राजस्थान सरकार चिकित्सा एवं स्वास्थ्य विभाग औषधि परीक्षण प्रयोगशाला, राजस्थान

(कार्यालय : राजकीय विश्लेषक राजस्थान, सेठी कॉलोनी, जयपुर-04)

क्रमांकः डीटीएल/2018/५७५

दिनांकः 14/8/17

औषधि नियंत्रक राजस्थान, जयपुर।

विषय:— दैनिक भारकर दिनांक 9/05/2018 में प्रकाशित समाचार ''नियम तो आक्सीजन की शुद्धता जॉचने के भी, लेकिन कभी सैम्पल ही नहीं लिया'' के संदर्भ में तथ्यात्मक विवरण

सदर्भ:-आपका पत्रांक डी सी/डी-3/एक-लूज (सर्म्पक पोर्टल) 2018/296 दिनांक 19/07/2018 तथा राजस्थान सर्म्पक परिवाद क्रमांक 05180533655848

उपरोक्त विषय एवं संदर्भ में तथ्यात्मक विवरण निम्न प्रकार है:-

इण्डियन फार्माकोपिया 2014 में आक्सीजन 93 प्रतिशत के मानक तय है तथा आवश्यक उपकरणों का विवरण उपलब्ध है। प्रयोगशाला में आज दिनांक तक कोई नमूना जॉच हेतु प्राप्त नहीं हुआ हैं निर्धारित मानकों के अनुसार प्रयोगशाला में आवश्यक उपकरण भी उपलब्ध नहीं है। मानक के विवरण हेतु छायाप्रति संलग्न कर प्रेषित है।

संलग्नः-छायाप्रति

१५/१८ उपनिदेशक औषधि परीक्षण प्रयोगशाला अटराजस्थान, जयपुर।

Oxygen

02

Mol. Wt. 32.0

Oxygen contains not less than 99.0 per cent v/v of O₂.

This monograph applies to oxygen for medicinal use only.

Description. A colourless gas; odourless.

Identification

A. A glowing splinter of wood bursts into flame on contact with the gas.

B. Shake with *alkaline pyrogallol solution*; the gas under examination is absorbed and the solution becoming dark brown.

C. When tested as described in the Assay, not more than $1.0\,\mathrm{ml}$ of gas remains.

Tests

Carbon dioxide. Not more than 300 ppm v/v, determined by using a carbon dioxide detector tube (2.1.1).

Carbon monoxide. Not more than 5 ppm v/v, determined by using a carbon monoxide detector tube (2.1.1).

Water vapour. Not more than 67 ppm v/v, determined by using a water vapour detector tube (2.1.1).

Assay (2.3.33). Use 100 ml of the gas under examination and place spirals of freshly cleaned copper wire and 125 ml of ammonia buffer pH 10.9 in the pipette. The volume of the residual gas in the burette is not more than 1.0 ml.

Storage. Store under pressure in metal cylinders of the type conforming to the appropriate safety regulations. Valves and taps should not be lubricated with oil or grease.

Labelling. The shoulder of the metal cylinder should be painted white and the remainder should be painted black. The cylinder should carry a label stating "Oxygen". In addition, "Oxygen" or the symbol "O₂" should be stencilled in paint on the shoulder of the cylinder.

Oxygen 93 Per Cent

Oxygen 93 per Cent contains not less than 90.0 per cent and not more than 96.0 per cent, v/v of O_2 , the remainder consisting mostly of argon and nitrogen. It is produced from air by the molecular sieve process.

Description. A colourless gas; odourless.

Identification

A. A glowing splinter of wood bursts into flame on contact with the gas.

B. Shake with alkaline pyrogallol solution; the gas under examination is absorbed and the solution becomes dark brown.

C. When tested as described in the Assay, not more than 10.0 ml and not less than 4.0 ml of gas remain.

Test

Carbon dioxide. Not more than 300 ppm v/v, determined by using a *carbon dioxide detector tube* (2.1.1).

Carbon monoxide. Not more than 5 ppm v/v, determined by using a *carbon monoxide detector tube* (2.1.1).

Assay (2.3.33). Use 100 ml of the gas under examination and place spirals of freshly cleaned copper wire and 125 ml of ammonia buffer pH 10.9 in the pipette. The volume of the residual gas in the burette is not more than 10.0 ml and not less than 4.0 ml.

Storage. Store in cylinders or in a low pressure collecting tank. Containers used for Oxygen 93 Per Cent 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 Per Cent is used.

Labelling. Label each outlet "Oxygen 93 Per Cent", when it is piped directly from the collecting tank to the point of use. If it is stored 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 minimise contamination or change of the specimens. The shoulder of the cylinder should be painted white and the remainder should be painted black. The cylinder should carry a label stating "Oxygen 93 Per Cent" and "For medicinal use".

Oxytetracycline Dihydrate

Oxytetracycline

C22H24N2O9,2H2O

Mol. Wt. 496.5

Oxytetracycline is (4S,4aR,5S,5aR,6S,12aS)-4-dimethyl amino-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxonaphthacene-2-carboxamide dihydrate, a substance produced by the growth of certain strains of *Streptomyces rimosus* or obtained by any other means. It contains a variable quantity of water.