NATO STANDARD

AMedP-8.17

MINIMUM STANDARDS FOR OXYGEN 93 PERCENT PRODUCED ON OPERATIONS

Edition A Version 1

JUNE 2017

NORTH ATLANTIC TREATY ORGANIZATION

ALLIED MEDICAL PUBLICATION

Published by the
NATO STANDARDIZATION OFFICE (NSO)

INTENTIONALLY BLANK

NORTH ATLANTIC TREATY ORGANIZATION (NATO)

NATO STANDARDIZATION OFFICE (NSO)

NATO LETTER OF PROMULGATION

23 June 2017

1. The enclosed Allied Medical Publication AMedP-8.17, Edition A, Version 1, MINIMUM STANDARDS FOR OXYGEN 93 PERCENT PRODUCED ON OPERATIONS, which has been approved by the nations in the Military Committee Medical Standardization Board is promulgated herewith. The agreement of nations to use this publication is recorded in STANAG 2558.

2. AMedP-8.17, Edition A, Version 1, is effective upon receipt.

4. This publication shall be handled in accordance with C-M(2002)60.

Edvardas MAŽEIKIS
Major General, LTUAF
Director, NATO Standardization Office

INTENTIONALLY BLANK

RESERVED FOR NATIONAL LETTER OF PROMULGATION

INTENTIONALLY BLANK

RECORD OF RESERVATIONS

CHAPTER	RECORD OF RESERVATION BY NATIONS
The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.	

INTENTIONALLY BLANK

RECORD OF SPECIFIC RESERVATIONS

[nation]	[detail of reservation]
CZE	At present CZE does not match the requirements of AMedP-8.17(A) publication defined in the following points: - Point 3.2 - Point 3.3 - Point 4.2
NLD	Ad 3.2 Mobile Oxygen Generating System (MOGS): On board of Netherlands Naval ships the oxygen generating system consists of only one production line, but with a back-up system that holds an inline bulk vessel and medicinal oxygen containers capable of supplying at least 24 hours of medicinal oxygen. Ad 4.2 Analysis techniques: Netherlands MOGS are equipped with continuous online analysis monitoring (02 percentage, CO, C02). The monitored parameters are documented by printouts instead of electronically. The replacement of this printout by an electronic monitoring system is planned at the midlife update in 2017/2018.
The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.	

INTENTIONALLY BLANK

TABLE OF CONTENTS

INTENTIONALLY BLANK

CHAPTER 1 INTRODUCTION

1.1. GENERAL

1.1.1. Medicinal oxygen has always been considered as a key asset for treatment at all levels of medical care.
The re-supply of Role 2 / 3 Medical Treatment Facilities (MTF) in remote and austere operational environments with oxygen in pressurized containers (otherwise also referred to as medical gas cylinders) can be extremely difficult and is sometimes impossible to ensure by means of transport logistics alone due to highly restrictive legislation and transport capacities.

1.1.2. This publication establishes the minimum requirements for the drug Medicinal Oxygen 93 Percent (hereafter referred to as Oxygen 93 Percent) produced on field operations. The need and priority of individual member nations to set and observe higher quality standards under their own authority shall remain unaffected by these.
The document primarily addresses pharmacists and medical technicians.

1.1.3. It is intended that this STANAG will apply to any member nation, service or organization that uses Oxygen 93 Percent.

It is also proposed that this STANAG is applicable to any military testing or research institution concerning with the testing or development of medical equipment using medicinal oxygen.

1.1.4. This publication specifies the requirements, including essential purity and dryness for Oxygen 93 Percent produced for the use in life-support applications.

1.1.5. This STANAG will help to ensure that on operations Oxygen 93 Percent is produced by using similar systems and has a uniform and safe level of contaminants only. This will enable the uncomplicated exchange of this oxygen between member nations, especially, when hosting other member nation´s medical teams.

The list of potential contaminants specified by this standard is comprehensive but by no means complete. It includes likely contaminants generated by the oxygen production and compression techniques described in this document. In addition to the limits specified in this standard, the limit for all other possible contaminants is to be regarded as nil unless special dispensation is obtained from the responsible authority of the final user (member nation).

