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Standard Operating Procedures

Medical Oxygen Sample Collection in Tedlar Bag

Medical Oxygen Sample for Analysis in Gas Chromatography

COAG # 7200AA19CA00003

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Contents

Abbreviations

COA	Certificates of Analysis
GC	Gas Chromatograph
IP	Indian pharmacopeia
NABL	National Accreditation Board for Testing and Calibration Laboratories
PP	Polypropylene
PTFE	Polytetrafluoroethylene
PU	Polyurethane
PVF	Polyvinyl Fluoride
USP	United States Pharmacopeia
WHO	World health organization

Introduction

Oxygen therapy is an essential component of medical care. It is used in emergency care, for anesthesia, in surgery, and for managing acute and chronic respiratory conditions. However, the COVID-19 pandemic led to an unprecedented surge in the demand for oxygen supply, given its crucial role in treating COVID-19 patients. The respiratory complications due to COVID-19 can lead to hypoxemia in patients, a condition in which the oxygen level in the blood is abnormally low. In such a condition, a patient requires oxygen therapy and access to quality-assured medical oxygen. Reliable access to quality-assured medical oxygen can mean the difference between life and death for patients.

Purpose of the Standard Operating Procedure

In this standard operating procedure (SOP), we have outlined procedures to be followed during the collection of medical oxygen sample into "Tedlar bag" and sending them off for analysis at a laboratory to check the quality of medical oxygen. This document provides guidance to all staff on sampling procedures and how to reduce sampling error.

This document, titled "**Taking samples and sending them off for gas analyzing at the labs**", provides guidance to all staff on sampling procedures and how to reduce sampling errors. The SOP includes the following components: types of gas sampling, Tedlar bag sampling procedures and precautions, and tips to reduce sampling errors. The SOP intends to bridge the knowledge and skill gap among health care facility staff by providing in-depth information on taking samples and sending them off for gas analysis at the labs.

Scope

This procedure is applicable to taking medical oxygen samples in Tedlar bag—that are either being manufactured in-house or by a third party—and sending them off for gas analysis at the laboratory.

Process Interface

CAUTION

Imp: Take all safety precautions before starting the sample collection
Associated Safety Hazards: Asphyxiation, Striking object

Tedlar Bag

Plastic bags specially designed for the purpose are available in different capacities depending on applications in hand. These can be used successfully for sampling of both organic and inorganic gases. Such bags are made from materials such as polyester, Teflon, and fluorocarbons. The choice of material is based on the absorption or reaction of the gas with the bag material. The bags are connected to a pump for drawing gas samples inside. Normally, for oxygen, we are collecting oxygen sample in Tedlar bag due to the inert nature of oxygen with its made material.

