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A REVIEW ON STANDARD OPERATING PROCEDURE INSTRUMENT

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ABSTRACT

SOPs are living documents that detail written instructions describing specific steps to follow in all activities under defined condition. SOP1 is necessary to ensure the continuity of processes to achieve quality performance and quality product/preparation. The purpose statement identifies the goal of the SOP. It answers the question of why the SOP is being written. For example, "The purpose of this Standard Operating Procedure (SOP) is to specify the processes used to manage SOPs". The purpose statement needs to be detailed enough so that the intended user can recognize what the docs. They must be revised continuously to manage the same quality. Standart operation procedures have an important role in the processes which cannot be known before, so with SOPs, management groups will manage more useful works with less time. This study tries to explain which techniques are used, what are necessary and which type of works needs must be done for writing SOPs.

INTRODUCTION

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result. The term "SOP" may not always be appropriate and terms such as protocols, instructions, worksheets, and laboratory operating procedures may also be used.[1] For this document "SOP" will be used. SOPs describe both technical and fundamental programmatic operational elements of an organization that would be managed under a work plan or a Quality Assurance (QA) Project Plan [EPA Requirements for QA Project Plans (QA/R-5) (EPA 2001a)], or Chapter 5 of the EPA Quality Manual for Environmental Programs, (EPA Manual 5360 A) and under an organization's Quality Management Plan [EPA Requirements for Quality Management Plans (QA/R-2) (EPA 2001b)], or Chapter 3 of the EPA Quality Manual. This document is designed to provide guidance in the preparation and use of an SOP within a quality system.[2]

PURPOSE

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations. If not written correctly, SOPs are of limited value. In addition, the best written SOPs will fail if they are not followed. [3]

BENEFITS

The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes. SOPs can indicate compliance with organizational and governmental requirements and can be used as a part of a personnel training program, since they should provide detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns. When historical data are being evaluated for current use, SOPs can also be valuable for reconstructing project activities when no other references are available. In addition, SOPs are frequently used as checklists by inspectors when auditing procedures. Ultimately, the benefits of a valid SOP are reduced work effort, along with improved comparability, credibility, and legal defensibility. [4]

SOP PROCESS

The organization should have a procedure in place for determining what procedures or processes need to be documented. Those SOPs should then be written by individuals knowledgeable with the activity and the organization's internal structure. These individuals are essentially subject-matter experts who actually perform the work or use the process. A team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical, which also promotes “buy-in” from potential users of the SOP. SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised. The experience requirement for performing an activity should be noted in the section on personnel qualifications. For example, if a basic chemistry or biological course experience or additional training is required that requirement should be indicated.[5]

Fig: SOP Process

1. SOP Review and Approval

SOPs should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process. It is especially helpful if draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalized. The finalized SOPs should be approved as described in the organization’s Quality Management Plan or its own SOP for preparation of SOPs. Generally, the immediate supervisor, such as a section or branch chief, and the organization’s quality assurance officer review and

approve each SOP. Signature approval indicates that an SOP has been both reviewed and approved by management. As per the Government Paperwork Elimination Act of 1998, use of electronic signatures, as well as electronic maintenance and submission, is an acceptable substitution for paper, when practical. [6]

2. Frequency of Revisions and Reviews

SOPs need to remain current to be useful. Therefore, whenever procedures are changed, SOPs should be updated and re-approved. If desired, modify only the pertinent section of an SOP and indicate the change date/revision number for that section in the Table of Contents and the document control notation. SOPs should be also systematically reviewed on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed. The review date should be added to each SOP that has been reviewed. If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.[7]

3. Checklists

Many activities use checklists to ensure that steps are followed in order. Checklists are also used to document completed actions. Any checklists or forms included as part of an activity should be referenced at the points in the procedure where they are to be used and then attached to the SOP. In some cases, detailed checklists are prepared specifically for a given activity. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists should be then maintained in the file with the activity results and/or with the SOP. Remember that the checklist is not the SOP, but a part of the SOP.[8]

4. Document

Control Each organization should develop a numbering system to systematically identify and label their SOPs, and the document control should be described in its Quality Management Plan. Generally, each page of an SOP should have control documentation notation, similar to that illustrated below. A short title and identification (ID) number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed. When the number of pages is indicated, the user can quickly check if the SOP is complete. Generally, this type of document control notation is located in the upper right-hand corner of each document page following the title page.[9]

