

**COMPARISON OF EUROPEAN,
US & JAPANESE
PHARMACOPOEIA
MONOGRAPHS
FOR MEDICINAL GASES**

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EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL 

AVENUE DES ARTS 3-5 • B-1210 BRUSSELS
Tel: +32 2 217 70 98 • Fax: +32 2 219 85 14
E-mail: info@eiga.eu • Internet: <http://www.eiga.eu>



COMPARISON OF EUROPEAN, US & JAPANESE PHARMACOPOEIA MONOGRAPHS

PREPARED BY :

| | |
|--------------------|---------------------------|
| Atoosa Bayat | Linde |
| Peter Henrys | BOC |
| Dennis King | CGA (BOC) |
| Stefania Mariani | SOL |
| Ichirou Nakayama | JIMGA (Nippon Sanso Corp) |
| Peter Neu | Air Liquide |
| Herbert Schöfnagl | Messer Group |
| François Simondet | Air Liquide |
| Cristofaro Stefano | Praxair |
| Jan Strybol | Air Products |
| Erica Sundström | Linde |

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1 Introduction

The European, United States and Japanese Pharmacopoeia organisations are responsible for the preparation and publication of Pharmacopoeia monographs, covering the commonly used substances involved in the manufacture and supply of medicinal products.

For medical gases this includes the medicinal gases used either as active ingredients (medicinal substances) or excipients (auxiliary substances which have no therapeutic effect) in gases administered to patients or the pharmaceutical gases used in the manufacture, storage or distribution of all medicinal products.

The purpose of the monographs is to specify a minimum quality for each product that is suitable for medicinal use and to define the appropriate test methods that have been validated as the reference method for determining quality of the product.

This document provides a comparison between the specifications and the test methods defined in each of the regional pharmacopoeia compendiums.

2 Scope and purpose

2.1 Scope

The scope of this document covers the pharmacopoeia monographs for the medicinal and pharmaceutical gases covered by the:

- European Pharmacopoeia (Ph Eur)
- United States Pharmacopoeia (USP)
- Japanese Pharmacopoeia (JP)

It covers the monographs of all medical gases used in the manufacture and supply of medicinal products including:

- Medicinal gases, which are active ingredients in medical gases and gas mixtures supplied for patient use
- Excipient gases, which are added to gas mixtures but have no therapeutic effects
- Pharmaceutical gases, which are specified in the manufacture, storage and distribution of medicinal products.

The comparison tables in the Appendix cover the comparison between the European and the United States Pharmacopoeia monographs for all specified gases.

A separate table is included to detail the monographs for the Japanese Pharmacopoeia, where the monographs do not specify the acceptance limits and only provide the test criteria for compliance.

2.2 Purpose

The purpose of the document is to provide simple cross reference between the three sets of monographs to enable a comparison of requirements. This is intended to demonstrate compliance between monographs but should not be used as a detailed method of carrying out the relevant tests. Where the testing to a specific monograph is required, the user should refer to the original document (and all supporting documents within the relevant pharmacopoeia) to ensure that the tests are carried out correctly.

3 Specifications and Test Methods

The most commonly used medicinal gases have been included in the Pharmacopoeia for many years but recently a number of new medical gases have been added.

The following table gives a quick reference for the different gases that have been covered by published monographs in the three Pharmacopoeias:

| Gases | Monograph Reference | | |
|-------------------------|------------------------|------------------|------------------------|
| | European Pharmacopoeia | US Pharmacopoeia | Japanese Pharmacopoeia |
| Medical Oxygen | 0417 | 7782-44-7 | |
| Oxygen 93% | NS | | NS |
| Nitrous Oxide | 0416 | 10024-97-2 | |
| Nitrogen | 1247 | 7727-37-9 | |
| Nitrogen 97% | NS | | NS |
| Low Oxygen Nitrogen | 1685 | NS | NS |
| Carbon Dioxide | 0375 | 124-38-9 | |
| Medicinal Air | 1238 | | NS |
| Synthetic Medicinal Air | 1684 | NS | NS |
| Helium | 2155 | | NS |
| Nitric Oxide | 1550 | NS | NS |
| Argon | - | IP | NS |
| Methane | - | IP | NS |
| Carbon Monoxide | - | IP | NS |

NS: Not specified

IP: In preparation

Each monograph defines the specification of the medicinal gas, including the assay and maximum impurity levels for those specified contaminants allowed in the product. It also details the approved analytical method for identifying the gas, determining the assay and the approved analytical test method for determining each contaminant specified within the monograph. The validated analytical methods described in the monographs are the official test methods upon which the specifications in the relevant Pharmacopoeia are based.

