

**- Comments Paper -**  
**Feedback Regarding USP Proposed Revisions**  
**To Medical Gas Monographs PF 35(4)**  
**(as of 7 July 2009)**

The proposed revisions to the medical gas monographs in PF 35(4) are generally significant improvements to the antiquated methodology in earlier versions of USP. The following suggestions seek to correct the typos and inconsistencies in the proposals. The basic analytical concepts of the proposed revisions are not challenged.

**Helium, USP**

**Helium Comment #1:**

The column proposed is 2.1-mm × 3.6-m; packing 80/100 mesh S3. This is inconsistent with the other similar analyses using the S3 column, nitrous oxide.

**Suggest** – using the same column as nitrous oxide: “2.1-mm × 2.4-m; packing 80/100 mesh S3”

**Helium Comment #2:**

The column temperature was not specified.

**Suggest** – using the same column conditions as nitrous oxide, 70 °C

**Helium Comment #3:**

The system suitability test specifies: “The resolution between nitrogen and oxygen. The S3 column does not separate nitrogen from oxygen.”

**Suggest** – Delete this system suitability requirement. Resolution is only appropriate where two peaks are compared.

**Helium Comment #4:**

The system suitability test specifies: “Retention time: The retention time of the peak response for the Sample gas corresponds to that of the Standard gas.” The

retention time of the helium peak is meaningless since there is no peak. If the retention time of the air impurity is what was intended, this is a problem as well since the sample likely will not contain air about the limit of detection.

**Suggest** – using the following, “Retention time: The retention time of the air peak response (if any) for the Sample gas corresponds to that of the air peak in the Standard gas.”

#### **Helium Comment #5:**

The calculation for the helium assay was listed as:

$$\text{Result} = 100 - (r_U/r_S)$$

$r_U$  = peak response from the Sample gas

$r_S$  = peak response from the Standard gas

**Suggest** – The formula should read:

$$\text{Result} = 100 - ((r_U/r_S) * \text{Std})$$

$r_U$  = peak response from the Sample gas

$r_S$  = peak response from the Standard gas

Std = concentration of the air in the Standard gas

#### **Nitrous Oxide, USP**

##### **Nitrous Oxide Comment #1:**

The temperature (70 deg C) is specified for the column, injector, and detector.

The injection type is specified to be a gas sampling loop. Many GCs do not have the ability to heat the gas sampling loop ... and it is not important for gas phase samples anyway.

**Suggest** – Delete the requirement to heat the injector.

##### **Nitrous Oxide Comment #2:**

One of the system suitability requirements lists the “Relative retention time: NLT 1.5.”

**Suggest** – Reword this to read that the “Relative retention time between the nitrous oxide and air peaks: NLT 1.5.”

## **Nitrogen, NF**

### **Nitrogen Comment #1:**

The column proposed is 2.1-mm × 2.4-m; packing 80/100 mesh S3. The specified column will not separate the oxygen impurities from the nitrogen.

**Suggest** – Use the following column: 2.1-mm × 2.4-m; packing 80/100 mesh molecular sieve.

### **Nitrogen Comment #2:**

The system suitability requirements state: “Retention time: The oxygen peak response from the Sample exhibits a retention time corresponding to that from the Standard.” It is likely that no oxygen peak will be observed since the nitrogen typically produced has very low ppm oxygen impurities.

**Suggest** –Reword to the following: “Retention time: The oxygen peak response from the Sample (if any) exhibits a retention time corresponding to that from the Standard.”

### **Nitrogen Comment #3:**

Under impurities, the proposed revision lists the testing for carbon monoxide. The text includes the following, “Analysis: Pass the Sample through a carbon dioxide detector tube at the rate specified for the tube.”

**Suggest** –Reword to the following: “Analysis: Pass the Sample through a carbon monoxide detector tube at the rate specified for the tube.”