5. SOP Document

Tracking and Archival The organization should maintain a master list of all SOPs. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. The QA Manager (or designee) is generally the individual responsible for maintaining a file listing all current quality-related SOPs used within the organization. If an electronic database is used, automatic “Review SOP” notices can be sent. Note that this list may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

Fig: Areas of SOP

Fig: Writing of SOP

The Quality Management Plan should indicate the individual(s) responsible for assuring that only the current version is used. That plan should also designate where, and how, outdated versions are to be maintained or archived in a manner to prevent their continued use, as well as to be available for historical data review. Electronic storage and retrieval mechanisms are usually easier to access than a hard-copy document format. For the user, electronic access can be limited to a read-only format, thereby protecting against unauthorized changes made to the document.[10]

6. Failure to Write and use Good

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 coach 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. [11]

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. [12]

Ten reasons for writing SOPs: [14]

1. To arm those who conduct operations with the necessary operational, environmental, safety, and health knowledge to do them.

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 enhancing safety procedures and operations.

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 . 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. [15]

1. 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. [16]

2. 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). 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.

SOP HANDLING INSTRUMENT[17-18]

1. TABLET COMPRESSION MACHINE:

Object: To establish the tablet compression machine's effective operation.

Fig; Tablet Compression Machine

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
- 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.

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.

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.

2. TABLET COATING

Object: This SOP outlines the steps necessary to carry out the tablet coating operation.

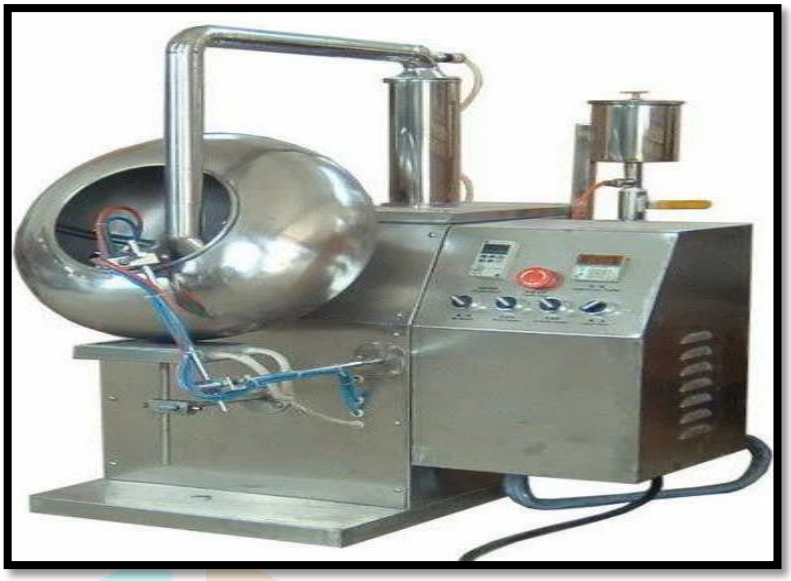

Fig: Tablet Coating Machine

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 cleaned 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

3. CAPSULE FILLING MACHINE

Objective: To lay down the operation procedure for manual capsule filling machine for filling of capsule.

Fig: Capsule Filling Machine

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.

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.

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.

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. 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

4. FLUIDIZED BED DRYER

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

Fig: Fluidized Bed Dryer (FBD)

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

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).

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.

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.

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.

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.

5. FREEZE DRYER

Objective The following document describes the procedure on the operation of Millrock Bench-Top Freeze-Dryer.

Definitions

Biological materials typically must be dried to stabilize them for storage, preservation, or shipping. Many times, drying causes damage and some loss of cellular or protein activity. Lyophilization, called freeze-drying, is a method of sample preservation that significantly reduces damage to biological samples.

