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Review on Preparation of SOPs for Different Instruments or Equipment

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Abstract: *This chapter discusses the operating procedures of various equipment used in amolecularbiologylaboratory,whichinvolveshandling,riskmanagement,requirements,standards,andmaintenanceoftheequipment&theirpurpose,benifit, desgining sop, procedure ect. The equipment discuss tablet coating, tablet compression, capsule filling, In This review article i review on no. Of articles and as summary of those all articles this article is presenting information regarding the SOP's their manufacturing, use, advantages, Goals behind the SOP preparation as well safe and effective operation of any process.(1) SOP'sarethedocumentornotethetisusefullinindustryFromenteyinindustryto exit from the industry, The SOP guide us to what to do?, how to do?, when to do? e.t.c. in industry their are some authority who prepare SOP's . An SOP should be regularly checked, signed and approved as when required. Different examples of SOP are given in This review article.(1).*

Keywords: Standard Operating Procedure

I. INTRODUCTION

Standard Operating Procedure

SOP is the written step by step instrument that how to Perform the activities to complete the task. All concern person are required to follow these steps. SOP are the application in all type of industries, Rules & Regulation, Government laws & Organization to running the own business.

Figure 1: Area of SOP

Figure 2: Writing Of SOP

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Other Names of SOP:

- SOP: WI (Work Instruction)
- SSOP: Safe Standard Operating Procedure.
- PCS: Process Work Sheet.
- SWS: Standard Work Sheet.

Figure 3: SOP Process

- **Objective:** Specify the goal of the action or activity.
- **Scope:** Indicate the purposes for using the process or method, any organisational or legal requirements, and any restrictions on its use.
- **Responsibilities:** Indicates the level of personal responsibility and the required experience The user should be required to use the tools correctly.
- **References:** References were consulted to create these SOPs and to provide further in-depth details.
- **Definitions:** This section defines any acronyms, abbreviations, or technical terminology that are used**.**
- **Precautions:** Indicate the activities that can harm equipment, degrade samples, or perhaps affect important phases in the method and the validation of results.

Procedure

The supplies needed to achieve that aim are listed together with all relevant steps that must be taken in order. Each person using the instruments—students, instructors, lab technicians, and researchers—must read and understand every element of the SOP. This will be updated on a regular basis and is meant to be dynamic. Mentioning brand names or commercial goods does not imply support or advice for their use.

Purpose

The goal of SOP is to carry out the procedure accurately and consistently in order to maintain the consistency of the output. It need to be accessible where work is being done. The SOP must be followed by all operators.

Examples:

In Work shop, in Manufacturing, in Lab., in Physical Life.

Benefits SoP

To give employees the knowledge they need to do their jobs safely, healthily, environmentally, and operationally. It is expensive in the long term to prioritise productivity over safety, health, and the environment. It is preferable to teach staff members thoroughly before allowing accidents, penalties, or legal action to occur.

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In order to maintain quality control of the processes and products, it is important to make sure that manufacturing procedures are carried out consistently. Customers desire items with consistent quality and requirements, whether they are individuals or businesses. SOPs outline the tasks that standardise goods and subsequently quality.
To guarantee that procedures run without interruption and are finished according to a set timeline. You can prevent process shutdowns brought on by equipment failure or other facility damage by adhering to SOPs.
To prevent malfunctions in production and other procedures that might endanger anyone in the neighbourhood. Following the health and environmental precautions outlined in SOPs protects against spills and pollutants that endanger plant neighbours and spark uproar in the local community. to guarantee compliance with corporate and governmental requirements and the execution of approved processes. Well-written SOPs aid in ensuring that legal requirements are met. Additionally, they show a company's sincere desire to conduct business appropriately.)

Failure to Write and use Good(23)

SOPs merely serve to demonstrate to government authorities that your business is not committed to compliance. to act as a training manual for users learning the procedure for which the SOP was created.
Employees who are new to the position or who need retraining might be given standardised training using thorough SOPs as the foundation.
To act as a checklist for coworkers who watch how the job is being done in order to emphasise correct performance. One worker coaches another in all facets of good job performance as part of the process of actively caring for one's coworkers. Any employee can mentor another to assist them develop their job abilities when the necessary processes are followed and defined in a strong SOP.
To act as an auditing team's check list. Similar to the observation procedure discussed in the preceding item, auditing work performance typically include record keeping. The development of the thorough audit checklists should be supported by SOPs.
To function as a historical record of the how, why, and when of stages in a current process so that there is a factual foundation for changing those steps when the process or equipment is altered. Unwritten knowledge and skills vanish from the workplace when workers shift from position to position both inside and across firms.
To the best of my knowledge, well maintained and created SOPs may be chronic, helping new employees after the more seasoned ones leave the company. (22) To serve as a description of a process's phases so that they may be examined during accident investigations.
Despite the tragic nature of the incidents, see them as teaching moments on how to make the situation better. A solid SOP provides you with the framework on which to start an accident investigation

