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ASTM International Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products

Scope

The scope of the Committee shall be the development of standardized nomenclature and definitions of terms, test methods, specifications, and performance standards for the manufacture of pharmaceutical and biopharmaceutical products. The Committee will encourage research in this field and sponsor symposia, workshops, and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.

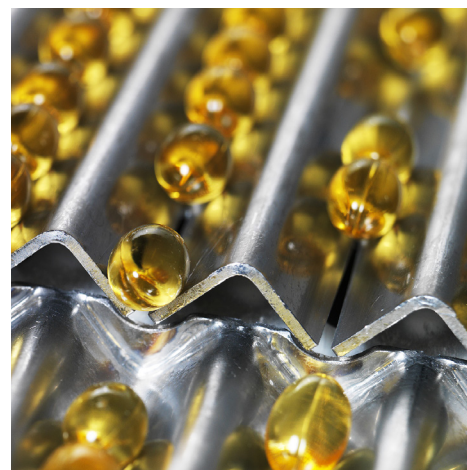
Technical Subcommittees

- E55.01 Process Understanding and PAT System Management, Implementation and Practice
- E55.03 General Pharmaceutical Standards
- E55.04 General Biopharmaceutical Standards
- E55.05 Lyophilization
- E55.06 Microbial/Sterility Assurance for Pharmaceutical and Biopharmaceutical Products
- E55.90 Executive
- E55.91 Terminology
- E55.94 Outreach and Education
- E55.95 Roadmap for Standards Development

Key Documents

- E2474 Standard Practice for Pharmaceutical Process Design Utilizing Process Analytical Technology
- E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
- E2503 Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus
- E2537 Standard Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing
- E2888 Standard Practice for Process for Inactivation of Rodent Retrovirus by pH
- E2968 Standard Guide for Application of Continuous Processing in the
- E3106 Standard Guide for Science-Based and Risk-Based Cleaning Process Development and Validation Pharmaceutical Industry

Learn more about Committee E55
www.astm.org/COMMIT/E55



Quick Facts

Established 2003

Number of Members 165+

Number of Standards 24

Global Participation

19 Countries represented

The standards are available in

Volume 14.05 in the *Annual Book of ASTM Standards*

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