Fig: Freeze Drying

Scope: Freeze Drying, or lyophilization as it is referred to in the Pharmaceutical and Diagnostic industries, is a dehydration technique, which enables liquid or slurry products, which have previously been frozen to be dried under a vacuum. The applications of freeze drying are numerous, such as

- Preservation of temperature sensitive products, particularly those of biological origin, such as enzymes, blood plasma, vaccines, etc.
- To achieve a chemical balance, such as for biological reagents.
- To provide a practical solution for certain delivery problems, for example, the packaging of constituents that cannot be mixed in the liquid state, but which are solidified in successive stages and then freeze dried.
- To implement an important stage of a product (such as concentration).
- To improve storage life and improved marketing of the pharmaceutical product

Responsibilities

- It is the responsibility of designated personnel in Research lab to train staff and students on this procedure and to ensure adherence to this procedure.
- It is the responsibility of designated personnel (staff or Student) to follow the instructions of this procedure.

Precautions

- Wear Appropriate Eye Protection at All Times When Working with Or Anywhere Near a Lyophilized.
- For Medical Emergencies, Fires, Or Explosions, Call emergency number Immediately and Report the Details of The Incident.
- If solvents are part of the product being freeze dried, they may be flammable or hazardous. Proper precautions should be taken.
- Acids and bases may cause damage to the stainless steel and vacuum pump.
- If the gas ballast is left open for extended periods, the oil can be pumped out the exhaust, causing the pump to fail.
- Do not fill the chamber above the vacuum port as water will enter the vacuum tubing and drain into the vacuum pump.
- Do not chip the ice from the condenser or chamber If acid or base products are collected, immediately neutralize and dispose of properly

Procedure For Operating the Freeze Dryer

Inspection of glassware & seals:

The lyophilizer, when in good working order, should have a pressure of 5-50 millitorr (normal atmospheric pressure is 760 torr), as indicated on the LED screen. (If the pressure is outside of this range, contact one of the people listed above.) This means that all glassware attached and under vacuum on the lyophilizer represents a significant implosion hazard.

All glassware used on the lyophilizer must be free of any visible defect (cracks, chips, or scratches), no matter how seemingly minor. Any glassware that is defective in this way must not be used under any circumstances. If such glassware is found, it should be discarded. The seals themselves are somewhat more forgiving, in that a defective seal reduces the vacuum. However, defective seals should still be removed from service.

A greater risk is present in seals that connect two pieces of glass. All seals of this type place rubber between joined pieces of glass. If these seals are used improperly, the glass pieces come into contact and scratch each other during installation. These scratches compromise the integrity of the glass thus creating a potentially serious implosion hazard. Install any seals of this type carefully to avoid this; if you are uncertain of how to do this do not proceed until you have received further training from one of the contact people given above.

Most vacuum pumps are supplied with a gas ballast adjustment. It is recommended that the gas ballast be closed during the operation of the Freeze Dryer. Push the RUN button 2X

- The first time you press the run button the displays a reminder to check the system.
- The second press activates the freeze-drying run.
- The Condenser will get below -40°C (CTVAC) within 10min (CTtim).
- After 10 minutes of operation, the vacuum pump will start.
- Vacuum will go to 500mT(VACRDY) within 10min(VACtim):
- If NO - alarm will sound and “VACU > 500mT, after 10min” will flash on the lower part of the screen.
- If YES – then “READY FOR FREEZEDRYING” will flash at the top of the screen.

Adding product to the manifold for freeze-drying:

- Make sure that the product is frozen in the flask before attaching to the freeze dryer.
- When freezing product in flasks, the flask should be tilted on its side.
- If the flask is not tilted the expansion of freezing will break the flask.
- Attach the flask to the vacuum valve using a ¾” to ½” adapter.
- Make sure that the adapter is greased.
- Slowly open the valve to apply vacuum to the flask.
- Wait for the “READY FOR FREEZE-DRYING” indication before adding additional product.

Removing product from the system:

To remove the product from the system, you must remove the vacuum in the flask/vial/container (without removing the vacuum in the freeze dryer). Simply turn the valve stem past closed to release the vacuum. The vacuum is released through a small opening in the valve stem.

Defrost:

When a sufficient amount of material accumulates on the condenser, the frozen material will obstruct the vapor flow. At this point, the system must be defrosted. Remove any unfinished product and keep it frozen. The Opti-dry offers hot gas-defrost to speed the defrosting process.

- Add approximately 1 liter of warm water to the condensing chamber, making sure not to fill above the vacuum port at the rear of the chamber.
- Press the “DEFROST” button. The compressors will direct hot gas to the condenser coil until it reaches +40°C then cycle off. If the presence of cold water is detected the controller will repeat the process

until all ice is melted.

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