Medical Air

DEFINITION

Medical Air is a natural or synthetic mixture of gases consisting largely of nitrogen and oxygen. It contains NLT 19.5% and NMT 23.5%, by volume, of oxygen (O_2).

IDENTIFICATION

- **A.** The paramagnetic signal exhibited by the *Sample gas* in the *Assay* confirms the presence of oxygen.
- **B.** The *Sample gas* in the *Assay* meets the assay *Acceptance criteria*.

ASSAY

- **PROCEDURE**

The certified standards called for in the following test are listed in *Reagents, Indicators, and Solutions*.

Zero gas: Nitrogen certified standard

Span gas: 21% Oxygen certified standard. [NOTE—See *Reagents, Indicators, and Solutions*.]

Sample gas: Medical Air

Mode: Paramagnetic oxygen measurement (see *Medical Gases Assay ⟨415⟩*)

Analysis: Determine the concentration of oxygen in percentage by volume of Medical Air using a suitable paramagnetic analyzer.

Acceptance criteria: 19.5%–23.5% of oxygen by volume

IMPURITIES

Change to read:

See *Impurities Testing in Medical Gases* ▲▲(ERR-1-Nov-2020) ⟨413⟩. The detector tubes called for in the following tests are listed in *Reagents, Indicators, and Solutions*.

If the label indicates that Medical Air is a synthetic mixture of oxygen and nitrogen, and where oxygen complies to *Oxygen USP* and Nitrogen complies to *Nitrogen NF*, then the *Impurities* tests are not required.

- **LIMIT OF CARBON DIOXIDE**

  Sample: Detector tube manufacturer's recommended volume ±5% of Medical Air

  Analysis: Pass the *Sample* through a carbon dioxide detector tube at the rate specified for the tube by the detector tube manufacturer.

  Acceptance criteria: NMT 500 ppm

- **LIMIT OF CARBON MONOXIDE**

  Sample: Detector tube manufacturer's recommended volume ±5% of Medical Air

  Analysis: Pass the *Sample* through a carbon monoxide detector tube at the rate specified for the tube by the detector tube manufacturer.

  Acceptance criteria: NMT 10 ppm

- **LIMIT OF SULFUR DIOXIDE**

  Sample: Detector tube manufacturer's recommended volume ±5% of Medical Air

  Analysis: Pass the *Sample* through a sulfur dioxide detector tube at the rate specified for the tube by the detector tube manufacturer.

  Acceptance criteria: NMT 5 ppm

- **LIMIT OF NITRIC OXIDE AND NITROGEN DIOXIDE**

  Sample: Detector tube manufacturer's recommended volume ±5% of Medical Air

  Analysis: Pass the *Sample* through a nitric oxide–nitrogen dioxide detector tube at the rate specified for the tube by the detector tube manufacturer.

  Acceptance criteria: NMT 2.5 ppm

- **LIMIT OF WATER AND OIL**

  Analysis: Support one container in an inverted position (with the valve at the bottom) for 5 min. Cautiously open the valve slightly, maintaining the container in an inverted position. Vent the gas with a barely audible flow against a stainless steel mirror for a few seconds.

  Acceptance criteria: No liquid is discernible on the mirror.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in pressurized containers. Container connections shall be appropriate for air. Adaptors shall not be used to connect containers to patient use supply system piping or equipment.

https://trungtamthuoc.com/

• LABELING: Label states if Medical Air is a synthetic mixture of *Oxygen USP* and *Nitrogen NF*. Where it is piped directly from the collecting tank to the patient point of use, label each outlet "Medical Air".

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MEDICAL AIR	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

---

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(1)

Current DocID: GUID-A113E881-4666-4D6E-8B59-F6FB4E656AC9_2_en-US
DOI: https://doi.org/10.31003/USPNF_M1000_02_01
DOI ref: krm9v