For the European Pharmacopoeia, the test methods are verified against the protocols set out in the ICH Guidelines for accuracy and precision, linearity and range and specificity. In addition the results need to conform to the requirements of repeatability and peak symmetry. Alternative methods of analysis may be used, after agreement with the competent authority, provided that they have been validated in line with the ICH protocols to demonstrate that they are equivalent to the specified methods.

The monographs for medical gases in the European Pharmacopoeia are divided into two main sections:

- Production
- Tests

The PRODUCTION methods are intended to be the methods used by the manufacturers. These methods are the basis for the release of the product at the manufacturer's site. The methods specified in the PRODUCTION section of the monograph normally utilise the latest analytical instruments, that should be available to the manufacturers of the gases.

The TEST methods are intended to be the methods used by the end user to assure themselves that the medical gases are of the appropriate quality. For example, these could be used for routine testing by the Pharmacist at the hospital of the pipeline gases at the terminal outlets in the hospital. The

TEST methods generally utilise indicator tubes for the test method as it is unlikely that the end users would have the appropriate analytical instruments available to them for testing.

Where the hospital is the manufacturer, for example where they are producing medicinal air on site using an air compressor, the PRODUCTION test methods should be applied.

The United States and Japanese Pharmacopoeia monographs only specify one method for the analysis of the medical gas.

These test methods utilise either indicator tubes or wet chemistry techniques as the approved test method. The Japanese Pharmacopoeia monographs only detail the test methods and do not give the values of the specification limits in percentage terms or parts per million.

In all cases the test methods specified in the monographs should have been validated. For the European Pharmacopoeia, this work is normally undertaken by one of the national representative on the relevant Pharmacopoeia committee.

4 Currency of Information

The version of the relevant Pharmacopoeias used to provide the information for the comparison tables is:

| | |
|------------------------------|-----------------|
| European Pharmacopoeia: | 6.0 (June 2007) |
| United States Pharmacopoeia: | |
| Japanese Pharmacopoeia: | 15 (April 2006) |

As and when there are relevant changes to any of these monographs this comparison document will be updated. However, where it is important that the latest information is available, the original Pharmacopoeia document should be referenced to ensure that there has been no revisions to the individual monograph.

5 Comparison Tables

The following tables provide a comparison between the European and US Pharmacopoeia monographs for each of the specified medicinal or pharmaceutical gas.

5.1 Medical Oxygen

| Oxygen | | | |
|-------------------------|-------------------|---|--|
| Monograph | | Ph Eur | USP |
| Name | | Oxygen | Oxygen |
| Reference | | 0417 | 7782-44-7 |
| Chemical Formula | | O₂ | O₂ |
| Definition | | Oxygen contains not less than 99.5% V/V of O ₂ . | Oxygen contains not less than 99.0% V/V of O ₂ . (Note: Oxygen produced by the air-liquefaction is exempt from the requirements of CO and CO ₂ testing) |
| Identification | | Complies with the Assay | Complies with the Assay Distinction from CO ₂ detector tube |
| Production | | | |
| Assay | Specification | ≥ 99.5% V/V O ₂ | ≥ 99.0 % V/V O ₂ |
| | Analytical Method | Paramagnetic Analyser | Volumetric Gas Absorption Apparatus |
| Impurities | | | |
| CO | Limit | ≤ 5 ppm V/V | ≤ 0.001% V/V |
| | Analytical Method | IR analyser | Detector tube |
| CO₂ | Limit | ≤ 300 ppm V/V | ≤ 0.03% V/V |
| | Analytical Method | IR analyser | Detector tube |
| H₂O | Limit | ≤ 67 ppm V/V | Not Specified |
| | Analytical Method | Electrolytic hygrometer | |
| Odour | Limit | Not Specified | No odour |
| | Analytical Method | | Organoleptic |
| Tests | | | |
| CO | Limit | ≤ 5 ppm V/V | No Tests Section specified |
| | Analytical Method | Detector Tube | |
| CO₂ | Limit | ≤ 300 ppm V/V | |
| | Analytical Method | Detector Tube | |
| H₂O | Limit | ≤ 67 ppm V/V | |
| | Analytical Method | Detector Tube | |

