Gas Industries Association

Webinar on Standards, Testing Methods and conversions between Industrial and Medical Oxygen

Prasenjit Chakrabarti - Senior Manager- Quality, Linde South Asia,
Kolkata, 30th Apr 2021

Making our world more productive

Disclaimer

All publications of GIA or bearing GIA's name contain information, including Codes of Practice, safety procedures and other technical information that were obtained from sources believed by GIA to be reliable and/ or based on technical information and experience currently available from members of GIA and others at the date of the publication. As such, we do not make any representation or warranty nor accept any liability as to the accuracy, completeness or correctness of the information contained in these publications.

While GIA recommends that its members refer to or use its publications, such reference to or use thereof by its members or third parties is purely voluntary and not binding.

GIA or its members make no guarantee of the results and assume no liability or responsibility in connection with the reference to or use of information or suggestions contained in GIA's publications.

GIA has no control whatsoever as regards, performance or non performance, misinterpretation, proper or improper use of any information or suggestions contained in GIA's publications by any person or entity (including GIA members) and GIA expressly disclaims any liability in connection thereto.

GIA's publications are subject to periodic review and users are cautioned to obtain the latest edition.

Gas Industries Association

Difference between Oxygen I.P. (Medical Oxygen) and Industrial Oxygen

- ✓ The basic difference between Oxygen I.P. (Medical Oxygen) and Industrial Oxygen is in assuring the control as per the specification demanded in the finished product to achieve at with respect to the standard IP 2018.
- ✓ The process for manufacturing of Oxygen I.P. (Medical Oxygen) should be as per the requirements of “Schedule M” of Drugs and cosmetics Acts and Rules.
- ✓ The testing protocol as demanded by Indian Pharmacopoeia in its latest edition IP 2018 is should be followed in Oxygen I.P. (Medical Oxygen).
- ✓ To achieve this some process regulations are stringently followed in case of Oxygen I.P. (Medical Oxygen).

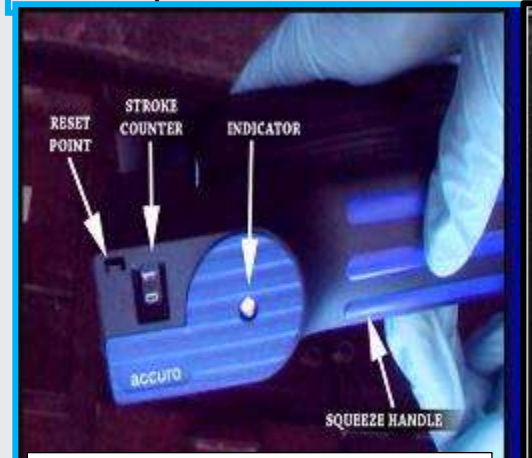
Specification of Oxygen I.P. (Medical Oxygen)

SL. No.	Characteristic	Specification	Testing Method
1	Identification	Conformance to identification test A, B and C	As ascribed in IP 2018
2	Carbon dioxide	Not more than 300 ppm (v/v)	Carbon dioxide detector tube method as ascribed in 2.1.1
3	Carbon monoxide	Not more than 5 ppm (v/v)	Carbon monoxide detector tube method as ascribed in 2.1.1
4	Water Vapour	Not more than 67 ppm (v/v)	Water Vapour detector tube method as ascribed in 2.1.1
5	Assay	The volume of residual gas is not more than 1.0 ml when 100 ml gas is taken. *	Method ascribed in 2.3.33**

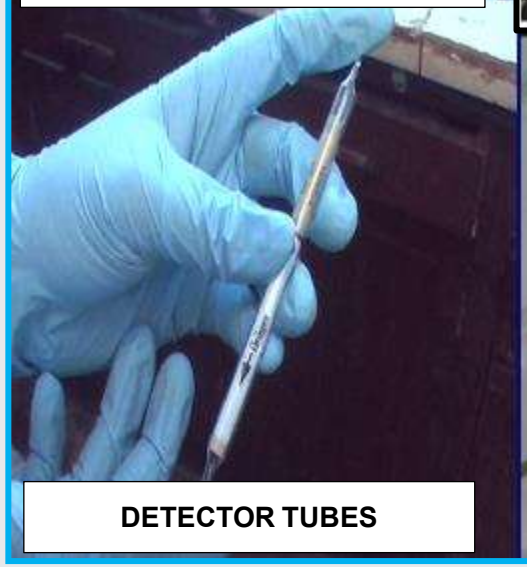
*Thus, Assay as O_2 is minimum 99.0 %(v/v)
**Classical absorption method commonly known as Orsat method.