1.1.6. Some member nations have developed and / or procured deployable and Mobile Oxygen Generating Systems (MOGS) and Portable Oxygen Generating Systems (POGS) employing the molecular sieve process to produce Oxygen 93 Percent.

Advantages of these over other methods and systems, producing (medicinal) Oxygen 99.5 Percent under operational conditions in the field are:

- Lower weight and volume;
- Lower procurement and maintenance costs, including power supply for their operation;
- A higher degree of mobility;
- Easier Implementation;
- A greater variety of filling and connector capabilities.

1.2. AIM

The aim of this STANAG is to:

- Define the minimum requirements for field medical installations employing a molecular sieve oxygen concentrator system;
- Define the minimum standards for Oxygen 93 Percent produced on operations for the continuous, circuit-based supply of a Role 2-3 MTF or to fill pressurized gas containers;
- Establish a standardised approach to ensure the quality of Oxygen 93 Percent produced on operations, including guidelines for quality testing capabilities on operations and the analysis techniques and sampling regime to be used there;
- Enhance the effectiveness of NATO forces when conducting joint operations by introducing a uniform and safe level of oxygen production for medical life support applications, enabling partnering member nations to share production and pressurized container filling capacities between themselves and also exchange filled pressurized gas containers produced by different member nations using their own respective production installations.

1.3. AGREEMENT

Participating nations agree:

- That the provision of safe Oxygen 93 Percent in the field is a key operational requirement;
- That installations used to produce Oxygen 93 Percent during field operations (MOGS and POGS) as well as the thereby produced Oxygen 93 Percent itself shall meet the minimum requirements detailed herein;
- To follow the procedures described within this document;
- To notify other member nations participating in mutual medical support when they are unable to meet the described requirements of this document.

CHAPTER 2 DEFINITIONS

2.1 COMPRESSED AIR

Compressed air is air which is directly taken from the atmosphere without additional gaseous additives and kept under a pressure greater than that of the atmosphere. Compressed air can be used to produce Oxygen 93 Percent.

2.2 PHARMACOPOEIA

The European and United States pharmacopoeia organizations are responsible for the preparation and publication of pharmacopoeia monographs covering the commonly used substances involved in the manufacture and supply of medicinal products. The purpose of any 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 methods for determining the quality of the product.

The monographs of all medicinal gases used in the manufacture and supply of medicinal products include:

- Medicinal gases, which are active ingredients in medicinal 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.

According to the pharmacopoeias, a bottle containing medicinal oxygen will therefore be considered as a medicine (contents and pressurized container).

2.3 MEDICINAL GASES

The main medicinal gases used are Oxygen, Oxygen 93 Percent, Nitrous Oxide, Nitrogen, Nitrogen 97 percent, Low Oxygen Nitrogen, Carbon dioxide, Medical Air, Synthetic Medical Air.

Oxygen 93 Percent is a medicinal gas obtainable from ambient air and its production actually addresses the need for the supply of oxygen to sites where access to pressurized gas containers or liquid oxygen for medical use is difficult or impossible on most expeditionary NATO missions.

2.4 OXYGEN 93 Percent

Oxygen 93 Percent is described in both U.S. and EU pharmacopoeia and is defined as a medicinal gas (mixture) used therapeutically for oxygen supplementation.

Oxygen 93 Percent is produced from air by the molecular sieve process. It contains no less than 90.0 percent, and no more than 96.0 percent by volume of O_2; the remainder consisting mostly of argon and nitrogen.

CHAPTER 3 MINIMUM REQUIRED SPECIFICATIONS FOR MOBILE AND PORTABLE OXYGEN 93 PERCENT GENERATING SYSTEMS

3.1 TECHNOLOGY

Installations for the production of Oxygen 93 Percent on operations shall function on the principle of a molecular sieve.
This involves the so-called Pressure Swing Adsorption which is the most commonly used non-cryogenic concentration method for the production of oxygen from ambient or compressed air and also most effective for small and medium capacity production facilities.