5.2 93% Oxygen

| Oxygen 93 | | | |
|-------------------------|--|---------------|--|
| Monograph | | Ph Eur | USP |
| Name | Monograph in preparation by the European Pharmacopoeia | | Oxygen 93 Percent |
| Reference | | | Not Specified |
| Chemical Formula | | | O₂ |
| Definition | | | Oxygen 93 is Oxygen produced from Air by molecular sieve process. It contains not less than 90.0 % V/V and not more than 96 % O ₂ V/V, the remainder consisting mostly of Argon and Nitrogen |
| Identification | | | Complies with the Assay. Distinction from CO ₂ (detector tube) |
| Production | | | |
| Assay | Specification | | 90.0% ≤ O ₂ ≤ 96.0% V/V O ₂ |
| | Analytical Method | | Volumetric Gas Absorption Apparatus |
| Impurities | | | |
| CO | Limit | | ≤ 0.001 % V/V |
| | Analytical Method | | Detector tube |
| CO₂ | Limit | | ≤ 0.03 % V/V |
| | Analytical Method | | Detector tube |
| H₂O | Limit | | Not Specified |
| | Analytical Method | | |
| Odour | Limit | | No odour |
| | Analytical Method | | Organoleptic |
| Tests | | | |
| CO | Limit | | No specific Tests Section |
| | Analytical Method | | |
| CO₂ | Limit | | |
| | Analytical Method | | |
| H₂O | Limit | | |
| | Analytical Method | | |

5.3 Nitrous Oxide

| Nitrous Oxide | | | |
|------------------------|-------------------|--|--|
| Monograph | | Ph Eur | USP |
| Name | | Nitrous Oxide | Nitrous Oxide |
| Reference | | 0416 | 10024-97-2 |
| Chemical Formula | | N ₂ O | N ₂ O |
| Definition | | Contains not less than 98.0% V/V of N ₂ O in the gaseous phase, when sampled at 15°C. | Nitrous Oxide contains not less than 99.0% V/V of N ₂ O |
| Identification | | IR absorption spectrophotometry | Comparison of pressure between N ₂ O container and certified standard. Distinction from CO ₂ detector tube. Distinction from O ₂ (alkaline pyrogallol solution) |
| Production | | | |
| Assay | Assay | ≥ 98.0% V/V N ₂ O Measured in gas phase at 15°C | ≤ 1.0% air indicating ≥ 99.0% V/V of N ₂ O |
| | Analytical Method | IR analyser | Gas Chromatography |
| Impurities | | | |
| CO | Limit | ≤ 5 ppm V/V | ≤ 0.001% V/V |
| | Analytical Method | Gas Chromatography | Detector tube |
| CO ₂ | Limit | ≤ 300 ppm V/V | ≤ 0.03% V/V |
| | Analytical Method | Gas Chromatography | Detector tube |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V in total in the gaseous and liquid phases | NO ≤ 1ppm, NO ₂ ≤ 1ppm |
| | Analytical Method | Chemiluminescence Analyser | Detector Tube |
| H ₂ O | Limit | ≤ 67 ppm V/V | ≤ 150 mg/m ³ |
| | Analytical Method | Electrolytic hygrometer | Detector Tube |
| NH ₃ | Limit | Not Specified | ≤ 0.0025 % V/V |
| | Analytical Method | | Detector Tube |
| Halo- gens | Limit | Not Specified | ≤ 1ppm |
| | Analytical Method | | Detector Tube |
| Tests | | | |
| CO | Limit | ≤ 5 ppm V/V | No specific Tests Section |
| | Analytical Method | Detector Tube | |
| CO ₂ | Limit | ≤ 300 ppm V/V | |
| | Analytical Method | Detector Tube | |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V | |
| | Analytical Method | Detector Tube | |
| H ₂ O | Limit | ≤ 67 ppm V/V | |
| | Analytical Method | Detector Tube | |