Ten reasons for writing SOPs:

1. To arm those who conduct operations with the necessary operational, environmental, safety, and health knowledge to do their
2. To safe guard both the environment and the health and well-being of workers.
3. To keep the neighbourhood safe.
4. To make certain that procedures are followed consistently in order to keep process and product quality under control.
5. To ensure that processes continue and completed on a prescribed schedule.
6. To make sure that procedures continue and are finished according to a set timeline.
7. Preventing any manufacturing and associated process failures that might damage staff members or anybody in the neighbourhood.
8. To guarantee compliance with corporate and governmental requirements and the execution of approved processes.
9. To be used as a training manual to instruct users on a procedure.
10. To serve as a historical record of the how, why, and when of a process's steps to be used when the process is changed and a SOP has to be updated.
11. To serve as a description of the steps in a procedure that may be examined in incident reviews with the goal of

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enhancing safety procedures and operations.(20)

SOP Review and Approval

One or more people with the necessary training and process knowledge should evaluate (i.e., validate) the SOPs. Before the SOPs are completed, it is extremely beneficial if draught SOPs are actually tested by someone other than the original author.(3,21). The organization's quality management plan or its own SOP for the creation of SOPs should be followed while approving the finished SOPs. The organization's quality assurance officer and the immediate supervisor, such as a section or branch head, typically examine the management. The Government Paperwork Elimination Act of 1998 states that, when practicable, using electronic signatures in place of paper for document maintenance and submission is permissible. (6,23).

Frequency of Revisions and Reviews

SOPs must be kept up to date to be effective. Therefore, the SOPs should be updated and reapproved anytime processes are amended. If desired, just the relevant portions of the SOP should be changed, and the new date and revision number should be included in the document's control notation and Table of Contents.

In order to make sure that the policies and procedures are still current and suitable, or to assess if the SOPs are even necessary, policies and procedures should be systematically reviewed on a regular basis, such as every one to two years. (8)

Each SOP that has been evaluated should have the review date appended. If a SOP outlines a procedure that is no longer required, it has to be removed from the active file and archived.

Checklists

Checklists were utilised for a lot of tasks to make sure the processes were carried out in the right sequence. lists that are also used to record actions that have been accomplished. Any checklists or forms included as a component of an activity should be appended to the SOP after usage and referenced at the appropriate places in the process.

Occasionally, special comprehensive checklists are created for the relevant activity. In certain situations, the SOP ought to at least broadly outline how the checklist is to be created or the basis for it. The activity outcomes and/or SOP should be kept in that file together with copies of specified checklists. Keep in mind that the checklist is a component of the SOP, not the SOP itself.(6)

Document Control

Each business must create a system of numbers to methodically and clearly identify the label of its SOPs, and it must establish that control in its quality management plan.

The control documentation notation should typically be present on each page of a SOP, as seen in the illustration below. A reference to such designation can be provided by a succinct title and identification (ID) number. When reviewing historical data, the revision number and date are crucial for identifying the SOP in use. They are also highly helpful when the requirement for evidential evidence is present and when the action under review.

The user may easily determine whether the SOPs are complete by counting the given number of pages. Following the title page, this kind of document control notation is often seen in the top right corner of each document page. (7)

SOP Document Tracking and Archival

A comprehensive list of all SOPs should be kept up to date by the organisation. The SOP number, version number, date of issue, title, author, status, organisational division, branch, section, and historical data on previous versions should all be listed in this file or database. The person in charge of keeping a file outlining all current quality-related SOPs and practises utilised by the company is often the QA Manager (or designee). Automatic "Review SOP" messages can be delivered if an electronic database is utilised. It should be noted that this list may also be utilised when audits are being considered or when concerns about organisational procedures are raised. (5)

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SOP Preparation

For deciding which processes or procedures need to be recorded, the business should have a procedure in place.

Those SOPs ought to be created by experts who are familiar with the activity and the internal workings of the organisation.

These people are essentially the subject-matter experts who use the procedure or actually conduct the task.

A team technique that may be used, especially for multi-tasking procedures where the collective wisdom of the participants is crucial, and that also encourages "buy-in" from future SOP users (15).

