GAWDA USP/NF Proposed Revision Update

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Before we start…..

FDA Electronic Registration and Listing

- We attended a six hour FDA training session this week
- Drafted GAWDA SOPs to register and list
- Ten GAWDA members are road-testing the SOPs. We will revise as needed and post SOPs online
- We will also hold a Webinar when the SOPs are ready for use

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Agenda

This presentation is designed for medical gas manufacturers. Some parts of the proposal are omitted because they do not apply to us.

- USP/NF Revision Process/Timeline
- Monograph Proposals
  - *Only differences discussed*
- General Chapter Proposals
- What's Next?

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USP/NF Revision Process/Timeline

- CGA provided significant input into the present proposals
- USP uses a highly structured (slow) process to revise it's monographs
- Proposed revisions are published in Pharmacopeial Forum (PF) six times per year
- Public comment is invited

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USP/NF Revision Process/Timeline

- This issue PF 35(4)
- 90 day comment period - October 15, 2009
- Targeted official publication - USP 33–NF 28, 2nd Supplement
  - Release Date - June 2010
  - Official date - December 1, 2010
- Future teleconferences as content/process changes

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Medical Air (19.5% to 23.5% Oxygen)

- Electrochemical cell analyzer
- A paramagnetic analyzer
  - Zero gas: Nitrogen certified standard
  - Span gas: 21% oxygen in nitrogen certified standard
- Simplified the detector tube instructions
- No impurity testing if USP O_2 and NF N_2 are blended

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Helium

- ID – burning splint and buoyancy test
- Assay – GC with 4-mm × 6-m porous polymer column
- ID – absence of any peak on the chromatogram over 0.1% (4x Air RT)
- Assay – GC with 2.1-mm × 3.6-m S3 column, 30 ml/min (typo?)
- System Suitability
  - Rs 2.0 (O_2/N_2????)
  - RT Comparison
- Slight change in calculations

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Nitrous Oxide

- ID
  - Pressure differential
  - CO_2 Detector Tube
  - Pyrogallol test
- Assay – GC with 4-mm × 6-m porous polymer column
- ID – passes assay
- Assay
  - GC with 2.1-mm × 2.4-m S3 column
  - Col/Det/Inj 70 °C
  - 30 ml/min carrier
  - Gas sampling loop
- System Suitability
  - Rs 1.5 (Air/N_2O)
  - Relative RT 1.5

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Oxygen

- Assay – Orsat, ammonium chloride-ammonium hydroxide solution
- Assay – a paramagnetic analyzer for oxygen
  - Zero Gas: Nitrogen certified standard
  - Span Gas: Oxygen certified standard

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Nitrogen

- ID – burning splint test
- Assay – GC
  - 3 m × 4 mm MS column
- ID – RT comparison (1% O_2 in N_2 standard)
- Assay – GC
  - 2.1 mm x 2.4 m S3 column (typo?)
  - 30 ml/min carrier gas
  - Col temp – 70 ^oC
- System Suitability
  - Rs 2.0 (O_2/N_2)
  - RT Comparison
- CO/CO_2 typo

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General Chapters

- 413 - Impurities Testing in Medical Gases
- 415 - Medical Gases Assay

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Impurities Testing in Medical Gases

- Discussion about detector tubes
  - Hand pumped vs. continuous flow instructions

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Medical Gases Assay

- Sampling and qualification for GC and paramagnetic analyzers
- Validation and calibration of these instruments

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Medical Gases Assay

- GC
  - IQ, OQ, PQ procedures defined
- Paramagnetic Oxygen Measurement
  - Drift, temperature and pressure
  - IQ, OQ, PQ procedures defined
  - Routine calibration can substitute for OQ/PQ
  - Zero/span/sampling procedures

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Certified Standards/Reference Materials

- NIST Traceable!
  - Nitrogen Certified Standard - 99.99%
  - 1.0% Oxygen in Nitrogen
  - 21.0% Oxygen in Nitrogen
  - Delete - 1.0% Oxygen in Helium (Prior N_2 NF standard)

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What's Next

- GAWDA/CGA will review, correct typos, prepare comments
- USP will likely correct the problems and adopt the new monographs for release summer 2010
- GAWDA – revise SOPs and online reference materials, as needed

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What's Next

- GAWDA Validation – we will want to validate at least an alternative to the Nitrogen, NF identity test. Let me know if you want to participate.
- Future teleconferences as the USP revision conversation continues

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Questions

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