5.4 Nitrogen

| Nitrogen | | | |
|-------------------------|-------------------|---|---|
| Monograph | | Ph Eur | USP |
| Name | | Nitrogen | Nitrogen |
| Reference | | 1247 | 7727-37-9 |
| Chemical Formula | | N₂ | N₂ |
| Definition | | Nitrogen contains not less than 99.5% V/V of N ₂ . | Nitrogen contains not less than 99.0%,by volume of N ₂ |
| Identification | | Retention time of peak with Gas Chromatography | Extinguishing of burning wood splinter in a Nitrogen test tube. Identification test currently under review. Gas chromatography currently under review |
| Production | | | |
| Assay | Assay | ≥ 99.5% V/V N ₂ | ≤ 1.0% O ₂ indicates ≥ 99.0% V/V of N ₂ |
| | Analytical Method | Gas Chromatography | Gas Chromatography |
| Impurities | | | |
| CO | Limit | ≤ 5 ppm V/V | ≤ 0.001 % V/V |
| | Analytical Method | IR analyser | Detector tube |
| CO₂ | Limit | ≤ 300 ppm V/V | Not specified |
| | Analytical Method | IR analyser | |
| O₂ | Limit | ≤ 50 ppm V/V | ≤ 1.0 % |
| | Analytical Method | Oxygen Analyser with electrochemical cell | Determined in Assay |
| H₂O | Limit | ≤ 67 ppm V/V | Not specified |
| | Analytical Method | Electrolytic hygrometer | |
| Odour | Limit | Not specified | No odour |
| | Analytical Method | | Organoleptic |
| Tests | | | |
| CO | Limit | ≤ 5 ppm V/V | No specific Tests Section |
| | Analytical Method | Detector Tube | |
| CO₂ | Limit | ≤ 300 ppm V/V | |
| | Analytical Method | Detector Tube | |
| H₂O | Limit | ≤ 67 ppm V/V | |
| | Analytical Method | Detector Tube | |

5.5 97% Nitrogen

| Nitrogen 97% | | |
|-------------------------------|---|--|
| Monograph | Ph Eur No equivalent European Pharmacopoeia monograph | USP |
| Name | | Nitrogen 97 Percent |
| Reference | | Not Specified |
| Chemical Formula | | N₂ |
| Definition | | Nitrogen 97 Percent is Nitrogen produced from Air by physical separation. Contains not less than 97.0% N ₂ V/V |
| Identification | | Extinguishing of burning wood splinter in a Nitrogen test tube. Gas chromatography currently under review |
| Production | | |
| Assay | Assay | ≤ 3.0% O ₂ indicates ≥ 97.0% V/V of N ₂ |
| | Analytical Method | Gas Chromatography |
| Impurities | | |
| CO | Limit | ≤ 0.001 % V/V |
| | Analytical Method | Detector tube |
| CO₂ | Limit | ≤ 0.03 % V/V |
| | Analytical Method | Detector tube |
| SO₂ | Limit | ≤ 5 ppm V/V |
| | Analytical Method | Detector tube |
| NO/ NO₂ | Limit | ≤ 2.5 ppm V/V |
| | Analytical Method | Detector Tube |
| O₂ | Limit | ≤ 3.0 % V/V |
| | Analytical Method | Gas Chromatography (determined in the Assay) |
| Odour | Limit | No odour |
| | Analytical Method | Organoleptic |
| Tests | | |
| | Limit | No specific Tests Section |
| | Analytical Method | |

