> **Sample document.** Prepared by Laafon Galaxy Pharmaceuticals to show the format of a site-specific SOP. Company name, people and dates are redacted; a live SOP carries your site's details, numbering and approvers. Badge key: `R 17.2.2` = a requirement of Revised Schedule M, Part I (G.S.R. 922(E)), with the clause; `Site policy` = a choice the site makes and records, not a regulatory figure.

Pharmaceuticals Pvt. Ltd.	**STANDARD OPERATING PROCEDURE**	
	Preparation, Review, Approval, Issue and Control of SOPs	
Department: Quality Assurance	SOP No.: `QA-001-00`	Supersedes: Nil (new SOP)
Effective date:	Next review due:	Copy No.: (Controlled)

	Prepared by	Checked by	Approved by
Name			
Designation	Executive, QA	Manager, QA	Head, Quality Assurance
Signature and date			

1.0 Purpose

To lay down the procedure for preparing, numbering, reviewing, approving, issuing, revising, periodically reviewing, withdrawing and archiving Standard Operating Procedures (SOPs), so that only current, approved procedures are in use at the site. `R 17.2.1` `R 17.2.4`

2.0 Scope

Applies to all SOPs of all departments at (Quality Assurance, Quality Control, Production, Stores, Engineering, Microbiology, Human Resources and Administration), in paper and electronic form. Specifications, master formula records, batch records and protocols are controlled under their own SOPs but follow the numbering and approval principles of this SOP.

3.0 Responsibilities

Role	Responsibility
Originator (user department)	Identifies the need, drafts the SOP in the approved format, and ensures the procedure matches actual practice and equipment.
Head of user department	Checks the draft for technical correctness and practicability; trains department staff before the effective date.
Quality Assurance	Allots SOP numbers, reviews for compliance and consistency with other SOPs, approves, issues controlled copies, retrieves superseded copies, maintains the SOP master index and archive.
Head, Quality Assurance	Final approval of all SOPs. `R 17.2.2`

4.0 Definitions

- **Controlled copy:** an issued copy carrying the "CONTROLLED COPY" stamp in a colour other than black, a copy number and the QA issuer's signature and date.
- **Master copy:** the original signed SOP held by QA. It is not issued.
- **Superseded SOP:** a version replaced by a later revision; withdrawn from use and retained by QA. `R 17.2.4`
- **Uncontrolled copy:** any copy issued for information (for example to an auditor) and stamped "UNCONTROLLED - FOR INFORMATION ONLY".

5.0 Procedure

5.1 Initiating a new SOP or a revision

1. Any new SOP, or a revision that changes the procedure, is raised through a change control request. `R 8.1`
2. Editorial corrections that do not change the procedure (typing errors, formatting) may be made at the next revision and are recorded in the revision history.
3. QA records the request in the SOP master index (Annexure IV) and allots the SOP number.

5.2 Numbering system

Format `DD-NNN-RR`, where `DD` is the department code, `NNN` a three-digit serial number and `RR` the revision number starting at `00`. Department codes: QA, QC, PR (Production), ST (Stores), EN (Engineering), MB (Microbiology), HR (Human Resources). A withdrawn SOP number is not re-allotted. `Site policy`

5.3 Format and content

Every SOP is prepared on the format in Annexure I, with the header on every page (company name, title, SOP number, revision, effective date, page x of y) and the following sections: 1.0 Purpose, 2.0 Scope, 3.0 Responsibilities, 4.0 Definitions (if needed), 5.0 Procedure, 6.0 Records and annexures, 7.0 References, 8.0 Revision history. Language is clear, written in the imperative ("Switch on", "Record"), and describes the equipment, room and record actually used at the site. Each step that generates a record names the record format.

5.4 Review

1. The Head of the user department checks the draft against actual practice on the shop floor or in the laboratory.
2. QA reviews it for compliance with Revised Schedule M, consistency with related SOPs, and the correct record formats.
3. Comments are resolved with the originator before approval. The review is documented on the draft.

