



## STATEMENT

### THE SAFETY OF OXYGEN FOR MEDICAL USE

12 July, 2021

Government ministries of health and hospitals considering options for increasing the supply of medical oxygen to treat COVID-19 and other patients can procure and safely use oxygen from:

(1) Oxygen plants using Pressure Swing Adsorption (PSA) or Vacuum Swing Adsorption (VSA) technologies to generate 90 to 96% pure oxygen, which is often described as **Oxygen 93%**

(2) Air separation units using fractional distillation to produce cryogenic or liquid oxygen to generate not less than 99% pure oxygen, which is often described as **Oxygen 99%**

(3) Oxygen concentrators (bedside and portable) producing between **82% and 96% oxygen** purity<sup>1</sup>

**All of these methods of oxygen generation are safe for medical use at these levels of purity.**

The World Health Organization (WHO) is currently revising the monograph on Oxygen in [The International Pharmacopoeia](#) to include Oxygen 93% alongside Oxygen 99%.

The latest (June 2021) International Pharmacopoeia revision, "[Oxygen for Respiratory Care](#)," states:

*"Oxygen for respiratory care is generated by mixing Oxygen 93% or Oxygen 99% with ambient air of a suitable quality to a concentration appropriate for its intended medicinal use. Oxygen 93% contains not less than 90.0% and not more than 96.0% (v/v)<sup>2</sup> of O<sub>2</sub>, the remainder mainly consisting of argon and nitrogen. Oxygen 99% contains not less than 99.0 % (v/v) of O<sub>2</sub>."*

The updated revision more closely aligns the International Pharmacopoeia with the European Pharmacopoeia,<sup>3</sup> the US Pharmacopoeia,<sup>4</sup> [ISO Standard 7396-1:2016](#),<sup>5</sup> and the WHO [Technical Specifications for Pressure Swing Adsorption \(PSA\) Oxygen Plants](#), published in June 2020.<sup>6</sup>

WHO has released the revision for public consultation during July and August 2021 and plans to submit the revision to the 56th meeting of the Expert Committee on Specifications for Pharmaceutical Preparations in October 2021.

The International Pharmacopoeia has legal status whenever a national or regional government authority introduces it into appropriate legislation.

<sup>1</sup> Oxygen concentrator specifications are not covered by the International Pharmacopoeia but can be found in [WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices](#), June 2019. See: [https://www.who.int/medical\\_devices/publications/tech\\_specs\\_oxygen\\_therapy\\_devices/en/](https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/)

<sup>2</sup> % v/v means volume per volume and measures the concentration of a solution.

<sup>3</sup> 93% Oxygen Monograph: European Pharmacopoeia, Supplement 7.1, 2011. See: <http://www2.sol.it/AreaClienti/solconsulting/consulting/farmacopea/dwn/oss93.pdf>

<sup>4</sup> Oxygen 93%: US Pharmacopoeia. Monograph 5231, 2016. See [http://ftp.uspbpep.com/v29240/usp29nf24s0\\_m59560.html](http://ftp.uspbpep.com/v29240/usp29nf24s0_m59560.html)

<sup>5</sup> The International Organization for Standardization (ISO) is an international standard-setting body composed of representatives from various national standards organizations to develop and publish worldwide technical, industrial, and commercial standards.

<sup>6</sup> See: [https://www.who.int/publications/i/item/technical-specifications-for-pressure-swing-adsorption\(psa\)-oxygen-plants](https://www.who.int/publications/i/item/technical-specifications-for-pressure-swing-adsorption(psa)-oxygen-plants)

Given the current oxygen shortages that many LMICs are experiencing as a result of the pandemic, and the tragic loss of life that results, it is vital that governments ensure national laws and regulations are consistent with the revised International Pharmacopoeia so that they can increase the supply of medical oxygen quickly and safely from multiple sources - liquid, PSA/VSA plant, and/or concentrators.

Every Breath Counts has received reports that there is still a widespread belief among LMIC government and hospital officials that medical oxygen below 99% is not safe for medical use.

Our major concern is that this mistaken view is limiting access to medical oxygen as technologies which produce oxygen below 99% (e.g., PSA/VSA plants) are restricted from supplying hospitals limiting overall oxygen availability and increasing deaths from COVID-19 and other causes.

We believe that with greater clarity, the revised International Pharmacopoeia could make a major contribution to correcting the common misconception that lower oxygen concentrations are less effective for a patient and give governments and hospitals more confidence that they have several options to maximize oxygen supply during the pandemic and beyond.

Oxygen is a WHO **essential medicine** with many applications. It is used to treat respiratory illnesses like COVID-19 and pneumonia, other infections like malaria, HIV/AIDS, and tuberculosis, and chronic conditions like chronic obstructive pulmonary disorder (COPD). It is also essential for emergency care and surgery, including during childbirth.

The multiple applications for oxygen make it a vital foundation for quality national health system.

The countries that ensure that all health facilities have adequate oxygen to treat every patient who needs it will not only reduce COVID-19 case fatality rates but will also make faster progress to achieving most of the health-related Sustainable Development Goals.

**Special notes:**

- (I) Oxygen purity is not the same as the percentage of oxygen a patient actually receives during treatment. This is called the fraction of inspired oxygen, or FiO<sub>2</sub>, which is the percentage of oxygen that enters a patient's body when medical oxygen is mixed with room air in the process of inhalation or when healthcare providers "blend" it for patients. FiO<sub>2</sub>s typically range between 21% (the % of oxygen in normal air) and 50%, but can reach 100%. FiO<sub>2</sub> is calculated as a percentage of the total flow (liters per minute or LPM) of air a patient receives, which depends on the oxygen delivery device and other factors. For example, nasal cannula can deliver up to 44% FiO<sub>2</sub> at flows of 6LPM, venturi masks up to 60% FiO<sub>2</sub> at flows of 15LPM, and high flow nasal cannula up to 100% FiO<sub>2</sub> at flows of 60LPM. FiO<sub>2</sub> of 100% is never sustained for long periods of time.
- (II) Oxygen purity is not the same as the percentage of oxygen in a patient's blood. This is called the saturation of peripheral oxygen, or SpO<sub>2</sub>, and a safe range is typically between 95% and 100%. Measurements of less than 95% could indicate that a patient has "hypoxemia," which is a deficiency in the amount of oxygen in the blood that can lead to death if it progresses to hypoxia, or low levels of oxygen in the tissues. SpO<sub>2</sub> is typically measured by using a pulse oximeter.
- (III) Oxygen purity is not the same as lack of contamination from other types of gases, oil, grease, bacteria and other materials in the oxygen supply and/or in the cylinder or in the tank that oxygen is stored in and/or piped through. Medical oxygen has to be tested both for oxygen purity as well as for contamination. This results in what is known as a "C of A" – a certificate of analysis – which should always be provided to the purchaser of the product.

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