SOP TITLE: **GOOD DOCUMENTATION PRACTICES**

1. **Objective:**

The objective of this document is establish a standard written procedure for good documentation practices including basics, GMP documents preparation, issuance and retrieval of records, recording of time, correction of entries, handling of missing entries, blank space and cancellation of GMP records.

1. **Scope:**

This procedure applies to but not limited to; batch manufacturing & packaging records,  
logbooks/formats, laboratory logbooks/records/formats, change controls, training documents,  
equipment/instrument usage records, validation reports/protocols, deviation and product complain investigation records.

1. **Reference:**

WHO TRS 996, Annex 5

1. **Responsibility:**
   1. Deputy Manager Compliance & DI/designee is responsible to prepare and revise the SOP
   2. Deputy Manager Compliance & DI/designee is responsible to check compliance and provide training on the SOP.
   3. Designated person (s) in every department is responsible to follow the SOP
   4. Departmental Heads/Managers of each operation or function is responsible for adherence to  
      this procedure.
   5. QA Department is responsible for controlling of SOP.
2. **Definitions:**
   1. **GDocP:**

Good documentation practice is a systematic procedure of preparation, reviewing, approving, issuing, recording, storing and archival of any document.

1. **Materials & Equipment:**

N/A

1. **Precautions:**

N/A

1. **Procedure:**
   1. **Premises**
      1. All documents must be accurate and written in a manner that prevents errors and ensures consistency.
      2. If documents are to be used together, e.g. a SOP and its annexure then each should refer each other.
      3. Ensure there is traceability between two or more documents/records using formal document numbers or record identification.
   2. **Using Indelible Ink:**
      1. All records must be filled out in indelible ballpoint pen for long term legibility.
      2. Do not use pencil or ink that can be erased.
   3. **Legible Handwritten Entries:**
      1. A document is unusable if it cannot be read, so care must be taken to ensure that handwriting is legible. All entries must be made at the time the tasks are performed and should be legibly signed and dated.
      2. The same is true for electronic documents and records – language should be clear and unambiguous.
   4. **Reviewing and Approving:**
      1. To ensure that the information is correct and accurate, documents and records should be reviewed by someone who has performed the task and has proper knowledge. A signature and date by the reviewer/approver confirms that a review has taken place.
      2. Unsigned documents or records are incomplete and should not be used to perform any task or considered as evidence of a completed task.
   5. **Employee Signatures:**
      1. Handwritten signatures must be unique to the individuals and listed within the signature register to ensure that the signature is traceable to the concerned employee (or contractor).
      2. Any employee should not be permitted to sign for another member of staff unless delegated. Signatures must never be forged.
      3. The management of the signature record should be governed by a procedure and routinely reviewed so that it remains current – new employee should sign the signature register during induction, the signature register must indicate that date employee exit.
   6. **Constitutes of Good Documentation:**
      1. Clear and concise titles should be used for headings, tables, graphs etc.
      2. Pages in the master document should be numbered as X of Y.
      3. Full text spellings with the abbreviation in brackets should be used for the first time. Abbreviation may be used in place of full text spelling in remainder of the document.
      4. All documents should have the signature and date of the person who prepared the document, reviewed the document and approved the document.
      5. All master documents should have effective date, approval date and current version number.
      6. Respective SOPs should be followed while preparing the documents.
      7. Words that everyone understands should be used. Unfamiliar words reduce the reader’s understanding of what is written.
      8. Definition of abbreviations should be included in the document for reference. This is most effectively done by including the definitions in a table format, at the start or end of the document.
      9. Ensure that contents of documents are not squeezed into a smaller area just to limit page numbers. Document with small margins and no spaces between paragraphs and headings can be difficult to look at, hard and slower to read. Space the contents out so that the type/font is easy to read for all users.
      10. When creating a document, consider the context in which the document may be used in the future and whether the reader has enough background information.
      11. People remember information best when there is a strong visual prompt, such as a diagram. When the document has to be lengthy, consider using tables to structure the information for easy understanding of the reader.
      12. Training of the document should be planned only after approval of document and shall be completed before the effective date.
   7. **Issuance and Retrieval of GMP Records:**
      1. All the forms associated with the activity should be part of respective SOP.
      2. QA maintains list of GMP impacting forms and its associated SOP.
      3. Records for issuance and retrieval of such forms should be maintained.
   8. **Recording the Time and Date in GMP Records:**
      1. Time shall always be expressed in HH:MM format, using the 12:00 hour cycle and AM or PM notation. For Example, Midnight shall be expressed as 12:00 AM and noon as 12:00 PM.
      2. Date should be entered in DD-MM-YY or DD.MM. YY or DD/MM/YY format. For example, 27th July 2013 should be written as 27.07.13. Place “0” before the digit if digit is less than 10 for recording of date.
   9. **Data Recording in GMP Records:**
      1. Date and time should be recorded in GMP records as mentioned above.
      2. Data should be recorded only in the format duly issued and approved by Quality Assurance.
      3. Entries in the logbooks should be made in chronological order. Entries should never be pre-completed or left incomplete. Aforementioned instances are a breach of documentation practices and ALCOA principles.
      4. Data recording should be done by trained and authorized person.
      5. Data should be recorded as it is displayed on the respective equipment panel or original value obtained after a test result.
      6. Unusual observation during the activity should be recorded, signed and dated. Same should be reported to area in-charge/manager and QA.
      7. If any observation / signature / date are to be repeated, the same should be rewritten. Ditto marking or “as above” or “do” shall not be used.
      8. Manual entries should be reviewed and signed by the second person for accuracy and completeness.
      9. Raw data / print outs generated during the activity should be signed at the left bottom with date and should be attached with relevant records.
   10. **Correction of Entry in GMP Records:**
       1. Incorrect entries in GMP records should not be overwritten or blocked to make it unreadable.
       2. Always use a single strike out line (For example: ~~Incorrect Entry~~) to mark the incorrect entry in such a manner that the previous entry remains readable.
       3. Correct entry should be written near to the strikeout entry. Person correcting the entry should put the initial/signature and date along with corrected entry. Only the person who made the original entry and strikethrough should make correction and get it verified by his Supervisor/ Manager by putting initial/signature with date. If this is not possible, notify to QA.
       4. Reason for correcting the entry should also be documented on the record. In case of space constraint in the document the reason for correction should be mentioned on the footer of the record with sign & date. An example is shown below:
   11. **Handling of Missing Entry in GMP Records:**
       1. Entries in the GMP records should be done in parallel with activity being performed. However, any Missing entry in the GMP records can be re-entered later if the data are Traceable. (For example: start time of blender is missed by the operator, but this record can be found in the equipment usage log book).
       2. In such case, entry should be made with clear indication of the date when the activity was performed and the date of recording of activity on the document.
   12. **Working with Blank or Unused Space:**
       1. Blank/Unused space in the GMP records should be strikeout with single line through the entire length of the format and “not applicable” or “N/A” shall be written to make sure that record cannot be altered or edited later.
   13. **Cancellation of GMP Records:**
       1. Cancellation of GMP records should only be allowed in the rare case with the approval of QA and in exceptional cases such as spillage of chemical on the record. Reason of cancellation should be documented for cancellation of document and signed by area person in-charge and QA.
2. **Training:**

Training will be imparted to the concerned personnel prior to implementation of this SOP and will be recorded on document QAG/5/142.

1. **Attachment:**

N/A

1. **Distribution List:**
2. **SOP Review History:**