The purification process works by using at least 2 columns filled with adsorbent, the molecular sieve, called zeolite. Pre-treated compressed air enters the first column and follows up through the zeolite. Nitrogen and some other gases are being trapped while the oxygen is allowed to flow through. When the active column is saturated, the air flow is directed to second column. The first column depressurizes allowing nitrogen to be purged out to the atmosphere and completely regenerates. The process is repeated continuously, when one column is productive, the other regenerates and at the end of each cycle they switch roles. The generator produces a constant flow of Oxygen 93 percent.

During the production process the oxygen content is continuously monitored by means of a paramagnetic analyser.

3.2 MOBILE OXYGEN GENERATING SYSTEM (MOGS)

Generating systems for Oxygen 93 Percent of this size are usually built in container hulls. The standard NATO container is defined as a 20 feet container.

MOGS shall comply with the following requirements:

- The system should be operational between -25 and +50 degrees Celsius so they can be fitted into shelters which are conditioned between 10 and 40 degrees Celsius (ideally 30 degrees Celsius) and at an altitude lower than 2000 metres above sea level;

- For safety reasons, the system must be developed within a conception of redundancy including 2 or more production lines, with cross-lining systems and a back-up source;

- The evacuation of connected pressurized gas containers prior to filling is recommended to prevent residual contamination of the newly filled gas batch in those containers;

- The filling rates of pressurized gas containers must be consistent with the number and capacity of containers to be filled to limit their heating-up in the process;

- The system must allow the production of Oxygen 93 Percent to fill pressurized gas containers;

- The quality of the oxygen produced must meet the regulations of the United States Pharmacopoeia – National Formulary (USP-NF) or the European Pharmacopoeia (Ph. Eur.) monographs, depending on the national legislation of the manufacturing member nation;

- The system should be equipped with a continuous monitoring unit. This is to ensure that the oxygen purity level, as well as the contents of CO and CO_2, remains within acceptable limits at all times.

3.3 PORTABLE OXYGEN GENERATING SYSTEM (POGS)

Generating systems for Oxygen 93 Percent of this size are usually built in appropriate transport boxes. Dimensions and weights may vary from nation to nation.

POGS shall comply with the following requirements:

- The system must be operational between 0 and 40 degrees Celsius;

- The system can be developed with at least 1 production line;

- The system must allow the production of Oxygen 93 Percent to be directly fed to a medical application (low pressure in order to supply patients' ventilators and 4-5 bar pressure to supply a distribution network);

- The quality of the oxygen produced must meet the regulations of the United States Pharmacopoeia – National Formulary (USP-NF) or the European Pharmacopoeia (Ph. Eur.) monographs, depending on the national legislation of the manufacturing member nation;

- The system should be equipped with a continuous monitoring unit. This is to ensure that the oxygen purity level, as well as the contents of CO and CO_2, remains within acceptable limits at all times.

3.4 PRESSURIZED CONTAINERS FOR OXYGEN 93 PERCENT

- All medical / medicinal gases stocked by NATO Forces will be held in cylinders termed pressurized containers;

- International standards (NF-EN 1089-3, ISO 5145) and colour codes are also applicable for Oxygen 93 Percent containers;

- Specific labelling “OXYGEN 93 PERCENT” USP or Ph. Eur. and traceability to be left to national discretion in accordance with national legislations but must include the minimum standard of serial number of the container and the batch number of the oxygen produced);

- Additionally, quality certificates must be delivered (specific document to be left to national discretion in accordance with national legislations and the respective pharmacopoeia);

- To be acceptable for refilling, delivered pressurized containers must contain a residual pressure to prevent damage or contamination.

INTENTIONALLY BLANK

CHAPTER 4 TECHNICAL ANALYSIS AND SAMPLING REGIME

4.1 QUALITY

Oxygen produced using MOGS or POGS must comply with the specifications given in the United States Pharmacopoeia or the European Pharmacopoeia monographs for “Oxygen 93 Percent” in their current versions.

4.2 ANALYSIS TECHNIQUES

All analysis of gases shall be referenced to conditions of 20°C, 101.3 kPa (1013 mbar). The exact analysis techniques used are described in the respective national Pharmacopoeias especially the United States Pharmacopoeia (USP) and the European Pharmacopoeia (Ph. Eur.). Test authorities and procedures shall have reached an approved standard. All equipment shall have traceable calibration standards.

