Acceptance criteria: Between 20.2% and 21.5% of $C_{18}H_{21}NO_4$, in the Oxycodone Terephthalate, calculated on the dried basis

- **Loss on Drying** ⟨731⟩: Dry it at 105° for 4 h: it loses NMT 1.5% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Oxycodone RS

Oxygen

⟨Comment on this Monograph⟩

O_2 32.00
Oxygen
Oxygen [7782-44-7].

DEFINITION

Oxygen contains NLT 99.0% of O_2, by volume.
[NOTE—Oxygen that is produced by the air-liquefaction process is exempt from the requirements of the tests for *Carbon dioxide* and *Carbon monoxide*.]

IDENTIFICATION

- **A. Procedure**
  When tested as directed in the *Assay*, NMT 1.0 mL of gas remains.
- **B. Procedure**
  Analysis: Pass 100 ± 5 mL released from the vapor phase of the contents of the Oxygen container through a carbon dioxide detector tube at the rate specified for the tube.
  Acceptance criteria: No color change is observed (distinction from carbon dioxide).

ASSAY

- **Procedure**
  Sample: Oxygen
  Analysis: Place a sufficient quantity of ammonium chloride–ammonium hydroxide solution, prepared by mixing equal volumes of water and ammonium hydroxide and saturating with ammonium chloride at room temperature, in a test apparatus composed of a calibrated 100-mL buret, provided with a two-way stopcock, a gas absorption pipet, and a leveling bulb, both of suitable capacity and all suitably interconnected. Fill the gas absorption pipet with metallic copper in the form of wire coils, wire mesh, or other suitable configuration. Eliminate all gas bubbles from the liquid in the test apparatus. Activate the test solution by performing two or three tests that are not for record purposes. Fill the calibrated buret, all interconnecting tubing, both stopcock openings, and the intake tube with liquid. Draw 100.0 mL of *Sample* into the buret by lowering the leveling bulb. Open the stopcock to the absorption pipet, and force the *Sample* into the absorption pipet by raising the leveling bulb. Agitate the pipet to provide frequent and intimate contact of the liquid, gas, and copper. Continue agitation until no further diminution in volume occurs. Draw the residual gas back into the calibrated buret, and measure its volume.
  Acceptance criteria: NMT 1.0 mL of gas remains.

SPECIFIC TESTS

- **Odor**
  Sample: Oxygen
  Analysis: Carefully open the container valve to produce a moderate flow of gas. Do not direct the gas stream toward the face, but deflect a portion of the stream toward the nose.
  Acceptance criteria: No appreciable odor is discernible.
- **Carbon Dioxide**
  Sample: 1000 ± 50 mL of Oxygen
  Analysis: Pass *Sample* through a carbon dioxide detector tube at the rate specified for the tube.
  Acceptance criteria: The indicator change corresponds to NMT 0.03%.
- **Carbon Monoxide**
  Sample: 1000 ± 50 mL of Oxygen
  Analysis: Pass *Sample* through a carbon monoxide detector tube at the rate specified for the tube.
  Acceptance criteria: The indicator change corresponds to NMT 0.001%.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in cylinders or in a pressurized storage tank. Containers used for Oxygen must not be treated with any toxic, sleep-inducing, or narcosis-producing compounds, and must not be treated with any compound that will be irritating to the respiratory tract when the Oxygen is used.
  [NOTE—Reduce the container pressure by means of a regulator. Measure the gases with a gas volume meter downstream from the detector tube to minimize contamination or change of the specimens.]
- **Labeling:** Label it to indicate whether or not it has been produced by the air-liquefaction process. Where it is piped directly from the cylinder or storage tank to the point of use, label each outlet "Oxygen."
  [NOTE—The various detector tubes called for in the respective tests are listed under *Reagents* in the *Reagents, Indicators, and Solutions* section.]

Oxygen 93 Percent

⟨Comment on this Monograph⟩

DEFINITION

Oxygen 93 Percent is Oxygen produced from air by the molecular sieve process. It contains NLT 90.0% and NMT 96.0%, by volume, of O_2, the remainder consisting mostly of argon and nitrogen.

IDENTIFICATION

- **A. Procedure**
  When tested as directed in the *Assay*, NMT 10.0 mL and NLT 4.0 mL of gas remains.
- **B. Procedure**
  Analysis: Pass 100 ± 5 mL released from the vapor phase of the contents of the Oxygen 93 Percent container or from the outlet at the point of use through a carbon dioxide detector tube at the rate specified for the tube.
  Acceptance criteria: No color change is observed (distinction from carbon dioxide).

ASSAY

- **Procedure**
  Analysis: Place a sufficient quantity of ammonium chloride–ammonium hydroxide solution, prepared by mixing equal volumes of water and ammonium hydroxide and saturating with ammonium chloride at room temperature, in a test apparatus composed of a calibrated 100-mL buret, provided with a two-way stopcock, a gas absorption pipet, and a leveling bulb, both of suitable capacity and all suitably interconnected. Fill the gas absorption pipet with metallic copper in the form of wire coils, wire mesh, or other suitable configuration. Eliminate all gas bubbles from the liquid in the test apparatus. Activate the test solution by performing two or three tests that are not for record

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purposes. Fill the calibrated buret, all interconnecting tubing, both stopcock openings, and the intake tube with liquid. Draw 100.0 mL of Oxygen 93 Percent into the buret by lowering the leveling bulb. Open the stopcock to the absorption pipet, and force the Oxygen 93 Percent into the absorption pipet by raising the leveling bulb. Agitate the pipet to provide frequent and intimate contact of the liquid, gas, and copper. Continue agitation until no further diminution in volume occurs. Draw the residual gas back into the calibrated buret, and measure its volume.
Acceptance criteria: NMT 10.0 mL and NLT 4.0 mL of gas remains.

