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<413> IMPURITIES TESTING IN MEDICAL GASES

INTRODUCTION

This general test chapter defines the safe and proper means to sample high-pressure gas containers of different medical gas compositions using the detector tube manufacturer's suggested total gas volume for the purpose of conducting detector tube analysis to satisfy the *USP* monographs. See *Reagents* in the section [Reagents, Indicators, and Solutions](#) for information on each referenced detector tube.

There are two types of detector tubes currently manufactured: those to be used with a manual hand pump of fixed volume (e.g., 100 mL/pump stroke) and those used in a continuous flow system that can be set to pass a volume of gas through the detector tube at approximately 1 atmosphere. It is important to match the appropriate detector tube type to the mode of gas volume exchange.

To ensure that the required gas volume has passed through the detector tube, measure the gas volume at the time of the analysis either by using a hand pump or using a flowmeter that is calibrated to the subject gas or corrected via a calibration chart. Flowmeter manufacturers generally provide a chart of the gas volume flow of common gases for each of the flow tubes identified in this general chapter.

[NOTE—See general chapter [Medical Gases Assay \(415\)](#) for sampling.]

CONTINUOUS FLOW SYSTEM

Identify the gas contained in the container, and select the appropriate gas regulator. Secure the regulator to the gas container. Do not apply lubricant or Teflon tape to the container-to-regulator connections. Purge the regulator with the gas under test. Select float setting to obtain the proper flow rate to achieve total gas volume as recommended by the manufacturer. Attach the detector tube, then adjust the flow rate to the required level as indicated by the charts that accompany the flowmeter and the detector tube. Time the gas flow to achieve the desired total gas volume ± 10 s. At the allotted time close the regulator valve, then the main container valve. Observe the tube while it is still attached to determine the degree of color change, and record the result. Remove the tube, and disconnect the apparatus, vent the regulator gas pressure to atmosphere, and remove the regulator from the container. Dispose of the tube after use.

HAND PUMP—FIXED VOLUME

The alternative approach is to apply the gas detector hand pump. The system draws a consistent volume with each pump stroke. To ensure the accuracy of the total gas volume, the user must follow the pump manufacturer's suggested recommendation about how to pump.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
<413> IMPURITIES TESTING IN MEDICAL GASES	Kahkashan Zaidi Principal Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020

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