

POSITION STATEMENT

FDA ESTABLISHMENT REGISTRATION AND LISTING FOR MIXTURES OF DESIGNATED MEDICAL GASES

Introduction

The U.S. Food and Drug Administration (FDA) drug registration and listing regulations, Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 207, do not address the unique properties of designated medical gas mixtures. Certain accommodations as presented in this position are made to conform with FDA's requirements for electronic registration and listing submissions [1].

Question 1

What is the active ingredient for drug mixtures of designated medical gases?

Answer 1

Oxygen is the active ingredient for drug mixtures of designated medical gases because of oxygen's life sustaining property.

Question 2

Because medical air is manufactured by two different methods (i.e., by compression and reconstitution) what is listed as the active ingredient for each method of manufacture?

Answer 2

For medical air manufactured by compression, air (100%) is listed as the active ingredient.

For medical air manufactured by reconstitution (synthetically blended), oxygen (21%) is listed as the active ingredient and nitrogen is listed as the inactive ingredient.

Question 3

What is the active ingredient in drug mixtures of designated medical gases when air is used as the balance gas?

Answer 3

When drug mixtures of designated medical gases include air as the balance gas, oxygen is listed as the active ingredient. The mixture is manufactured to ensure a nominal 21% oxygen concentration. For example, a 20% carbon dioxide in air mixture would be manufactured as a 20% carbon dioxide, 21% oxygen, balance nitrogen mixture.

When a different nominal percent oxygen is requested by the physician/customer the manufacturer will not consider this a balance air mixture but will identify each of the components. Oxygen is still listed as the active ingredient.

Question 4

How do you list drug mixtures of designated medical gases that have a range(s) with multiple component concentrations?

Answer 4

When drug mixtures of designated medical gases have a range of concentrations a listing with the oxygen concentration in the middle of that range shall be used provided that all concentrations in the range use the same

label. For example, if a 15% oxygen balance nitrogen mix and a 20% oxygen balance nitrogen mix are manufactured the drug listing will indicate 18% oxygen.

When drug mixtures of designated medical gases have a range of concentrations that are significantly different, requiring different labels, each mixture shall be listed separately. To be consistent with CGA C-7, *Guide to Classification and Labeling of Compressed Gases* if the text of the label is substantively different for opposite ends of a mixture range, submit each label under its own listing (for example 20% oxygen balance nitrogen uses a different label than 30% oxygen balance nitrogen) [2].

Question 5

How should concentrations of active ingredients be listed?

Answer 5

The active ingredient strength should indicate the number of liters per 100 liters (20% oxygen in nitrogen is listed as 20 liters per 100 liters).

References

Unless otherwise specified, the latest edition shall apply.

[1] *Code of Federal Regulations*, Title 21 (Food and Drugs), U.S. Government Printing Office. www.gpo.gov

[2] CGA C-7, *Guide to Classification and Labeling of Compressed Gases*, Compressed Gas Association, Inc. www.cganet.com

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