Glimpse of Apparatus & Devices Required for Testing of Oxygen I.P.

A Glimpse of Detector Tube Testing : Oxygen IP



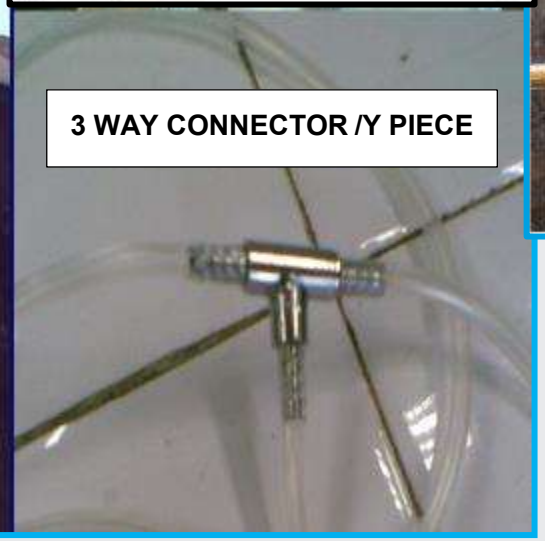
DETECTOR TUBE PUMP



DETECTOR TUBES

DETECTOR TUBES & EXPIRY INFO

TE



3 WAY CONNECTOR /Y PIECE

DETECTOR TUBE TEST FOR IMURITIES

ORSAT TEST SET FOR OXYGEN ASSAY

Standard to be maintained for Oxygen I.P. (Medical Oxygen)

- This product comes under purview of Drugs and Cosmetics Act 1940 & Rule 1945 as amended from time to time thereafter. Concerned Drugs department of the respective state issues licence for manufacture for sale.

- The process of manufacturing is aligned with GMP through the requirement stated in “Schedule M” of the said rule

- Each and every “Batch” is being tested and only after complying the specified limits as ascribed in IP 2018 the “Batch” is released.
- Storage – Stored under pressure in metal cylinders of the type conforming to the appropriate safety regulations.
- Labelling – As per the guideline of IP 2018

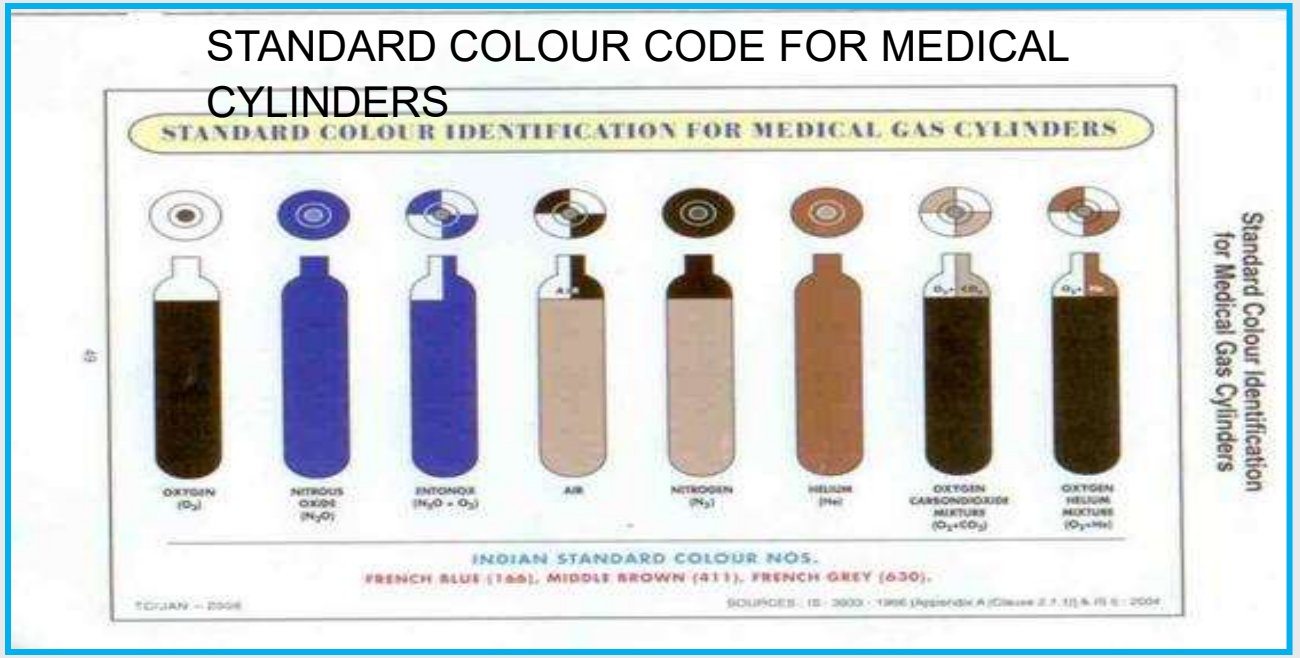
- Valves and taps should not be lubricated with oil or grease