MOGS and POGS shall be equipped with continuous online analysis monitoring (O_2 percentage, CO, CO_2). The monitored parameters should be documented electronically at least offline once in a production day. This documentation should be stored for 5 years.

The recommended minimum standard to identify other impurities (such as NO, NO_2, SO_2, Oil, H_2O, CO, CO_2) is the use of suitable detection tubes.

4.3 SAMPLING REGIME

Gas sampling should be conducted during production (within the Oxygen Generating Systems as in-process control) and from pressurized gas containers filled with this equipment. All batches produced should be tested. Additionally, sampling has to be conducted after each maintenance / repair of the production unit.
Evidence of correct sampling and analysis should be available at the time of the gas usage and be documented for at least 5 years.

INTENTIONALLY BLANK

CHAPTER 5 LEVELS FOR OXYGEN 93 PERCENT

Property	Units	NATO Grade
Oxygen	%	93 +/– 3,0%
Water	ppm (v)	< 67
Carbon monoxide	ppm (v)	< 5
Carbon dioxide	ppm (V)	< 300
Oil	mg/m^3	< 0.1
Nitrogen monoxide	ppm (V)	< 2
Nitrogen dioxide	ppm (V)	< 2
Sulfur dioxide	ppm (V)	< 1

Notes

- Where tolerances are expressed as percentages these are absolute values (i.e. of the total gas mixture) and not a percentage of the specified value.
- All containers used for Oxygen 93 Percent must not be filled with another gas than medicinal oxygen (99 or 93 percent) and in any case not with any toxic, sleep-inducing, or narcosis-producing compounds, or with any compound that will be irritating to the respiratory tract when the Oxygen 93 Percent is used.
- Particulate matter can arise from the internal surface of storage container and / or supply hoses.

INTENTIONALLY BLANK

ANNEX A – EUROPEAN PHARMACOPOEIA MONOGRAPH - OXYGEN 93 %

Oxygenium 93 per centum

O_2 M_r 32.00

DEFINITION

Content: 90.0 per cent *V/V* to 96.0 per cent *V/V* of O_2, 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.).

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*).

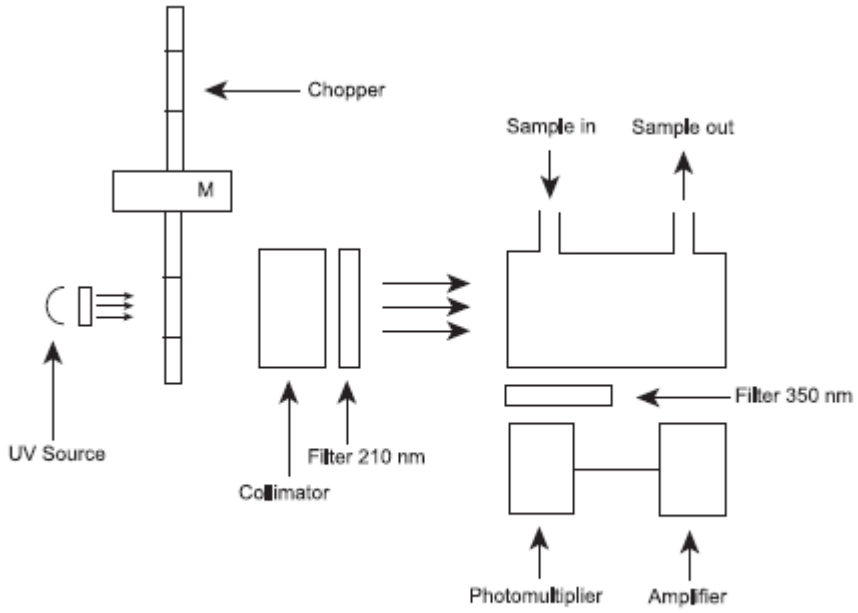

Figure 2455.-1. – *UV fluorescence analyser*

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. CO_2: carbon dioxide,

B. CO: carbon monoxide,

C. SO_2: sulfur dioxide,

D. NO and NO_2: nitrogen monoxide and nitrogen dioxide,

E. oil,

F. H_2O: water.

ANNEX B – UNITED STATES PHARMACOPOEIA 38 – MONOGRAPH
OXYGEN 93 PERCENT

Oxygen 93 Percent

DEFINITION

Oxygen 93 Percent is Oxygen produced from air by the molecular sieve process. It contains not less than 90.0 percent and not more than 96.0 percent, by volume of oxygen, the remainder consisting mostly of argon and nitrogen.

