

Medicinal Oxygen (Oxygenium Medicinalis)

2022-01

Molecular formula. O₂

Relative molecular mass. 32.00

Chemical name. Oxygen; CAS Reg. No. 7782-44-7.

Description. A colourless gas.

Category. Gas for inhalation.

Additional information. Oxygen is mentioned in the current *WHO Model list of essential medicines* (EML) and in the *EML for Children*.

Depending on the clinical medicinal necessity, and in accordance with clinical guidelines, Medicinal Oxygen is used either (1) in the undiluted form, (2) as mixtures of Oxygen 93%, Oxygen 99.5% or other oxygen products, or (3) in the undiluted form or as mixtures in combination with ambient or compressed air of a suitable quality or other medicines.

This monograph does not apply to gas produced using portable concentrators for home care or bedside use ^[1].

[1] Specifications for portable concentrators for home care or bedside use can be found in: WHO-UNICEF technical specifications and guidance for oxygen therapy devices. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2019 (WHO medical device technical series) (<https://www.who.int/publications/i/item/9789241516914> accessed 7 October 2021). And in interim guidance for Priority medical devices list for the COVID-19 response and associated technical specifications, <https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>.

Requirements

Definition. Medicinal oxygen is Oxygen 93% or Oxygen 99.5%. Other products with different oxygen concentrations and/or produced using different production methods may also be considered as Medicinal oxygen, if approved by the appropriate national or regional authority.

Oxygen 93%

Definition. Oxygen 93% contains not less than 90.0% and not more than 96.0% (v/v) of O₂, the remainder mainly consisting of argon and nitrogen.

Production. Oxygen 93% is produced from ambient air by pressure swing adsorption (PSA) or vacuum swing adsorption (VSA). During production, the oxygen content is continuously monitored. The production method is validated to demonstrate that Oxygen 93% complies with the following limits: carbon dioxide: maximum 300 ppm (v/v); carbon monoxide: maximum 5 ppm (v/v); nitrogen monoxide and nitrogen dioxide: maximum 2 ppm (v/v) in total; sulfur dioxide: maximum 1 ppm (v/v); oil: maximum 0.1 mg/m³; water: maximum 67 ppm (v/v) and that viable and non-viable particulates are eliminated or minimized and adequately controlled in the product.

Identity test. Carry out the test as described under "Assay". The sample gas complies with the limit. The paramagnetic signal exhibited confirms the presence of oxygen.

Carbon monoxide. Determine the content using a carbon monoxide detector tube according to the manufacturer's instruction. Pass the required volume of the test gas through the tube and read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale; not more than 5 ppm (v/v).

Carbon dioxide. Determine the content using a carbon dioxide detector tube according to the manufacturer's instruction. Pass the required volume of the test gas through the tube and read the value corresponding to the length of the coloured layer or the intensity of the colour on the graduated scale; not more than 300 ppm (v/v).

Water. Determine the content using a water vapour detector tube according to the manufacturer's instruction; not more than 67 ppm (v/v).

Assay . Determine the percentage content of Oxygen (O₂) using a paramagnetic analyser which electronically measures the molecule's interaction with magnetic fields.

Impurities

- A. CO₂, carbon dioxide.
- B. CO, carbon monoxide.
- C. Water.

Oxygen 99.5%

Definition. Oxygen 99.5% contains not less than 99.5% (v/v) of O₂.

Production. Oxygen 99.5% is produced from ambient air by cryogenic distillation.

The production method is validated to demonstrate that Oxygen 99.5% complies with the following limits: carbon dioxide: maximum 300 ppm (v/v), carbon monoxide: maximum 5 ppm (v/v), water: maximum 67 ppm (v/v).

Identity test. Carry out the test as described under "Assay". The sample gas complies with the limit. The paramagnetic signal exhibited confirms the presence of oxygen.

Water. Not more than 67 ppm (v/v) determine by water vapor detector tube or electrolytic hygrometer.

Assay. Determine the percentage content of Oxygen (O₂) using a paramagnetic analyser which electronically measures the molecule's interaction with magnetic fields.

Impurities

A. Water.