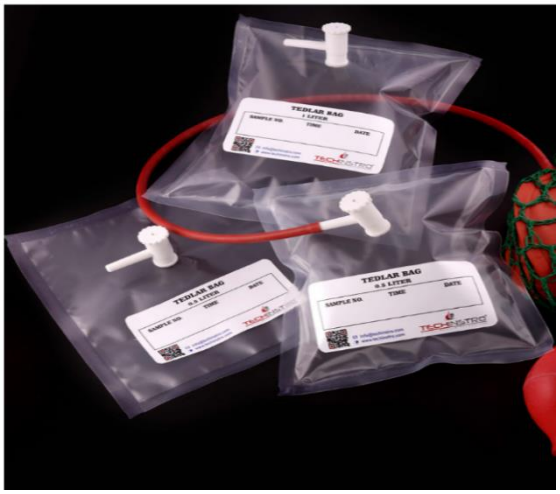

Fig 1: Tedlar bag

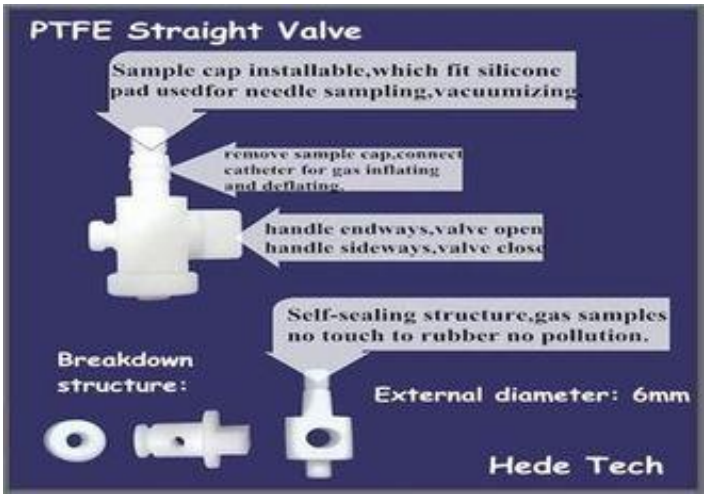

Fig 2: Filling/withdrawal valve

Prerequisites

- Purge the bag with sample gas two to three times before the final sample is collected.
    1. Open the valve of the Tedlar bag by rotating anticlockwise.
    2. Connect the silicon or polyurethane (PU) filling tube to the source and check flow by opening the source valve; it should not exceed flow 5 liters per minute.
    3. Connect the sample tube to the Tedlar valve's nozzle and fill the bag gradually.
    4. Fill the bag half of its capacity with sample oxygen and wait for 2 minutes to mix impurity.
    5. Remove the sample tube and vent the gas from the bag by pressing the bag from one side.
    6. Repeat steps 3-5 at least two to three times before taking the final sample.
- Run the sample pump for some time before the start of sampling to optimize the representative sample collection.
- The sampling bag material should be inert to the gases collected, and before transferring the samples to the laboratory, the bags should be sealed tightly with suitable caps and stoppers.
- Use only silicone or PU or polytetrafluoroethylene (PTFE) tubing/inner layer PTFE tube to connect the sample bag to the pump to prevent sample loss by adsorption on tubing walls, and then thoroughly flush with purified air or nitrogen before using.

Procedure

- Prepare to attach the Tedlar bag to the sampling port using appropriate connection and accessories; flexible silicon/PU/PTFE tubing *must* be used to connect to the valve on the Tedlar bag to ensure a leakproof connection.
- Attach the Tedlar bag to the sampling port. The sampling port is the outlet of the Pressure Swing Adsorption (PSA) plant or outlet point at the oxygen tank.
- Open the plastic valve on the Tedlar bag slowly and fill the bag until it is about half full.
- Close the valve and disconnect the bag from the sample tube.
- Check the valve and its connection ports with soap solution to determine any leakage.
- Label the bag with the sample identification and other information desired.
- Keep bags out of sunlight to present degradation of the sample.

- The bags do not need to be cooled, but an ice chest is a convenient shipping container since the bags are less likely to be damaged.

Precautions

Follow the below important information before sending the samples.

- Do not ship sample bags by air unless the cargo cabin is pressurized or fill the Tedlar bag only 75-80% full. If the bags are shipped by overnight carrier, they will be transported in a plane that may not be pressurized, which could result in the bursting of full bags.
- To avoid any sampling error, an extra bag can be filled with the gas.
- Analyze the sample within 24 to 48 hours. Long-term storage of air-contaminant mixtures in bags is not recommended. The maximum holding time for a bag is 72 hours; thus, be sure to notify NABL approved laboratory before shipping the bags. If possible, try to ship bags the same day they are collected and try to avoid collecting bags on Friday.
- Samples should be stored under appropriate temperature conditions and protected from exposure to light to prevent decomposition.
- Whenever possible, the sample should be analyzed at the earliest opportunity after collection to avoid any changes in composition during storage and transportation.
- If you have any questions, please call the Technical Manager.

Transport Sample to Lab

- Sample bag should be store in a hard box; all six sides need to place polystyrene 1” sheet to protect the bag.
- Prior to shipping, inform the laboratory.
- Send the bag to a NABL (National Accreditation Board for Testing and Calibration Laboratories)-accredited lab.

Handling Sample in Lab

- Register the sample into the laboratory logbook.
- Store in a dry and ambient temperature with the laboratory reference tag.
- If insufficient quantity is received, please check physically for any leak or damage on the bag.
- If the sample quantity is insufficient or there is abnormal sample bag condition, please create a non-conformance report (NCR) and report to the sender.

Sample Running in the GC or Analytic Instrument in Lab

- Samples should be analyzed within 24 hours of receiving the sample.
- Before taking sample from the sample bag for gas chromatograph (GC) or analyzer, please be sure that the GC or analyzing instrument are ready for analysis; the instruments shall be cross verified with the standards gas.

- For a satisfactory report, the sample shall be used twice or more; therefore, make sure the sample quantity is sufficient for multiple analyses.
- Register the content of gases, e.g., impurity and purity, in the logbook or have auto data saving in the computer for a period of six months.
- Prepare the certificate of analysis (COA) according to the results.

Record

- Quality Assurance Log Sheet
- Control of Non-Conforming Report
- COA

References

- Manufacturer user manual
- Government of India Department of Health and Family Welfare
- World Health Organization
- Indian Pharmacopoeia 2018
- United States Pharmacopeia
- European Pharmacopeia

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