- Requires chrome-plated valves as per IS requirement like IS : 3224 , IS 3745

Container appearance for Gaseous Medical Oxygen (Oxygen I.P.)

MEDICAL CYLINDER

STANDARD COLOUR CODE FOR MEDICAL CYLINDERS



INDUSTRIAL CYLINDER

Container appearance for Liquid Medical Oxygen (Oxygen I.P.)

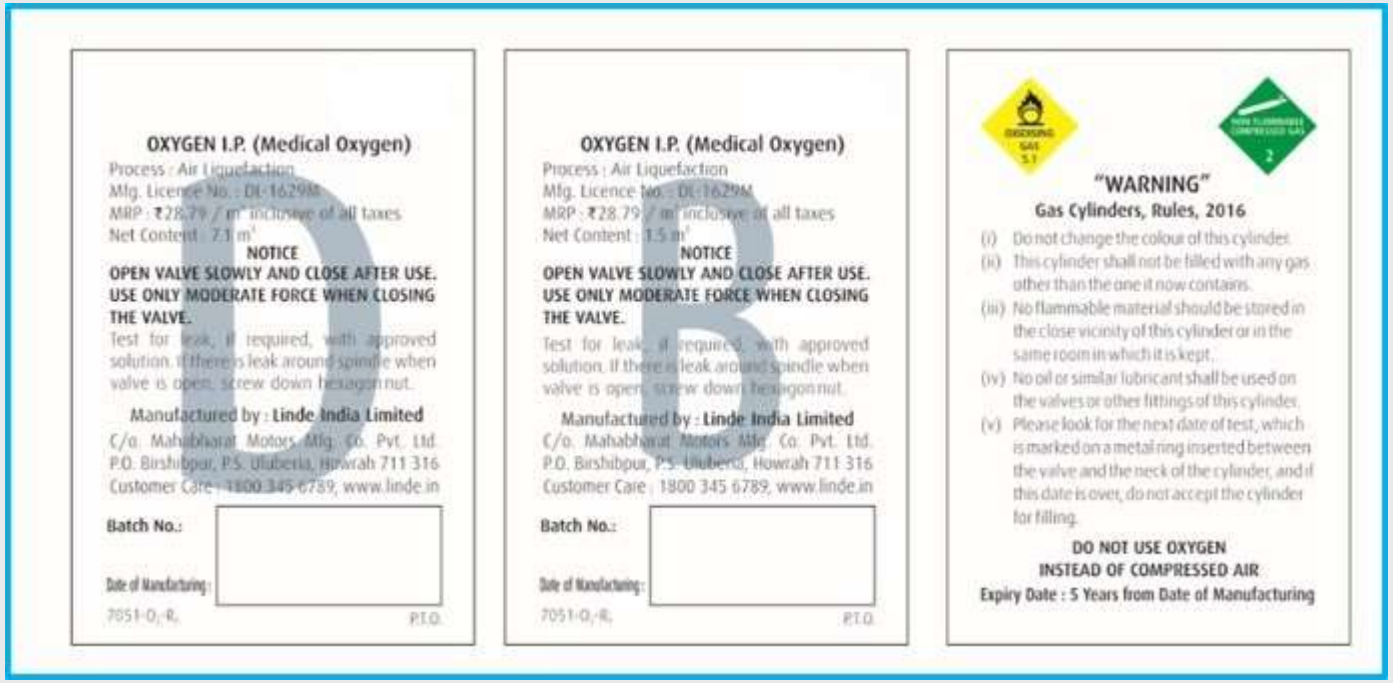
PORTABLE CRYOGENIC CONTAINE

CRYOGENIC ROAD TANKER

Cylinder labels and tags for Oxygen I.P. (Medical Oxygen)

