The hard & soft copies of original approved documents shall be retained with QA.
- 5.2.10 The soft copy of existing approved document which is available with QA shall be used for preparation of revised document and hard copy of original approved document shall be considered as final reference in case differences, if any are observed between soft & hard copies of existing approved documents.
- 5.2.11 In case of new or revised document, If the change is major, all the concerned personnel shall be trained before effective date.
- 5.2.12 All original copies shall be treated as Master copies and “MASTER COPY” stamp shall be put on each page of the document.

5.3 Document Distribution:


- 5.3.1 Documents which are distributed to various departments for reference purpose are stamped as “CONTROLLED COPY”.

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- 5.3.2 QA shall take photocopy of Master copy i.e. SOPs, STPs, Schedules, validation protocols etc., and put the Controlled Copy stamp as (in blue ink) figure-2 on the top left corner of the first page and remaining pages stamped as figure-3 accordingly.
- 5.3.3 Controlled copies distribution details shall be recorded in “Document distribution and retrieval record” (QA002-FM016) individual SOP / Document wise.
- 5.3.4 Controlled Copy shall be permitted within the premises.
- 5.3.5 In case of the copies requested by external agencies and customers, QA shall take the photocopy of Master Copy and stamped as “UNCONTROLLED COPY” (red color) figure-6.
- 5.3.6 In case existing distributed controlled copy is damaged a new “CONTROLLED COPY” shall be issued with damaged copy number. Retrieve and Destroy the damaged copy and details shall be recorded in (QA002-FM016).
- 5.3.7 During technology transfer of product from customers, request the customers to share the documents as “Controlled copy” to use further at Discovery labs.
- 5.3.8 The controlled copy which is issued by customer shall be considered as ‘Master Copy’ for Discovery labs.
- 5.3.9 QA shall be authorized to take required number of photocopies of customer controlled copy for distribution to functions/ departments as per requirement.
- 5.3.10 The photocopies shall be stamped as CONTROLLED COPY and distributed to concerned departments. The details of distribution shall be recorded.
- 5.3.11 The customer controlled copies can be used for first few batches / validation batches, once the product is commercialized, the documents shall be converted into Discover format and the same shall be used.

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5.3.12 If customer provided “uncontrolled copy” during tech transfer, such documents shall be converted into Discovery labs format and the same shall be used for regular usage. The changes shall be informed to the customer.

5.3.13 In case the documents are required for customer / Regulatory requirements such as responding to deficiencies, support to Regulatory submissions etc., QA shall photocopy the documents and submit to customers without any stamp or shall follow the specific customer requirements, if any.

5.4 Retrieval:

5.4.1 Controlled copies from all departments shall be retrieved wherever master document is revised and effective. Retrieved copies shall be destroyed by shredding or burning, the particulars of destruction shall be recorded in the Document distribution and retrieval record.

5.4.2 Superseded controlled documents / papers shall not used for any other purpose.

5.4.3 On the effective date of new version of document, QA shall stamp on master copy of the previous version (superseded) as ‘OBSOLETE’ (in red ink) and shall retain the same.


5.5 Document Issue:

5.5.1 Documents/Formats which are giving to various departments for execution purpose are stamped as “QA-ISSUED COPY”.

5.5.2 User department shall raise a document request form (QA002-FM090) to QA, the copy should be maintained at QA.


5.5.3 QA shall take the photocopy of master copy according to request, and affix the “QA-ISSUED COPY” (in blue ink) stamp as figure-4 top of the first page, remaining pages stamped as figure-5 accordingly. The issued details shall be recorded in respective issued record.

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- 5.5.4 Log books/registers request received by user department, QA shall check the format number, have continuous page numbers of the printed log book/registers and “QA - ISSUED DETAILS” shall be stamped or printed on the front page of the book as shown in figure-7 and record the details. The issuance details shall be recorded in QA002-FM144.
- 5.5.5 QA Issued Details numbering as follow:
XXXX-YYNNN
XXXX : Format number (without revision & effective date)
YY : Last two Digits of the Calendar Year
NNN represent : Sequential Serial Number (format wise)
Ex: QA001-FM001-19001 : First log book issued (format wise) to QA department in the year 2019.
- 5.5.6 Once the records are executed, the completed records shall handover to QA as soon as possible for archival purpose. The completed documents shall not retain with user department.
- 5.5.7 The following timelines shall be followed to handover the documents to QA, if any delay shall be justified;
- 5.5.8 After completion of execution of process and testing of a batch the BPR and testing documents shall be handover within 48 hours or before release of product whichever is earlier to QA.
- 5.5.9 QC Analytical Reports after completion of analysis shall be handover within 48 hours to QA. Remaining all other reports and registers on monthly basis or whenever the record is completed like logs / register shall handover and new log / register shall take from QA.

