Antibiotics manufacturing workflows
USP standards support antibiotics manufacturing from beginning to end

Antibiotics manufacturing process:
- **Qualification of raw materials**
- **Media preparation & sterilization**
- **Fermentation**
- **Centrifugation**
- **Filtration**
- **Biomass removal**
- **Extraction & Precipitation**
- **Drying**
- **Lyophilization**
- **Purification & Concentration**
- **Chemical synthesis**
- **Drug Substance testing**
- **Formulation & Drug Product testing**
- **Packaging and distribution**

**Drug Substance testing**
USP Antibiotic Drug Substance monographs, Reference Standard (RS) and Pharmaceutical Analytical Impurities (PAIs), as applicable.

- **<426>** Histamine Test Method
- **<1083>** Supplier Qualification
- **<1140>** Guidelines for Assessing and Controlling the Physical Stability of Chemical and Biological Pharmaceutical Raw Materials, Intermediates and Dosage Forms

**Formulation & Drug Product testing**
USP Antibiotic Drug Product monographs, RS and PAIs. Excipient NF monographs and RS, as applicable. Chapters for “Drug Substance testing” plus: Pharmaceutical Analytical Impurities (PAIs), as applicable.

- **<1>** Injections and Implant Druc Products
- **<71>** Sterility Tests
- **<78>** Particulate Matter in Injections
- **<905>** Uniformity of Dosage Units
- **<711>** Dissolution
- **<1080>** Bulk Pharmaceutical Excipients—Certificate of Analysis
- **<1223>** Validation of Alternative Methods to Antibiotic Microbial Assays

- **<2>** Oral drug Oral Products—Product Quality Tests
- **<3>** Topical and Transdermal Drug Products—Product Quality Tests
- **<4>** Mucosal Drug Products—Product Quality Tests
- **<5>** Inhalation and Nasal Drug Products—General Information and Product Quality Tests
- **<467>** Residual Solvents
- **<232>** Elemental Impurities—Limits

**Packaging and distribution**

- **<7>** Labeling
- **<659>** Packaging and Storage Requirements
- **<1079>** Risks and Mitigation Strategies for the Storage and Transportation of Finished Dosage Products

Contact us:

uspbiologics@usp.org
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
Telephone: +1 (301) 881-0666
+1 (800) 487-5555

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USP Antibiotic Drug Product monographs, RS and PAIs. Excipient NF monographs and RS; as applicable. Chapters for “Drug Substance testing” plus: Pharmaceutical Analytical Impurities (PAIs); as applicable.

‡ PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

To learn more, please visit us at [www.usp.org/biologics/antibiotics](http://www.usp.org/biologics/antibiotics)