



Edition: BP 2025 (Ph. Eur. 11.6 update)

Oxygen (93 per cent)



[General Notices](#)

(Ph. Eur. monograph 2455)

O₂ 32.00

Action and use

Oxygen supplementation for medical emergencies.

Ph Eur

DEFINITION

Content

90.0 per cent V/V to 96.0 per cent V/V of O₂, the remainder mainly consisting of argon and nitrogen.

This monograph applies to oxygen (93 per cent) for medicinal use. It does not apply to gas produced using individual concentrators for domiciliary use.

PRODUCTION

Oxygen (93 per cent) is produced in single-stage concentrators by adsorption purification of ambient air using zeolites. During production, the oxygen content is continuously monitored by means of a paramagnetic analyser ([2.5.27](#)). Following the design and installation of the concentrator, and after any modification or significant intervention, the gas produced complies with the following requirements.

[Carbon dioxide](#)

Maximum 300 ppm V/V, determined using an infrared analyser ([2.5.24](#)).

Gas to be examined The substance to be examined. It must be filtered to avoid stray light phenomena.

Reference gas (a) [Oxygen R](#).

Reference gas (b) A mixture of 7 per cent V/V of [nitrogen R1](#) and 93 per cent V/V of [oxygen R](#), containing 300 ppm V/V of [carbon dioxide R1](#).

Calibrate the apparatus and set the sensitivity using reference gases (a) and (b). Measure the content of carbon dioxide in the gas to be examined.

Carbon monoxide

Maximum 5 ppm V/V, determined using an infrared analyser ([2.5.25](#)).

Gas to be examined The substance to be examined. It must be filtered to avoid stray light phenomena.

Reference gas (a) [Oxygen R](#).

Reference gas (b) A mixture containing 5 ppm V/V of [carbon monoxide R](#) in [nitrogen R1](#).

Calibrate the apparatus and set the sensitivity using reference gases (a) and (b). Measure the content of carbon monoxide in the gas to be examined.

Nitrogen monoxide and nitrogen dioxide

Maximum 2 ppm V/V in total, determined using a chemiluminescence analyser ([2.5.26](#)).

Gas to be examined The substance to be examined.

Reference gas (a) A mixture of 21 per cent V/V of [oxygen R](#) and 79 per cent V/V of [nitrogen R1](#), containing less than 0.05 ppm V/V of nitrogen monoxide and nitrogen dioxide.

Reference gas (b) A mixture containing 2 ppm V/V of [nitrogen dioxide R](#) in [nitrogen R1](#).

Calibrate the apparatus and set the sensitivity using reference gases (a) and (b). Measure the content of nitrogen monoxide and nitrogen dioxide in the gas to be examined.

Sulfur dioxide

Maximum 1 ppm V/V, determined using an ultraviolet fluorescence analyser (Figure 2455.-1.).

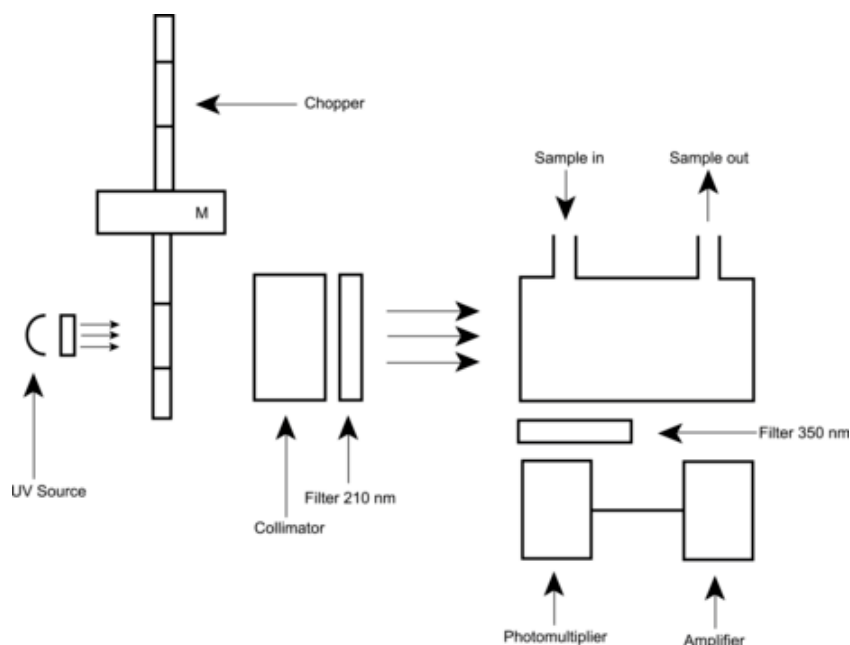


Figure 2455.-1. – UV fluorescence analyser

The apparatus consists of the following:

- a system generating ultraviolet radiation with a wavelength of 210 nm, made up of an ultraviolet lamp, a collimator, and a selective filter; the beam is blocked periodically by a chopper rotating at high speeds;

— a reaction chamber, through which flows the gas to be examined;

— a system that detects radiation emitted at a wavelength of 350 nm, made up of a selective filter, a photomultiplier tube and an amplifier.

Gas to be examined The substance to be examined. It must be filtered.

Reference gas (a) A mixture of 7 per cent V/V of [nitrogen R1](#) and 93 per cent V/V of [oxygen R](#).

Reference gas (b) A mixture of 7 per cent V/V of [nitrogen R1](#) and 93 per cent V/V of [oxygen R](#), containing 0.5 ppm V/V to 2 ppm V/V of [sulfur dioxide R1](#).

Calibrate the apparatus and set the sensitivity using reference gases (a) and (b). Measure the content of sulfur dioxide in the gas to be examined.

Oil

Maximum 0.1 mg/m³, determined using an oil detector tube ([2.1.6](#)).

Water

Maximum 67 ppm V/V, determined using an electrolytic hygrometer ([2.5.28](#)).

Assay

Determine the concentration of oxygen using a paramagnetic analyser ([2.5.27](#)).

CHARACTERS

Appearance

Colourless gas.

IDENTIFICATION

It complies with the limits of the assay.

TESTS

[Carbon dioxide](#)

Maximum 300 ppm V/V, determined using a carbon dioxide detector tube ([2.1.6](#)).

[Carbon monoxide](#)

Maximum 5 ppm V/V, determined using a carbon monoxide detector tube ([2.1.6](#)).

[Nitrogen monoxide and nitrogen dioxide](#)

Maximum 2 ppm V/V in total, determined using a nitrogen monoxide and nitrogen dioxide detector tube ([2.1.6](#)).

Sulfur dioxide

Maximum 1 ppm V/V, determined using a sulfur dioxide detector tube ([2.1.6](#)).

Oil

Maximum 0.1 mg/m³, determined using an oil detector tube ([2.1.6](#)).

Water vapour

Maximum 67 ppm V/V, determined using a water vapour detector tube ([2.1.6](#)).

ASSAY

Determine the content of oxygen using a paramagnetic analyser ([2.5.27](#)).

STORAGE

Oxygen 93 per cent obtained from an oxygen concentrator is normally used on the site where it is produced. It is fed directly into a medicinal gas pipeline or administration system. Where authorised by the competent authority, it may be stored in suitable containers complying with the legal regulations. Oils and grease are not to be used unless they are oxygen-compatible.

IMPURITIES

- A. CO₂: carbon dioxide,
- B. CO: carbon monoxide,
- C. SO₂: sulfur dioxide,
- D. NO and NO₂: nitrogen monoxide and nitrogen dioxide,
- E. oil,
- F. H₂O: water.

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