5.6 Low Oxygen Nitrogen

| Low Oxygen Nitrogen | | | |
|-------------------------|-------------------|--|--|
| Monograph | | Ph Eur | USP No equivalent US Pharmacopoeia monograph |
| Name | | Nitrogen Low Oxygen | |
| Reference | | 1685 | |
| Chemical Formula | | N₂ | |
| Definition | | This monograph applies to Nitrogen which is used for inerting finished medicinal products sensitive to degradation by oxygen. Does not necessarily apply to N ₂ used in earlier production steps of pharmaceutical manufacturing. | |
| Identification | | Examine the chromatograms obtained in the test for impurities. or Flame of burning wood splinter in a Nitrogen test tube/ Test with magnesium turnings. | |
| Production | | | |
| Assay | Assay | ≥ 99.5% V/V N ₂ | |
| | Analytical Method | Gas Chromatography | |
| Impurities | | | |
| O₂ | Limit | ≤ 5 ppm V/V O ₂ | |
| | Analytical Method | Oxygen Analyser with electrochemical cell | |
| Tests | | | |
| | Limit | No Test Methods specified | |

5.7 Carbon Dioxide

| Carbon Dioxide | | | |
|------------------------|-------------------|--|--|
| Monograph | | Ph Eur | USP |
| Name | | Carbon Dioxide | Carbon Dioxide |
| Reference | | 0375 | 124-38-9 |
| Chemical Formula | | CO ₂ | CO ₂ |
| Definition | | Carbon Dioxide contains not less than 99.5% V/V of CO ₂ . | Carbon Dioxide contains not less than 99.0%,by volume of CO ₂ |
| Identification | | Infrared absorption spectrophotometry | Carbon Dioxide Indicator Tube |
| Production | | | |
| Assay | Assay | ≥ 99.5% V/V CO ₂ | ≥ 99.0% V/V of CO ₂ |
| | Analytical Method | Infrared absorption spectrophotometry | Determined with volumetric gas absorption apparatus |
| Impurities | | | |
| CO | Limit | ≤ 5 ppm V/V | ≤ 0.001% V/V |
| | Analytical Method | Gas Chromatography | Detector tube |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V in total (in gas phase) | ≤ 2.5 ppm (in liquid phase) specifies 2.5 ppm for each species. |
| | Analytical Method | Chemiluminescence Analyser | Detector tube |
| Total Sulphur | Limit | ≤ 1 ppm V/V | Not Specified |
| | Analytical Method | UV Fluorescence Analyser | |
| H ₂ O | Limit | ≤ 67 ppm V/V | ≤ 150 mg/m ³ |
| | Analytical Method | Electrolytic hygrometer | Detector tube |
| NH ₃ | Limit | Not Specified | ≤ 0.0025 % V/V |
| | Analytical Method | | Detector tube |
| H ₂ S | Limit | Not Specified | ≤ 1 ppm |
| | Analytical Method | | Detector tube |
| SO ₂ | Limit | Not Specified | ≤ 5 ppm |
| | Analytical Method | | Detector tube |
| Tests | | | |
| CO | Limit | ≤ 5 ppm V/V | No specific Tests Section |
| | Analytical Method | Detector Tube | |
| SO ₂ | Limit | ≤ 2 ppm V/V | |
| | Analytical Method | Detector Tube | |
| H ₂ S | Limit | ≤ 1 ppm V/V | |
| | Analytical Method | Detector Tube | |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V | |
| | Analytical Method | Detector Tube | |
| H ₂ O | Limit | ≤ 67 ppm V/V | |
| | Analytical Method | Detector Tube | |