SOPs should always be stated in enough detail such that a person with only a basic grasp of the procedure, but little experience or knowledge, may effectively repeat it on their own. The section on personnel qualifications should include a comment on the experience needed to accomplish a task. For instance, it should be stated if prior experience or further training is necessary for the fundamentals of chemistry or biology. (8)

Formats for Standard Operating Procedures

Managers have a variety of organising and formatting options when drafting standard operating procedures. Your aim should be to produce a paper that is simple to understand and beneficial for the task at hand. Which SOP to employ is determined by two variables. How many selections would the user need to make initially in order to complete the procedure? How many phases and substeps are there in total in the method, secondly? Simple steps of format can be used to write routine operations that are brief and need few considerations. Long procedures with more than 10 stages and few decisions should be expressed in a visual manner or according to a hierarchy of steps. A flowchart should be used to document procedures that call for plenty of choices. (9)

Designing of SoP:

When creating SOP Considered are the following points:

Objective:

Establish a process for creating standard operating procedures.

Scope:

The SOPs used by the entire organisation must follow this method.

Responsibility:

Person Performing: The relevant HODs for the relevant department QA officer/HOD QA is in charge of monitoring.

Procedure:

Times New Roman typeface must be used for typing all SOPs. The SOP format must follow Annexure SOP/QA/002/1.

Each SOP has:

1. Body
2. Header
3. Signature block

Header: Located at the top of every page of the SOP and contains the concerned department's name, address, and company logo (In capital bold letters of font size 16)

Standard Operating Procedure Document (In capital bold letters of font size 14) Ref. No.: Similar to SOP/DC/YYY-Z

In DC, the department code is shown as follows:

Department of Personnel: PE

Production Division MT: Department of Maintenance

Department of Quality Assurance QC: Department of Quality Control ST: Store Division

PU: Department of Purchase.

The sequential number for each department is YYY, starting at 001. And Z represents the revision status, where 0 represents the original version, 1 the following version, and so on. (With a 12 point font size and all caps).

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Supersedes: It is the reference number for the previous edition. (With a 12 point font size and all caps). Effective Date: This is the day the SOP will be in effect. The required date format is
DD/MM/YYYY, where DD stands for the date, MM for the month, and YYYY for the year (for example, 01/11/2007). Date must be written in blue permanent ink. Review Date: This is the day of the month and year that the SOP will be amended, for example, 21/2013, and it is printed in blue permanent ink. The maximum period from the effective date is two years. page number It resembles X OR Y. where Y is the total number of pages and X denotes the specific page number. (Capital letters, 12 point font)
It must be concise and descriptive. (In large bold characters, size 12) (11)

SOP Handling Instrument:
Tablet compression machine:

Figure 4: Tablet Compression Machine

Purpose:
To establish the tablet compression machine's effective operation

Scope:
This method may be used to operate a tablet compression machine

Responsibility–SOP for Tablet Compression Machine
The machine's upkeep and proper operation must be handled by the operator in accordance with the established protocol.
The production officer is in charge of making sure the machine is cleaned and run according to the established method.
The machine's sequential log must be kept up to date by the production officer.
QA is in charge of seeing that the machine is maintained and used in accordance with established procedures. (10) The compression in-process inspections must be completed by the production officer.
In cases of batch to batch and product to product switching, QA is in charge of giving line clearance.

Accountability
HOD-Production

SOP FOR Tablet Compression Machine Abbreviations:

- Batch Manufacturing Records: BMR
- IPC: In Process Containers
- IPA: Isopropyl Alcohol
- Quality Control: QA

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- QC: Quality Check
- Relative Humidity (RH) Stainless steel, or SS To Be Cleaned: TBC