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5.5.10 For any revision in the form, the responsibility of withdrawing the superseded copies shall be with the departments/ functions heads / incharges, which distributed the controlled copies. The superseded documents shall not be used for any other purpose.

5.5.11 QA shall be responsible to withdraw the superseded copies from the operational use

5.5.12 “Document/Record issue and retrieval record” (QA002-FM144) shall be updated as and when the documents are received and the Document distribution and retrieval record shall be cross verified by the QA incharge on monthly basis for ensuring the retrieval of documents and updating of records at QA.

5.5.13 All annual records shall submit to QA on yearly basis like Warehouse Records, Engineering records, HR, production logs.

5.5.14 Issued copies shall be retrieved end of the year or whenever finished and stored for further reference as per document retention period. The details recorded in concerned issue retrieval record.

5.6 Registers/Log Books:

5.6.1 The registers/log books shall have continuous page numbers.


5.6.2 The size shall be decided based on the convenience to record the data.

5.6.3 The books can be given for outside printing, which proofs shall be verified by Quality assurance for correctness and the books shall be printed.

5.6.4 If books are prepared inhouse, the number of copies required can be photocopied from master document or the required format can be prepared as softcopy then check the correctness of data and print can be taken on required paper size then shall bind and issue the books by Quality assurance personnel.

5.6.5 Loose sheets shall be avoided and books shall be printed with page numbers and the same shall be used for recording the data.

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5.6.6 If loose sheets need to use, the same shall be printed as books and the individual pages shall be used for recording purpose and reconciliation of such pages shall be tracked and the same shall be verified or loose sheets can be issued as a individual document and the same shall be recorded in the Document issue and retrieval record and reconciliation shall be ensured once the document is returned to QA

5.7 If there is no change in format content against to previous version, old stock can be used till existing stock is completed. After that new format shall be implemented.

5.8 If any internal communications followed through Inter office communication (IOC).

5.9 Only QA personnel are authorized to use the stamps and the stamps shall be kept in lock and key to avoid the access to unauthorized personnel

5.10 **Model Stamps:**

Figure-1

MASTER COPY

Figure-2

CONTROLLED COPY
Copy No:
Sign:
Date:

Figure-3

CONTROLLED COPY

Figure-4

QA-ISSUED COPY

Sign _____ Date: _____

Figure-5

QA-ISSUED COPY

Figure-6

UNCONTROLLED COPY


Figure-7

QA - ISSUED DETAILS
Issued for: _____
Issued to department; _____
Register No.: _____
Issued by: _____
Date: _____

Figure-8

OBSOLETE COPY


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5.11 Retention period of documents:

- 5.11.1 At the beginning of current calendar year, the documents related to all departments pertaining to previous year should be handed-over to QA for archiving.
- 5.11.2 The received documents should be accounted by QA representative by appropriate documentation procedures. The records should be protected in box files or transparent protection cover.
- 5.11.3 All the received documents should be segregated and labeled by QA prior to archiving.
- 5.11.4 The documents should be archived in respective archiving area.
- 5.11.5 Access to the archive room should be restricted and List of authorized personals prepared by QA.
- 5.11.6 Access shall be restricted to un- authorized personnel.
- 5.11.7 The archiving room shall always be kept locked (when there is no operations inside) and keys are maintained at QA.
- 5.11.8 Documents shall be disposed within 12 months after the required retention period is reached
- 5.11.9 After expiry of the retention period, the documents should be destructed by means of shredding and/or burning and the details shall be recorded.
- 5.11.10 Retain all documents as per following retention period.


