

P3-A-001 TERMINOLOGY

ANSI/3-A P3-A 001-2008

General Glossary of Terminology Used in Pharmaceutical 3-A® Standards

FINAL BSR ACTION – Published March 7, 2008



Pharmaceutical 3-A® Standards
By 3-A Sanitary Standards, Inc.
an ANSI Accredited Standards Developer

P3-A-001 TERMINOLOGY

- ❖ FOUNDATION DOCUMENT TO BE REFERENCED BY ALL SUBSEQUENT STANDARDS
- ❖ ALLOWS DOCUMENTS TO FOCUS ON DESIRED TOPICS
- ❖ REFINES FOCUS ON API RELATED LEXICON INCLUDING DEFINITIONS AND ACRONYMS



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P3-A-001 TERMINOLOGY

❖ **UTILIZES CERTAIN TRADITIONAL 3-A DEFINITIONS WITH APPROPRIATE REFINEMENTS (i.e. Product is API)**

❖ **WILL BE AMENDED AS NEEDED TO ACCOMMODATE FUTURE STANDARDS**



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P3-A-001 MATERIALS

ANSI/3-A P3-A 002-2008

Pharmaceutical 3-A® Sanitary/Hygienic Standards for Materials for Use in Process Equipment and Systems

FINAL BSR ACTION – Published February 29, 2008



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P3-A-001 MATERIALS

- ❖ FOUNDATION DOCUMENT TO BE REFERENCED BY ALL SUBSEQUENT STANDARDS
- ❖ ALLOWS DOCUMENTS TO FOCUS ON DESIRED TOPICS
- ❖ REFINES FOCUS ON API MANUFACTURING NEEDS AND ENVIRONMENT OF INTENDED USE



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P3-A-001 MATERIALS

- ❖ **REFERENCES ICHQ7 (GMP Guidance for API Manufacturing)**
- ❖ **EMPHASIZES MATERIALS SELECTION SHALL CONSIDER THE ENVIRONMENT OF INTENDED USE**
- ❖ **DOCUMENT IS A BASELINE TO BEGIN THE MATERIALS SELECTION PROCESS**



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P3-A-001 MATERIALS

- ❖ **FINAL SURFACE FINISH CRITERIA WILL BE SPECIFIED IN THE EQUIPMENT STANDARDS**
- ❖ **FINAL MATERIALS PERFORMANCE REQUIREMENTS ARE SPECIFIED IN THE EQUIPMENT STANDARDS**
- ❖ **STANDARD COMBINES METALS, PLASTICS, CERAMICS, SYNTHETICS, ADHESIVES, LUBRICANTS IN SINGLE DOCUMENT**



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P3-A NEW STANDARDS ACTIVITY

**WORKING GROUPS ARE BEING ASSEMBLED TO
CREATE:**

- **FILTER DRYER STANDARDS FOR API MFG.**
- **VESSELS & AGITATORS FOT API MFG.**
- **MILLS & CLASSIFICATION EQUIPMENT**
- **PROCESS HEAT EXCHANGERS FOR API MFG.**



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