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1.0 PURPOSE:

To lay down a procedure for requirements that to be followed for documentation related to manufacture of product.

2.0 SCOPE:

This procedure is applicable to all quality system related records used for recording the data at Discovery Laboratories Pvt Ltd.

3.0 RESPONSIBILITY:

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

4.0 DEFINITIONS:


Nil

5.0 PROCEDURE :

5.1 The purpose of documentation is to;

- 5.1.1 To define the instruction to perform the operations related to manufacturing, testing and release of products.
- 5.1.2 To ensure that all personnel concerned with manufacture know what activity is to be carried out and when it is to be carried out.
- 5.1.3 All information related to manufacture of a product shall be documented during performing the operations / testing to have evidence to review the process.
- 5.1.4 To avoid errors so as to ensure that the authorized person has all the necessary information to make a decision about whether or not to release a particular batch of a particular product for sale.
- 5.1.5 To provide an audit trail, this would permit investigation into the history of any suspected defective product.


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5.2 Documentation practices:


- 5.2.1 All documents shall be signed or initialed and dated.
- 5.2.2 Record the data directly in the intended and authorized formats. Don't use uncontrolled note books, scrap pieces of paper, diaries and post-it notes to record any cGMP/ GLP data.
- 5.2.3 Record the data in a clear, legible and indelible manner contemporaneously i.e. at the time of activity. Capture the actual and clear observations.
- 5.2.4 Record the data using an indelible blue or black ball pen. Don't use pencil or erasable or water-soluble ink pen to record the cGMP documents
- 5.2.5 During part execution of the activity, record the information up to the extent performed and endorse with sign & date.
- 5.2.6 Data shall be recorded in proper places on the format or Batch Production execution / measuring/ testing/ calibrating etc....
- 5.2.7 Recorded data shall be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent and Enduring.
- 5.2.8 Don't back date and postdate the entries and missed entries shall not be filled on later dates without proper assessment.
- 5.2.9 All the entries shall be made as and when the operation is being completed.
- 5.2.10 Initials are acceptable, unless the document specially requires a signature. The initials and signatures shall be used as per specimen signature record.
- 5.2.11 Where recording of data by the personnel executing the activity is not possible due to operation constraint (e.g. working in a confined/restricted space such as working at height etc.,) data shall be entered by another person witnessing the operation.

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- 5.2.12 Document shall have the provision for "Recorded by" signature in addition to "Performed by" signature.
- 5.2.13 Person performing the activity shall sign the record after completion of the activity
- 5.2.14 Unused portion in a completed document shall be appropriately strike off by using a diagonal line across the page/section/table/rows/columns and entering NA or N/A on diagonal line with sign & date such that the data cannot be added at a later date. Don't discard empty/unfilled pages.
- 5.2.15 Proper units of measure (°C, Kg, L etc.) shall be used appropriately in documents.
- 5.2.16 Record the numerical value displayed or observed from the instrument or equipment with appropriate unit of measure (UoM) as applicable (such as kg, gm, mg etc.).
- 5.2.17 Record the conversion factor, if displayed or observed UoM is different than the UoM mentioned in the document.
- 5.2.18 Numerical value shall be recorded as is displayed or observed on the respective instrument or equipment.
- 5.2.19 Recording of UoM for each numerical value is not required, if the document has incorporated the UoM.
- 5.2.20 Decimals less than one shall be preceded by "Zero" such as "0.4 mg" not as ".4 mg"
- 5.2.21 Attachments to the document shall be sequentially numbered and the details shall be referred in the parent document.
- 5.2.22 Printout from the instrument or equipment shall be reviewed and signed by the concerned personnel. If any discrepancies are identified, the same can be documented and explained with a comment in foot note.

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- 5.2.23 Identify the attachments appropriately for easy traceability (i.e by recording of batch number, equipment number etc.).
- 5.2.24 Printout shall be affixed at appropriate place in the document.
- 5.2.25 Staple or affix the attachments to the document using tape or glue. Use paper clips for handling large bundles (such as BPR, ROA etc.) where stapling is not possible.
- 5.2.26 Incomplete records and/or unsigned documents shall not be used to perform any task or considered as evidence of completed task.
- 5.2.27 All the relevant documents shall be handed over as soon as their use is complete to the Quality Assurance department.
- 5.2.28 Superseded controlled copies shall be destroyed by QA as soon as possible and such documents shall not used for writing / printing of any draft copies or for any together purpose
- 5.2.29 It shall be the responsibility of the personnel making use of the documents to see that the documents are maintained properly without being subject to any sort of damage.
- 5.2.30 If any record is damaged and the recorded data is not clearly legible, deviation shall be raised to assess the impact and the available data shall be transcript into new document. The new document issue and retrieval details shall be recorded in issuance registers.
- 5.2.31 Transcribing of data is acceptable only when the original record is damaged and where the original record becomes illegible over a period of time.
- 5.2.32 Transcribed document shall be signed by the transcription person and verified by second person against a source document and shall be stored together with the original record

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- 5.2.33 Corrections shall be made by the person who has made the original entry and shall be signed with date.
- 5.2.34 If the person who has made the original entry is not available (i.e left the organization/department/in leave), HOD shall nominate other person for making the correction.
- 5.2.35 During regular entry of data, if entry made wrongly, strike out the incorrect entry with a single line and write the correct entry near the strikeout entry. Don't overwrite the previous entries and Don't use white ink or sticky notes to correct the entries.
- 5.2.36 Corrections made shall be clear, legible, accurate and the original entry shall be readable.
- 5.2.37 Multiple corrections in a same page and/or limited space can be numbered.
- 5.2.38 Attachment shall be used if the space is limited and the reference of attachment along with number of pages shall be included in the original record.