SPECIFIC TESTS

- **Odor**
  Analysis: Carefully open the container valve or system outlet to produce a moderate flow of gas. Do not direct the gas stream toward the face, but deflect a portion of the stream toward the nose.
  Acceptance criteria: No appreciable odor is discernible.
- **Carbon Dioxide**
  Sample: Oxygen 93 percent
  Analysis: Pass 1000 ± 50 mL through a carbon dioxide detector tube at the rate specified for the tube.
  Acceptance criteria: The indicator change corresponds to NMT 0.03%.
- **Carbon Monoxide**
  Sample: Oxygen 93 percent
  Analysis: Pass 1000 ± 50 mL through a carbon monoxide detector tube at the rate specified for the tube.
  Acceptance criteria: The indicator change corresponds to NMT 0.001%.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in cylinders or in a low pressure collecting tank. Containers used for Oxygen 93 Percent must not be treated with any toxic, sleep-inducing, or narcosis-producing compounds, and must not be treated with any compound that will be irritating to the respiratory tract when the Oxygen 93 Percent is used.
- **Labeling:** Where it is piped directly from the collecting tank to the point of use, label each outlet "Oxygen 93 Percent."
  [Note—The various detector tubes called for in the respective tests are listed in the *Reagents, Indicators, and Solutions—Reagents*.]
  Where it is preserved in cylinders, reduce the pressure by means of a regulator. Measure the gases with a gas volume meter downstream from the detector tube in order to minimize contamination or change of the specimens.

Water O 15 Injection

Assignment of an USAN *is pending.*

DEFINITION

Water O 15 Injection is a sterile solution of $H_2{}^{15}O$ in Sodium Chloride Injection suitable for intravenous injection, in which a portion of the molecules are labeled with radioactive ^{15}O (see *Radiopharmaceuticals for Positron Emission Tomography—Compounding* ⟨823⟩). It contains NLT 90.0% and NMT 110.0% of the labeled amount of ^{15}O expressed in MBq/mL (or mCi) at the time indicated in the labeling.

IDENTIFICATION

- **A. Radioactivity,** *Identification and Assay of Radionuclides* ⟨821⟩: Its half-life, determined using a suitable detector system, is between 1.83–2.08 min.
- **B. Radiochemical Identity:** The retention time of the major peak in the *Sample solution* corresponds to that of the water contained within the product formulation, as obtained in the test for Radiochemical purity.

ASSAY

- **Radioactivity** ⟨821⟩
  Analysis: Using a suitable calibrated system, determine the radioactivity of the Injection, in MBq/mL (or mCi).
  Acceptance criteria: 90.0%–110.0% of the labeled amount of ^{15}O

IMPURITIES

Inorganic Impurities

- **Heavy Metals,** *Method I* ⟨231⟩: NMT 5 ppm

Organic Impurities

- **Procedure 1: Radiochemical Purity**
  Chromatographic system
  (See *Chromatography* ⟨621⟩.)
  Mode: GC
  Detector: Thermal conductivity and radioactivity
  Column: 0.53-mm × 30-m column coated with a film of G16 stationary phase
  Temperature
  Column: 40°
  Injector: 200°
  Detector: 250°
  Carrier gas: Helium
  Flow rate: 10 mL/min
  Injection size: 50 µL
  System suitability
  Sample: *Sample solution*
  [Note—Measure the responses for the major peaks of both the radioactive and the nonradioactive detection systems (the volume of Injection being adjusted, if necessary, to obtain suitable detection system sensitivity).]
  Suitability requirements
  Column efficiency: NLT 10,000 theoretical plates
  Tailing factor: NMT 1.5
  Relative standard deviation: NMT 5.0%
  Acceptance criteria: NLT 95% of the radioactivity is Water O 15, and the retention time of the Water O 15 corresponds to the retention time of the water within the product formulation.
- **Procedure 2: Radioactivity,** *Radionuclidic Purity, Selection of a Counting Assembly* ⟨821⟩: Using a gamma-ray spectrometer, count an appropriate aliquot of the Injection for a period of time sufficient to obtain a gamma spectrum. The resultant gamma spectrum should be analyzed for the presence of identifiable photopeaks which are not characteristic of ^{15}O emissions. NLT 99.5% of the observed gamma emissions should correspond to the 0.511 MeV, 1.022 MeV, or Compton scatter peaks of ^{15}O.
- **Procedure 3: Chemical Purity:** This article can be synthesized by different methods and processes and, therefore, may contain different impurities. The presence of unlabeled ingredients, reagents, and by-products specific to the process must be controlled, and their potential for physiological or pharmacological effects must be considered.

SPECIFIC TESTS

- **Bacterial Endotoxins Test** ⟨85⟩: It contains NMT 175/*V* Endotoxin Unit per mL of Injection, in which *V* is the maximum administered total dose, in mL, at the expiration time.
- **Radiopharmaceuticals for Positron Emission Tomography—Compounding,** *Sterilization and Sterility Assurance* ⟨823⟩: It contains NMT 175/*V* Endotoxin Unit per mL of Injection, in

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