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 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

Sample gas: Oxygen 93 Percent under test

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

Analysis: Determine the concentration of oxygen in percentage by volume in Oxygen 93 Percent using a suitable paramagnetic analyser.

Acceptance criteria: 90.0% - 96.0% oxygen by volume

IMPURITIES

See Impurities Testing in Medical Gases Assay (413). The detector tubes called for are listed in Reagents, Indicators, and Solutions

Carbon dioxide

Sample: Detector tube manufacturer´s recommended volume +/-5% of Oxygen 93 Percent

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

Acceptance criteria: NMT 300 ppm

Carbon monoxide

Sample: Detector tube manufacturer´s recommended volume +/-5% of Oxygen 93 Percent

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

Acceptance criteria: NMT 10 ppm

ADDITIONAL REQUIREMENTS

Packaging and storage

Preserve in pressurized containers. Container connections shall be appropriate for Oxygen 93 Percent. Adaptors shall not be used to connect containers to patient use supply system piping or equipment.

Labeling

If Oxygen 93 Percent is piped from a remote location to the patient point of use, label each outlet “Oxygen 93 Percent”.

ANNEX C – COMPARISON BETWEEN US and EU PHARMACOPOEIAS

OXYGEN 93			
Monograph		**EUP (Ph. Eur.)**	**USP**
Name		Oxygen (93 per cent)	Oxygen 93 Percent
Chemical Formula		O_2	O_2
Definition		Oxygen 93% contains between 90.0% and 96% (V/V) of O_2. Remainder mainly consists of argon and nitrogen. Monograph applies to oxygen used on the site where produced. It does not apply to individual concentrators.	Oxygen 93 is oxygen produced from air by molecular sieve process. Contains NLT 90.0% and NMT 96.0% by volume of oxygen (O_2), the remainder consists mostly of argon and nitrogen.
Identification		Complies with the assay.	Complies with the assay.
Assay	Specification	90.0% ≤ O_2 ≤ 96.0% V/V	90.0% ≤ O_2 ≤ 96.0% V/V
	Analytical Method	Paramagnetic analyser	Paramagnetic analyser
Production parameters for contaminants			
CO	Limit	≤ 5 ppm V/V	Not specified
	Analytical Method	Infrared analyser	
CO_2	Limit	≤ 300 ppm V/V	
	Analytical Method	Infrared analyser	
H_2O	Limit	≤ 67 ppm V/V	
	Analytical Method	Electrolytic hygrometer	
NO/ NO_2	Limit	≤ 2 ppm V/V in total	
	Analytical Method	Chemiluminescence analyser	
SO_2	Limit	≤ 1 ppm V/V	
	Analytical Method	UV Fluorescence analyser	
Oil	Limit	≤ 01 mg/m^3	
	Analytical Method	Detector tube	
Purity tests for the product			
CO	Limit	≤ 5 ppm V/V	≤ 10 ppm
	Analytical Method	Detector tube	Detector tube
CO_2	Limit	≤ 300 ppm V/V	≤ 300 ppm
	Analytical Method	Detector tube	Detector tube
H2O	Limit	≤ 67 ppm V/V	Not specified
	Analytical Method	Detector tube	
NO/ NO_2	Limit	≤ 2 ppm V/V in total	
	Analytical Method	Detector tube	
SO_2	Limit	≤ 1 ppm V/V	
	Analytical Method	Detector tube	
Oil	Limit	≤ 01 mg/m3	
	Analytical Method	Detector tube	

.

AMedP-8.17(A)(1)