- Labels are of high importance as Oxygen I.P is a Drug. Always Check the labels.
- No Label , No Acceptance

IP Tags



Specification of Oxygen 93 Per Cent

SL. No.	Characteristic	Specification	Testing Method
1	Identification	Conformance to identification test A, B and C	As ascribed in IP 2018
2	Carbon dioxide	Not more than 300 ppm (v/v)	Carbon dioxide detector tube method as ascribed in 2.1.1
3	Carbon monoxide	Not more than 5 ppm (v/v)	Carbon monoxide detector tube method as ascribed in 2.1.1
4	Assay	The volume of residual gas is not more than 10.0 ml and not less than 4.0when 100 ml gas is taken. * The remainder in assay test consisting mostly argon and nitrogen.	Method ascribed in 2.3.33**

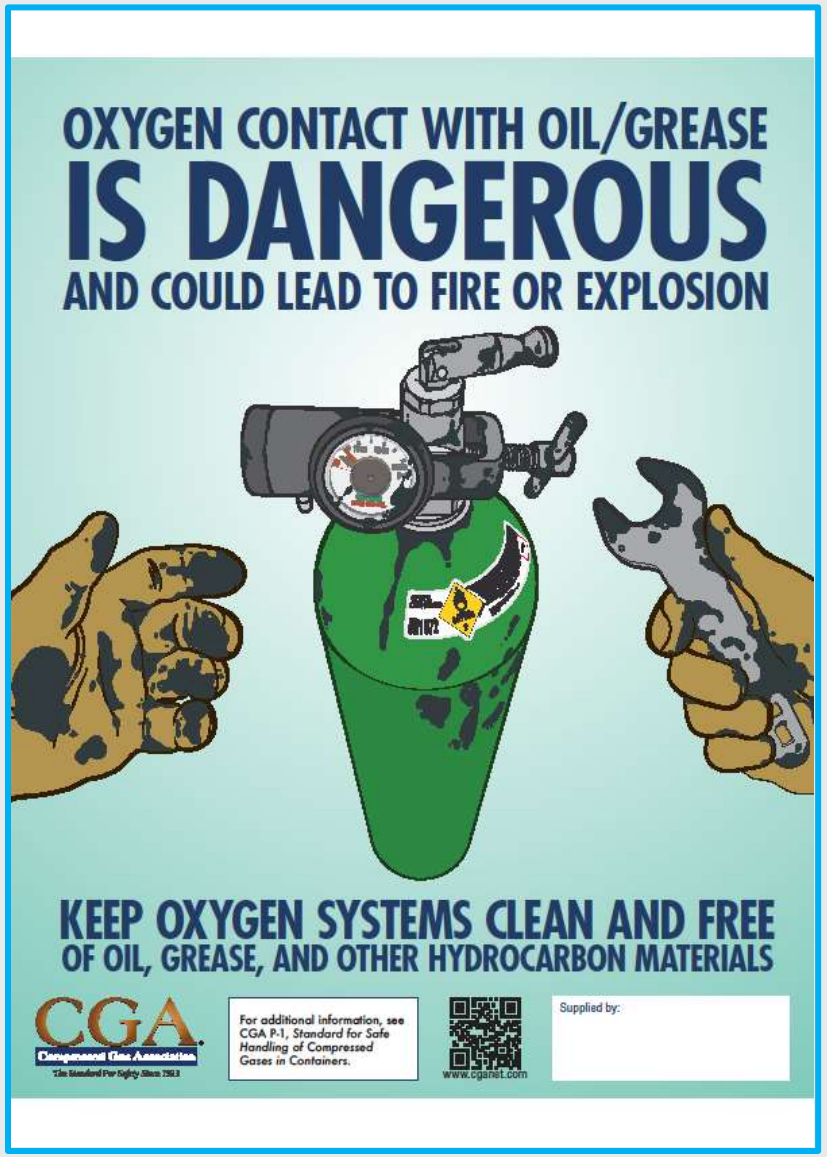
*Thus, Assay as O_2 is in the range 90.0 % -96.0% (v/v)
**Classical absorption method commonly known as Orsat method.

Standard to be maintained for Oxygen 93 Per Cent

- Storage – Cylinders / low pressure tanks are to be used. Containers used for Oxygen 93 Per cent must not be treated with any toxic , sleep-inducing and narcosis producing compounds and must not be treated with any compound that will be irritating to the respiratory tract when the Oxygen 93 Per Cent is used.

