

{COMPANY LOGO}	SOP No:		Version:		Effective Date:	{01-Jan-2021}
	Title: {Enter Title of Procedure Here}					
Author:				Approver:		
{Wet Signature}		{01-Jan-2016}	{Wet Signature}		{01-Jan-2021}	
<i>Signature</i>		<i>Date</i>	<i>Signature</i>		<i>Date</i>	

1.0 Purpose

{Why is this procedure important? The Rationale or Reasoning for the procedure.}

2.0 Scope

{Short summary of the Intent of the procedure.}

3.0 Objective

{What is the final result expectations? What is to be gained?}

4.0 Definitions

{List in outline format}

5.0 Attachments (Annexes)

{List sorted based on applicability, i.e., relevant forms, associated manuals, and other materials}

6.0 References

{List in outline format. All references must be Relevant!}

7.0 Roles and Responsibilities (R&R)

7.1 Specific or All Employees {Describe R&R for Employees}

7.2 Quality Assurance {Should define R&R for most procedures}

{Applicable Departments Below (see examples)}

- 7.3 IT Department (Delete if not applicable)
- 7.4 Manufacturing Department (Delete if not applicable)
- 7.5 Maintenance and Engineering Department (Delete if not applicable)
- 7.6 Quality Control and Laboratory (Delete if not applicable)
- 7.7 Warehouse Department (Delete if not applicable)

8.0 Procedure

(List in outline format)

9.0 Distribution

(List of physical and logical locations of all hard and electronic copies – Optional)

10.0 History

((Document Changes) Why at the end recommended?)

Date	Version/Rev.	Change Description

11.0 Attachments

Comment: Delete this page upon use.

1. Keep logo basic
2. Consider utilizing outline formats for all sections
3. For dates, preferable short dating for documents is dd-MMM-yyyy. You can change, however, the change must reflect the Good Documentation Practice procedure guidelines.
4. For SOP Number, consider the following;
 - a. QA-001 Quality Assurance related procedures, including Regulatory Affairs (RA), (with form relationships i.e. XX-001F(for Forms))
 - b. QC-001 Quality Control (in process, receivable, finished products, and other Laboratory Testing) related procedures (with form relationships i.e. XX-001F(for Forms))
 - c. IT-001 – Computer Systems related procedures (with form relationships i.e. XX-001F(for Forms))
 - d. RD-001 – Research and Development related procedures (non-GMP) (with form relationships i.e. XX-001F(for Forms))
 - e. FAC-001 – Facility Related procedures, i.e. Maintenance, Metrology, Housekeeping, Engineering, and other facility related procedures (with form relationships i.e. XX-001F(for Forms))
 - f. WH-001 Warehouse Procedures (with form relationships i.e. XX-001F(for Forms))