5.8 Medicinal Air

| Medicinal Air | | | |
|------------------------|-------------------|--|---|
| Monograph | | Ph Eur | USP |
| Name | | Air, Medicinal | Medical Air |
| Reference | | 1238 | |
| Chemical Formula | | N/A | N/A |
| Definition | | Compressed ambient air containing not less than 20.4 %V/V and not more than 21.4 % V/V of O ₂ . | Natural or synthetic mixture consisting largely of N ₂ and O ₂ , containing not less than 19.5% and not more than 23.5% V/V of O ₂ . |
| Identification | | Complies with the Assay or Glowing wood splinter not extinguished / Oxygen content tested by passing sample through potassium hydroxide / sodium dithionite solution. | |
| Production | | | |
| Assay | Assay | 20.4%V/V ≤ O ₂ ≤ 21.4 % V/V | 19.5% V/V ≤ O ₂ ≤ 23.5% V/V |
| | Analytical Method | Paramagnetic Analyser | Electrochemical Analyser |
| Impurities | | | |
| CO | Limit | ≤ 5 ppm V/V | ≤ 0.001% V/V |
| | Analytical Method | IR Analyser | Detector tube |
| CO ₂ | Limit | ≤ 500 ppm V/V | ≤ 0.05% V/V |
| | Analytical Method | IR Analyser | Detector tube |
| SO ₂ | Limit | ≤ 1 ppm V/V | ≤ 5 ppm V/V |
| | Analytical Method | UV Fluorescence Analyser | Detector tube |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V in total | ≤ 2.5 ppm V/V |
| | Analytical Method | Chemiluminescence Analyser | Detector Tube |
| Oil | Limit | ≤ 0.1 mg/m ³ | No condensate on mirror |
| | Analytical Method | Filtration of oil on micro fibre glass filter. Absorption of oil using trichlorotrifluoroethane. | |
| H ₂ O | Limit | ≤ 67 ppm V/V | No condensate on mirror |
| | Analytical Method | Electrolytic hygrometer | |
| Odo ur | Limit | Not specified | No odour |
| | Analytical Method | | Organoleptic |
| Tests | | | |
| CO | Limit | ≤ 5 ppm V/V | No Specific Tests Section |
| | Analytical Method | Detector Tube | |
| CO ₂ | Limit | ≤ 500 ppm V/V | |
| | Analytical Method | Detector Tube | |
| SO ₂ | Limit | ≤ 1 ppm V/V | |
| | Analytical Method | Detector Tube | |
| NO/ NO ₂ | Limit | ≤ 2 ppm V/V | |
| | Analytical Method | Detector Tube | |
| Oil | Limit | ≤ 0.1 mg/m ³ | |
| | Analytical Method | Detector Tube | |
| H ₂ O | Limit | ≤ 67 ppm V/V | |
| | Analytical Method | Detector Tube | |

5.9 Synthetic Medicinal Air

| Synthetic Medicinal Air | | | |
|-------------------------|-------------------|--|--|
| Monograph | | Ph Eur | USP No equivalent US Pharmacopoeia monograph specified |
| Name | | Air, Synthetic Medicinal | |
| Reference | | 1684 | |
| Chemical Formula | | N/A | |
| Definition | | Gas mixture of N ₂ (Ph.Eur) and O ₂ (Ph.Eur) containing between 95.0 % to 105.0 % of the nominal value which is between 21.0 % V/V to 22.5 % V/V of O ₂ . | |
| Identification | | Complies with the Assay. or Glowing wood splinter not extinguished in gas / Test oxygen content by passing sample through potassium hydroxide / sodium dithionite solution. | |
| Production | | | |
| Assay | Assay | Containing between 95.0% to 105.0% of the nominal value which is between 21.0 % V/V to 22.5 % V/V of O ₂ . | |
| | Analytical Method | Paramagnetic analyser | |
| Impurities | | | |
| H₂O | Limit | ≤ 67 ppm V/V O ₂ | |
| | Analytical Method | Electrolytic hygrometer | |
| Tests | | | |
| H₂O | Limit | ≤ 67 ppm V/V O ₂ | |
| | Analytical Method | Detector Tube | |