Operating Procedure of Tablet Compression Machine

1. After the compression machine has been cleaned in accordance with the applicable SCP, the Alr Handling Unit's racks, door frames, diffusers, return filters, dust extractor, and pipe must also be cleaned.
2. When installing the return filters, visually inspect them for integrity and the lack of leaks.
3. Inform the quality control division to gather swab samples and rinse water as needed.
4. Put a "cleaned" sticker on all of the equipment after getting the go-ahead from the quality control department. (11)
5. If a machine is to be kept in perfect condition, the turret must be coated with a thin layer of food-grade oil and marked "to be cleaned."
6. Before receiving approval from the quality control department, it must be cleaned with 70% isopropyl alcohol.
7. Remove the machine's "cleaned" status label and attach the machine's status label together with the product name and batch information that must also be compressed if the compression of a product is to begin.
8. Release the punch that set appropriate for the product to be compressed in accordance with SOP and the description of the punch set used in record compression for batch production.
9. Set the compression machine according to SOP and turn the hand wheel to test the machine's settings.
10. Bring the batch production record and all the containers containing the lubricated granules for that batch to the location. Check all of the container labels to make sure they include the right batch information according to the batch production record (MFR).
11. Configure the machine according to the tablet specifications listed in the batch production record.
12. Before turning on the machine to compress the batch in accordance with SOP, destroy the tablets from the first few revolutions. (5)
13. Gather the tablets made during machine setting and store them properly labelled and put in a container as the Utilizable residue. It should also be utilised in the current or following batch.
14. When the material in the hopper has been compressed to its lowest level, the compression is stopped, and the remaining feed frame residue is either destroyed or put to good use.
15. After the batch has been compressed, weigh the containers containing the compressed tablets, enter the weight in the batch production record, and reconstitute the container.
16. Clean all the outside containers before transferring them to the in-process storage area with labels containing the batch information.
17. If a batch of a fresh product is to be taken for compression, remove all the materials and records from the previous batch from the location and label the entire setup with "to be cleaned."
18. Remove the punch that established the record and the corresponding punch tool. Clean the punch set in accordance with the relevant SOP, and place it in the punch tool cabinet as directed.
19. When configuring and verifying the tablet's in-process settings, be sure.
20. Make sure that tools like the Vernier calliper, hardness tester, friability tester, and disintegration tester are calibrated.
21. Every time a disintegration test is conducted, new water is utilised; the old water is discarded. (5)

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Tablet Coating

Figure 5: Tablet Coating Machine

Purpose: This SOP outlines the steps necessary to carry out the tablet coating operation.
Scope: This SOP applied to managing the production department's personnel.
Responsibility: The production manager is in charge of making sure the protocol is followed.
Operating procedure of tablet coating machine:

1. Ensure it is celaned before beginning the operation.
2. Start the pan after fitting the air blower hose.
3. Local the weight quantity of the material to be coated from the container into the coating pan the warm up the material by which blowing warm air on to rotating material in coating pan.
4. Pour the coating solution over the material in the coating pan in case of granule or to tablet spray with the coating solution & allow the material to rotate stimultaneously dry the material with current of the warmair, continue the process till required level of the coating is allowed.
5. After the complete in of coating remove the coated material from the coating of pan & collect in cleaned polythenelined SS container & label is appropriately.

Abbreviation:

- SOP: Standard Operating procedure.
- SS: Stainless Steel.
- QA: Quality Assurance(14)

Capsule Filling Machine
Objective: To lay down the operation procedure for manual capsule filling machine for filling of capsule.
Scope: This SOP shall be applicable for the operation of manual capsule filling machine for filling of capsule in Capsule Section at Production department.
Responsibility:
Supervisor/ Machine Operator.
Production Pharmacist & above.
Accountability:
Manager-Production department.
Material and Equipment:
Manual Capsule Filling Machine.

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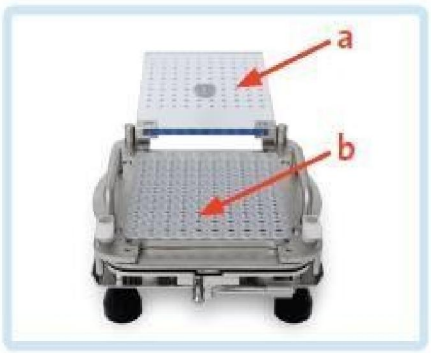

Procedure:

1. Locking Plate Open (a). On the Caps Tray, place the adapter (b). Look to see whether the Cam Lever is set to 3 o'clock.

2. Place the capsule bodies down and CapsiCards® (c) on the Adapter. Push capsules into the Caps Tray using the Pusher (d).

3. Remove the cardboard from the CapsiCards® and modify.

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4. Turn the two tabs to close and secure the Filler Locking Plate.

5. To secure bodies in Filler, gently pull Cam Lever in the direction of the post. Holding the capsule firmly is important, but you shouldn't crush it into an oval form.

6. Press palms down on grips and raise Caps Tray (top metal piece) with fingers to separate capsules. Remove the Caps Tray from the Filler. Step 5 should involve tightening the cam lever if full capsules are being drawn up.

7. Check to see whether some of the capsules were previously locked if only a few of them failed to split.

Figure 6: Capsule filling Machine

8. Allow the capsule bodies to fall into the filler by releasing the cam lever. Gently pat the capsules into position if some of them are higher than others.

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Powder Tray should be placed on Filler. Add Powder Tray Clamps if desired. Refer to chapter Special Fill Materials, page 14, for information on how to fill sticky powders.