Example-1: Calculation Error:


0.35	0.34	X	
0.35	0.34	✓	0.34 Sign. 30/07/19

Example-2: Entry Error:

Process	Prosess	X
Process	Prosess	✓ ③

- 5.2.39 Missing entries can be entered at a later time by the concerned personnel if there a definite objective evidence. Missing data shall preferably be entered by the person who has missed the entry along with the justification in current date.
- 5.2.40 Missing entries shall be identified and the reason for delay shall be mentioned at the bottom of the page with sign & date. Date when the activity was performed

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and date when the activity was recorded shall clearly be mentioned in the document with sign & date.

- 5.2.41 Document an explanation to substantiate the entry.
- 5.2.42 Supervisor shall verify supporting evidences for correctness and applicability. If supporting evidences are not available , it shall be routed through deviation
- 5.2.43 If the operations are not critical, Right curly bracket [}] shall be used with one signature to indicate verification of several operations.
- 5.2.44 All un-used sections of documents will be cross lined and marked with NA or Not Applicable, empty columns/entries when ever not required shall be crossed out with “___” initialed and dated.


1	Monday	35.6°C	Pass	For, 12/07/19	NA
2	Tuesday	35.4°C	Pass	For, 12/07/19	NA
3	Wednesday	35.5°C	Pass	For, 12/07/19	NA
NA For, 12/07/19					

- 5.2.45 **Date & Time entering procedure:** Entries requiring dates must be formatted in the order of day, month and year (DD/MM/YYYY) which are separated by ‘hyphen’ or ‘slash’ or ‘dot’.
- 5.2.46 The representation of calendar year may in the format of YYYY or lost two digits.
- 5.2.47 For example, the 01st day in the month of July for the year 2019 shall be written as follows.

DD/MM/YY① or DD/MM/YYYY② or DD-MM- YY① or DD-MM-YYYY②Or DD. MM.YY① or DD.MM.YYYY②.


01/07/19 ①	01/07/2019 ②
01-07-19 ①	01-07-2019 ②
01.07.19 ①	01.07.2019②

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- 5.2.48 Record the time in 24 hour format with 2 digits to indicate hour followed by another 2 digits to indicate minutes. Date shall be changed at 00:00 Hr.
- 5.2.49 If the operation is continued from one shift to another where the date is different, the date shall be recorded in the date column.
- 5.2.50 Time shall be converted to 24 hour format while recording if it is displayed or observed in 12 hour format (i.e) AM/PM. e.g. 03:14 PM can be entered as 15:14 hr.
- 5.2.51 **Correction of errors:**
- 5.2.51.1 Overwriting or erasing or blocking of data shall not be done.
- 5.2.51.2 Errors and over writings shall be corrected with a single line cross out, then initialed and dated.
- 5.2.51.3 Correction fluid shall never be used.
- 5.2.51.4 Post-it notes, scrape pieces of papers are not to be used for recording data.
- 5.2.51.5 Correction arising based on review of the document by concerned personnel in filled document such as BPR/ Analytical record/ validation documents etc., the correction shall be made with the current date and an Error rectification sheet shall be appended to original document.
- 5.2.51.6 This error rectification sheet shall be initiated and reviewed by the same departments by whom the main (original) document has been signed earlier and shall approved by Quality Assurance. If the errors observed in documents, where only typographical / transcriptional / printed errors, the error rectification can be initiated and approved by Quality assurance personnel.

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5.2.51.7 Quality assurance shall assesses the nature of error, If the errors has an impact on the Quality of product or Major impact on Quality system, such errors shall be investigated through Deviation procedure.

5.2.51.8 If the error is identified after batch release / the product into market and the error leads to alter the Quality of product shall be considered as Quality Impacting Error.

5.3 Numbering system for Error rectification:

The numbering system shall be followed as ERN/YYNNN

Where,

ERN indicates : Error rectification number

NNN indicates : Serial number (starts from 001)

YY indicates : Last two digits of calendar year

Ex: ERN/19001 (First Error rectification form raised in the year)

6.0 FORMATS:

6.1 Error Rectification Register :QA032-FM114

6.2 Error Rectification :QA032-FM113


7.0 ANNEXURE(S): NA

8.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.01.2017	SOP is prepared separately from "Document Control" SOP.	QA-CRF-014/16
01	01.01.2018	SOP format changed make to inline with SOP-QA-01-05.	CCF/GEN/17037
02	01.08.2019	Procedure for handling of over writings, damaged records, transcription of data and error rectification is revised with more clarity	CCF/GEN/19031

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