5.10 Helium

| Helium | | | |
|------------------|-------------------|--|---|
| Monograph | | Ph Eur | USP |
| Name | | Helium | Helium |
| Reference | | 2155 | 7440-59-7 |
| Chemical Formula | | He | He |
| Definition | | Helium contains not less than 99.5 % V/V of He. Applies to helium obtained by separation from natural gas supplies. | Helium contains not less than 99.0 % V/V of He |
| Identification | | Complies with the Assay | The flame of a burning splinter of wood is extinguished. A small balloon filled with helium shows decided buoyancy |
| Production | | | |
| Assay | Specification | ≥ 99.5 % V/V He | ≥ 99.0 % V/V He |
| | Analytical Method | Gas Chromatography | Gas chromatography |
| Impurities | | | |
| CH ₄ | Limit | ≤ 50 ppm V/V | ≤ 0.001 % V/V |
| | Analytical Method | IR analyser | Detector tube |
| O ₂ | Limit | ≤ 50 ppm V/V | Not Specified |
| | | Electrochemical Cell | |
| H ₂ O | Limit | ≤ 67 ppm V/V | Not Specified |
| | Analytical Method | Electrolytic hygrometer | |
| CO | Limit | Not Specified | ≤ 0.001 % V/V |
| | Analytical Method | | Detector Tube |
| Air | Limit | Not Specified | ≤ 1.0 % V/V |
| | Analytical Method | | Determined in the Assay |
| Odour | Limit | Not Specified | No odour |
| | Analytical Method | | Organoleptic |
| Tests | | | |
| | Limit | No Tests Section specified | No Tests Section specified |
| | Analytical Method | | |

5.11 Nitric Oxide

| Nitric Oxide | | |
|-------------------|--|---|
| Monograph | Ph Eur | USP |
| Name | Nitric Oxide | No equivalent US Pharmacopoeia monograph specified |
| Reference | 1550 | |
| Chemical Formula | NO | |
| Definition | Nitric oxide contains not less than 99.0% V/V of NO. | |
| Identification | Examine by IR spectrometry and compare with the reference spectrum | |
| Production | | |
| Assay | Specification | ≥ 99.0 % V/V NO |
| | Analytical Method | Determine content of NO by difference using the mass balance equation after determining the sum of the impurities described under production. |
| Impurities | | |
| CO ₂ | Limit | ≤ 3000 ppm V/V |
| | Analytical Method | Gas Chromatography |
| N ₂ | Limit | ≤ 3000 ppm V/V |
| | Analytical Method | Gas Chromatography |
| NO ₂ | Limit | ≤ 400 ppm V/V |
| | Analytical Method | UV Spectrophotometry Analyser |
| N ₂ O | Limit | ≤ 3000 ppm V/V |
| | Analytical Method | Gas Chromatography |
| H ₂ O | Limit | ≤ 100 ppm V/V |
| | Analytical Method | Electrolytic Hygrometer |
| Tests | | |
| | Limit | No Tests Section specified |
| | Analytical Method | |

6 Japanese Pharmacopoeia

6.1 Medical Oxygen

| Oxygen | | |
|------------------------------|---|---|
| Monograph | JP | |
| Name | Medical Oxygen | |
| Chemical Formula | O₂ | |
| Definition | Oxygen contains not less than 99.5%vol of O ₂ . | |
| Description | Oxygen is a colourless, odourless gas. | |
| Identification | 1. Put a glowing splinter of wood into the oxygen: it bursts into flames immediately 2. The retention time of the principle peak for oxygen coincides with that of oxygen for chromatography | |
| Purity | | |
| Acidity or alkalinity | Limit | Not specified |
| | Analytical Method | Pass through methyl red and bromothymol blue acidified solution in a Nessler tube. Compare colour against control solution |
| Oxidising Substances | Limit | Not specified |
| | Analytical Method | Pass through potassium iodide-starch solution in a Nessler tube. Compare colour against control solution |
| Chloride | Limit | Not specified (can be calculated by the method) |
| | Analytical Method | Pass through silver nitrate solution in a Nessler tube. Compare turbidity against control solution |
| CO₂ | Limit | Not specified (can be calculated by the method) |
| | Analytical Method | Pass through barium hydroxide in a Nessler tube. Compare turbidity against a control solution of barium hydroxide containing hydrogen carbonate |
| N₂ | Limit | The peak area of nitrogen in the oxygen is not larger than that of oxygen |
| | Analytical Method | Gas Chromatography |
| Assay | | |
| Assay | Specification | ≥ 99.5%vol of O ₂ . |
| | Analytical Method | Volumetric Gas Absorption Apparatus |