9. Pour powder over Filler, then use the Powder Spreader to spread the powder outwardly toward the Powder Tray Frame's four sides. To settle powder, use tamping, shaking, or tapping. As required, repeat the spreading and tamping.

10. Vibration, tapping, and tamping.

11. Pull the Cam Lever to firmly keep the bodies in place by tapping. To settle the powder, lightly tap the Filler Base Frame on the table while holding it. When tapping, powder tray clamps are suggested. Avoid holding the filler by the lifting plate because the capsule bodies will be forced out of the filler. As required, repeat the spreading and tamping. (11)

Vibration: As an alternative to or in addition to tamping or tapping, use the optional vibrator. The use of powder tray clamps is advised. As required, repeat the spreading and tamping. (13)

Tamping: Use Tamper to add more powder. As required, keep distributing and tamping.

12. Take the powder tray out. attach the Caps Tray to the Filler.

13. Put your thumbs down on the Locking Plate and raise the Lifting Plate to lock the capsules. Repeat numerous times, placing your thumbs in various Locking Plate locations.

14. Turn over Caps Tray onto table after removing it. To lock capsules, use the Capsule Locker. Put pressure on the capsules until you hear them lock and snap.

15. The entire capsule is locked. Utilize the Locked Capsule Indicator to ensure that capsules are completely locked. The Locked Capsule Indicator on the Caps Tray should not block a locked capsule.

Abbreviation

SOP: Standard operating procedure Ltd.: Limited

PM: Production machinery

PMO: Production machinery operation

F::Format

SS: Stainless steel(14)

Fluidized Bed Dryer

Figure: Fluidized bed Dryer

Objective: The SOP's objective is to outline the process for operating fluidized bed dryers (FBD).

Scope: This SOP is relevant to the operation of the fluidized bed dryer at the manufacturing site's department responsible for producing tablets. (13)

Responsibility: The duty of the production officer or executive is to oversee the use of the fluidized bed dryer.

The IPQA Officer or Executive is in charge of examining the fluidized bed dryer's performance. The Head of Production is in charge of making sure the SOP is followed.

The acronym SOP stands for standard operating procedure. IPQA stands for in-process quality control. Fluidized Bed Dryer (FBD).

Identification Number: I.D. (12)

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General Instructions

Examine the fluidized bed dryer's area, parts, and cleanliness. On the fluidized bed dryer, see if a label with the status "CLEANED" is there. Verify the FBD bowl's integrity, the sieve's integrity, and the finger bag's integrity. Verify the bowl, bowl retarding chamber, and finger bag good fixing. These FBD bags need to be labelled appropriately and kept in separate containers.

Use a separate FBD bag for each product, and then verify the FBD bag is properly fitted. Before using, make sure the steam filter is working. Push the trolley into the dryer after charging the powder in the FBD bowl. Verify whether the dryer is connected to the FBD trolley by an earthling. Additionally, the steam indication valve should be examined while it is in use. (13)

Procedure:

Operation of Fluidized Bed Dryer

1. Before beginning the operation, the production officer or executive must attach the activity status label to the equipment or area and notify the IPQA officer or executive for line clearance. The label must include information such as the product name, B.No., Stage, etc.
2. Adjust the FBD bowl underneath the chamber that retards.
3. Turn on the main power. And to apply a pneumatic pressure of 2.5 to 3.5 kg to lock the bowl, open the compressed air valve.
4. Keep the steam valve and bypass valve open when you first start the steam drying process so you may drain the condensed water that is travelling through that pipe. (13)
5. To get the desired air inlet temperature, close the condensed valve and modify the steam valve. Set the timer in accordance with the batch production records (BMR).
6. Verify that the FBD bowl and exit are not airtight.
7. After shaking, take out the container and rack the contents. Reset the product container once again, then hurry to finish drying. When necessary, remove the granules sporadically from those sample spots to monitor the loss during drying.
8. After the procedure is finished, turn off the steam valve and let the material air dry until the granules reach room temperature. (13)
9. Shake the FBD bag and give the contents a chance to settle.
10. To remove the FBD bowl from the retarding chamber, let go of the compressed air pressure. To continue on to the next step, remove the product container.
11. Affix should be cleaned and labelled on the apparatus.
12. The FBD bag must be examined for its integrity in accordance with the principles listed below. The bag must also be checked for any tiny tears or holes.
13. Look for undamaged stitches on the bag's finger.
14. Verify the bag's corners for integrity and corner stitches.
15. Before and after use, the FBD bag must also be inspected for integrity; this information must be recorded in the FBD bag usage record as specified in annexure II.
16. After that operation is finished, clean the equipment in accordance with the SOP for cleaning. (14)

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