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Retention of Records / Documents (Validity)		
S. No.	Description of the document	Retention Period
1.	Executed Batch Production Records Product change over cleaning records Recovery solvent executed batch records Line clearance records Reconciliation registers Deviation reports Complaint records Return goods records Batch related test reports including raw data note book, Record of Analysis (RoA), CoA, including GRN, inprocess sheets. Water analysis Reports (Chemical and MB), OOS and OOT log and investigation Reports Reagents, Volumetric solutions preparation and standardization records, Indicator, mobile phase solution, All Category Inward Registers Finished Product Labels reconciliation Registers Record of samples sent to outside laboratory Working Standard Preparation, Test Reports Finished Products Reserved samples Register Temperature monitoring Records.	Retest /Expiry + 1 year Or 3 Years (whichever longer)
2.	Consumption record (Intermediates / Recovered solvents) Production weighing Registers & daily performance check Temperature & Humidity Records of storage areas Filter bag changing records Filter integrity and cleaning record Calibration and Performance check Records Cleaning & Sanitization records related to Water systems Instrument /Equipment usage Log books, calibration /Performance check Records, Maintenance Records including requests Preventive & Break down Raw Material and packing material Stock and Distribution Records Pre-inspection reports. Material transfer records Reconciliation records Sampling and dispensing room logs	3 years

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Retention of Records / Documents (Validity)		
S. No.	Description of the document	Retention Period
	Document issue and retrieval register	
3.	House Keeping Records (Manufacturing, Storage and laboratory areas) Pest & Rodent control records, Agreements	2 years
4.	Site master file DMFs	Life time of manufacturing site
5.	Facility Plans (Manufacturing & Testing Equipment , Storage tanks , Utilities Systems and Area) , Manuals, Drawings and Qualification Reports of equipments Document disposal record	6 Years from the date the facility /system/equipment was last used.
6.	Technology Transfer / Site transfer documents Process validation protocols & reports, Development reports BPRs filed in the DMF Change control Annual product Quality review reports Cleaning validation & Analytical method validation protocols/ reports Master BPRs (Every version) Products Specifications & MOAs (Every version) Hold time / Stability Test Reports	Life time of the product i. e. One Year after the retest date or expiration of the last batch manufactured.
7.	Vendor Qualification documents	3 Years after the vendor ceases to supply
8.	Superseded version of Master copies of departmental SOPs and Forms Superseded version of Masters specs & MoA related to RM and Packaging materials	Every version 6 years from the date it was superseded or Last 3 versions.
9.	Regulatory & Certification Inspection Audit Reports and Responses	6 Years after all the actions are completed.
10.	Job description and Employee personal Training Record Analyst Qualification and Training Records	6 Years after the separation of the employee.
11.	Superseded organograms	Last two version or 2 years whichever is longer
12.	Customer contract Agreements	Till validity period
13.	Contract Laboratories Qualification Reports	3 Years after the contract services are discontinued.

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5.11.11 In case there is any specific requirement by the customer the documents shall be retained as per the customer requirement.

5.11.12 Quality Assurance shall dispose the documents. The disposal details shall be recorded (QA002-FM179)

5.11.13 In case of customized product execution, all relevant documents shall hand-over to customer and the same shall be documented.

6.0 FORMATS / ANNEXURE(S):


6.1	Document Distribution and Retrieval Record	: QA002-FM016
6.2	BPR / Analytical Raw Data Issue and Retrieval Record	: QA002-FM103
6.3	Document/Record Issue and Retrieval Record	: QA002-FM144
6.4	Document Request Form	: QA002-FM090
6.5	Document numbering log	: QA002-FM176
6.6	List of Authorized Personnel	: Annexure-1
6.7	Document Disposal record	: QA002-FM179

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.06.2007	New SOP is introduced	---
01	01.07.2009	SOP formats changed and reviewed for more clarity.	---
02	01.01.2014	1. Usage of stamps explained. 2. SOP revised more clarity.	---
03	15.06.2014	Removal period of documents included.	---
04	30.06.2016	Retention period of documents included.	---

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Revision No.	Effective Date	Details of Revision	Ref. CCF No.
05	01.08.2016	1. Retention period of documents included. 2. SOP title has been changed as “Document Control”. 3. Rephrase the procedure.	---
06	25.12.2016	1. SOP format changed in line with SOP-QA001-04. 2. BPR issue record contents were modified. 3. Document request form contents were modified. 4. Forms/ Records Issue and Retrieval Record contents were modified. 5. Altogether procedure has been rephrased for better clarity.	QA-CRF-014/16
07	01.01.2018	SOP format changed make to inline with SOP-QA001-05.	CCF/GEN/17037
08	01.08.2019	Procedure for preparation of GMP documents, handling of tech transfer documents, control of loose sheets, retention time of documents are elaborated for more clarity. FM089 merged into FM144 and FM176 is introduced.	CCF/GEN/19027
09	06.12.2021	Procedure for counterpart document distribution is imparted in 5.3.14	CCF/GEN/21026
10		New format introduced QA002-FM179	CCF/GEN/22003

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