5.5 Approval and effective date

1. The master copy is signed and dated by the preparer, checker and approver in the signature block. `R 17.2.2`
2. The effective date is set to allow training to be completed first; it is not earlier than the approval date. `Site policy: up to 7 working days after approval`

5.6 Training before use

The department head trains every person who performs the SOP before the effective date, and records the training on the training record under the site's written training programme. `R 11.4.1` `R 11.4.2` A person not trained on the current version does not perform the procedure.

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5.7 Issue of controlled copies

1. QA issues photocopies of the master copy, stamped "CONTROLLED COPY", numbered and signed, to the locations listed in the distribution record (Annexure II).
2. The receiving department signs for each copy on Annexure II.
3. Controlled copies are not photocopied by users. Extra copies are requested from QA. `R 17.2.1`

5.8 Revision and withdrawal of superseded copies

1. On the effective date of a revision, QA retrieves every controlled copy of the previous version against Annexure II and issues the new version. `R 17.2.4`
2. Retrieved copies are destroyed and the destruction is recorded. The superseded master copy is stamped "SUPERSEDED" with the date and archived by QA.
3. Superseded master copies are retained for at least the period this site sets in its document retention SOP. `R 17.2.4` `Site policy: retention period stated in QA-0xx`

5.9 Periodic review

Every SOP is reviewed regularly to keep it up to date `R 17.2.4`, and in any case at the interval this site sets `Site policy: every 2 years`, and earlier after a change in equipment, process, regulation, or an audit or inspection observation. The review is recorded on Annexure III; where no change is needed, the SOP is re-approved with a new review-due date.

5.10 Corrections on controlled copies and records

No handwritten change is made on a controlled SOP copy. On records generated under an SOP, any alteration is signed and dated, the original entry remains readable (single line strike-through), and the reason is written where the change is not self-evident. `R 17.2.6`

5.11 Electronic SOPs

Where SOPs are held in an electronic document system, only authorised persons can create, change or approve them, a record is kept of changes and deletions, and access is controlled by individual user IDs. `R 17.2.8`

5.12 Records generated under SOPs

Batch-related records are retained for at least one year after the expiry date of the finished product. `R 17.2.7` Other records follow the document retention SOP.

6.0 Records and annexures

Annexure	Title	Retained by
I	SOP format (template)	QA
II	SOP distribution and retrieval record	QA
III	SOP periodic review record	QA
IV	SOP master index	QA

7.0 References

1. Ministry of Health and Family Welfare. G.S.R. 922(E), Drugs Rules (Amendment) 2023: revised Schedule M, Part I, chapters 8 (Change control), 11 (Personnel) and 17 (Documentation). Gazette of India; 28 Dec 2023.
2. Site SOPs: QA-0xx Change control; QA-0xx Training; QA-0xx Document retention. `Site-specific`

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8.0 Revision history

Revision	Effective date	Change and reason	Change control no.
00		New SOP	

Annexure I: SOP format

[Company name]	STANDARD OPERATING PROCEDURE	
	[Title]	
Department:	SOP No.:	Supersedes:
Effective date:	Next review due:	Page x of y

`1.0 Purpose · 2.0 Scope · 3.0 Responsibilities · 4.0 Definitions · 5.0 Procedure · 6.0 Records and annexures · 7.0 References · 8.0 Revision history · Signature block (Prepared / Checked / Approved: name, designation, signature, date)`

Annexure II: SOP distribution and retrieval record

SOP No. and revision	Copy No.	Issued to (location)	Issued by / date	Received by / date	Retrieved by / date	Destroyed by / date

Annexure III: SOP periodic review record

SOP No.	Current revision	Review date	Changes needed? (Y/N)	Action (revise / re-approve)	Change control no.	Reviewed by / date	Next review due

Annexure IV: SOP master index

SOP No.	Title	Current revision	Effective date	Next review due	Status (current / superseded / withdrawn)

Want this SOP, or the rest of your SOP set, written for your own site and equipment? Scoped quotes at **laafon.com/pharma-sop-services** · WhatsApp or call +91 98124 46733 · contact@laafon.com. This sample is a format illustration, not a ready-to-use procedure: your SOP must describe your own site, people and records.