- Labelling – As per the guideline of IP 2018
  - Each outlet to be labelled as “Oxygen 93 Percent” when it is piped directly from the collecting tank to the point of use.
  - If it is through cylinder, the cylinder should carry a label stating “Oxygen 93 Per Cent” and “For medicinal use”.
- Valves and taps should not be lubricated with oil or grease

Oil Contamination – A must avoidable for any Oxygen Service



Testing Methods & Some Details (1)

- The common tests for both Oxygen I.P. and Oxygen 93 Per Cent are -
  - Assay (Purity Test) - This is to be done by classical method using ORSAT Apparatus as per section 2.3.33* of IP 2018
  - Impurities viz. CO and CO_2 the recommendation is Detector tube test to be carried out as per section 2.1.1 of IP 2018

- The additional impurity test recommended for Oxygen I.P. is water vapour
  - This “Water Vapour” test to be carried out by Detector tube test as per section 2.1.1 of IP 2018

Testing Methods & Some Details (2)

- The detector tube pump and “Y” piece are required for the testing of impurities along with suitable regulator to regulate the flow of gas.

- The detector tube pump function checking and detector tubes “expiry Information” checking is important prior to carry out the testing.

- The storage of the detector tubes as per manufacturers instruction is another important thing.

✓ Moreover, the testing and certification of the gas is of profound importance from the perspective of “Patient Safety” and so the control on the finished product is absolutely necessary

Conversion between Industrial and Medical Oxygen

- To convert Industrial oxygen to medical oxygen all the tests specified in “Slide No.3” need to be carried out.

- Only after conforming compliance to the specification (Slide No. 3, Column 3) the material can be declared as “Oxygen I.P.(Medical Oxygen)”
- The other requirements for this category is stated in “Slide No.5”
- In case the material is produced via PSA / Molecular sieve process , then the category changes to “Oxygen 93 Percent” the specification and other requirements there are stated in “Slide No. 8 & 9”

Note : The Industrial Oxygen and Medical oxygen can be both in liquid phase or gas phase.

Container Conversion from Industrial (Oxygen and Inert gas) to Medical Oxygen

- Container conversion should follow PESO guidelines be it a cylinder or a tanker –

- A memo (No.D-18019/Comp/Implementation dated 26th April 2021) has been circulated by PESO considering the COVID -19 unprecedented second wave on renewal of licenses under GCR 2016 and SMPV(U)Rules 2016 plus conversion of Liquid Nitrogen and Argon tankers to Liquid Oxygen Tankers with SOP for such conversion.

- A circular (No. D-21013/PBL/18-Exp dated 22nd April 2020) on Standard Operating Procedure for conversion of Industrial Oxygen Cylinders and Inert Gas Cylinders (Nitrogen, Argon and Helium only) to Medical Oxygen Cylinders has been issued.

Further checks for converting to Medical Oxygen

- For compressing and filling of the gases in the cylinders the certified raw material as " Oxygen I.P. (Medical Oxygen)" should be used. For that, if required a prior conversion is needed.

- For "Tanker" conversion also after filling with the certified raw material as " Oxygen I.P. (Medical Oxygen)" necessary tests as per IP 2018 (Slide No.3) to be conducted prior to "Release" for sell to customer.

One has to remember condition of storage and transport equipment are of profound importance and checks and balances are necessary to make sure that in such challenging situation also this is complied.

Key References

- Indian Pharmacopoeia 2018
- Drugs and Cosmetics Acts 1940 and Rule 1945 as amended from time to time there after
- IS 3224, IS 3745, IS 3933, IS 4379

<u>AIGA /EIGA /CGA References</u>

AIGA 049 - Guideline to medical Oxygen Supply system for healthcare facilities

AIGA 019 – Connections for Portable Liquid Cylinders

AIGA 024 – Connections for Transportable and Static Bulk Storage Tanks

AIGA 016 – Safety Features of Portable Cryogenic Liquid Containers for Industrial and Medical Gases

AIGA 059 – Use of Non-Metallic Materials in High Pressure Oxygen Breathing Gas Applications

AIGA 113-20 : Safe Design and Operation of Onsite Generation of O2 93% for Medical used

EIGA Doc 73/08/E Design Considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing systems

CGA M-1 2013 – Standard for Medical Gas Supply Systems at Healthcare Facilities

Thank you for your attention

Making our world more productive