6.2 Nitrous Oxide

| Nitrous Oxide | | |
|-----------------------|---|--|
| Monograph | JP | |
| Name | Nitrous Oxide | |
| Chemical Formula | N ₂ O | |
| Definition | Nitrous oxide contains not less than 97 vol% of N ₂ O | |
| Description | Nitrous oxide is a colourless, odourless gas at room temperature and at atmospheric pressure. | |
| Identification | 1 Put a glowing splinter of wood into nitrous oxide: it bursts into flame immediately. 2. The retention time of the main peak from nitrous oxide coincides with that of nitrous oxide by gas chromatography. | |
| Purity | | |
| Acidity or alkalinity | Limit | Not specified |
| | Analytical Method | Pass through acidified methyl red and bromothymol blue test solution in a Nessler tube. Compare colour against control solution |
| Reducing Substances | Limit | Not specified |
| | Analytical Method | Pass through potassium permanganate solution in a Nessler tube. Compare colour against control solution |
| Oxidizing Substances | Limit | Not specified |
| | Analytical Method | Pass through potassium iodide-starch solution in a Nessler tube. Compare colour against control solution |
| Chloride | Limit | Not specified (can be calculated by the method) |
| | Analytical Method | Pass through silver nitrate solution in a Nessler tube. Compare turbidity against control solution |
| CO ₂ | Limit | Not specified (can be calculated by the method) |
| | Analytical Method | Pass through barium hydroxide in a Nessler tube. Compare turbidity against control solution of barium hydroxide containing sodium hydrogen carbonate |
| CO | Limit | No peak observed at the same retention time as that for carbon monoxide |
| | Analytical Method | Gas Chromatography |
| Assay | | |
| Assay | Specification | ≥ 97.0 vol% of N ₂ O . |
| | Analytical Method | Gas chromatography |

6.3 Carbon Dioxide

| Carbon Dioxide | | |
|----------------------|---|---|
| Monograph | JP | |
| Name | Carbon Dioxide | |
| Chemical Formula | CO ₂ | |
| Definition | Carbon Dioxide contains not less than 99.5 vol% of CO ₂ | |
| Description | Carbon Dioxide is a colourless, odourless gas at room temperature and under atmospheric pressure. | |
| Identification | 1 Put a flaming splinter of wood into carbon dioxide and the flame is extinguished immediately. 2. Pass carbon dioxide into calcium hydroxide and a white precipitate is produced. Add acetic acid to the precipitate and it dissolves with effervescence. | |
| Purity | | |
| Acidity | Limit | Not specified |
| | Analytical Method | Pass through water in a Nessler tube and add methyl orange indicator. Compare colour against control solution. |
| Reducing Substances* | Limit | Not specified. |
| | Analytical Method | Pass through silver nitrate solution in a Nessler tube. Compare turbidity against control solution. |
| CO | Limit | No peak is observed at the same retention time as that for carbon monoxide. |
| | Analytical Method | Gas Chromatography. |
| Oxygen & Nitrogen | Limit | The peak area of air in carbon dioxide by chromatography is less than that of 0.5 %vol nitrogen. No other peak appears. |
| | Analytical Method | Gas Chromatography. |
| Assay | | |
| Assay | Specification | ≥ 99.5 vol% of CO ₂ . |
| | Analytical Method | Gas chromatography. |

* Reducing substances includes test for phosphine (PH₃) hydrogen sulphide (H₂S) and reducing organic substances.

6.4 Nitrogen

| Nitrogen | | |
|------------------|--|---|
| Monograph | JP | |
| Name | Nitrogen | |
| Chemical Formula | N ₂ | |
| Definition | Nitrogen contains not less than 99.5 vol% of N ₂ | |
| Description | Nitrogen is a colourless, odourless gas. | |
| Identification | Put a burning wood splinter into nitrogen and the flame is extinguished immediately. | |
| Purity | | |
| CO ₂ | Limit | Not specified (can be calculated by the method) |
| | Analytical Method | Pass through barium hydroxide in a Nessler tube. Compare turbidity against control solution of barium hydroxide containing hydrogen carbonate |
| Assay | | |
| Assay | Specification | ≥ 99.5 vol% of N ₂ . |
| | Analytical Method | Gas chromatography. |