

Product Chemistry



A characterization program for physical-chemical properties will generally include a determination of the composition, physical properties and a primary structure for the desired product. Measurement of physical-chemical properties such as pH, melting point and viscosity are usually unique and do not require a detailed explanation. Synomics Pharma Services offers a number of tests in this category, the selection of which is usually determined by the physical nature of the product and its intended use.

For example, for relatively viscous solutions or suspensions, it may be appropriate to include viscosity in the specification. In this case, test and acceptance criteria for viscosity should be stated that are consistent with the safety and/or efficacy of the product. Similarly, for pH, the acceptance criteria should be provided where applicable and the proposed pH range justified.

CONTRACT PRODUCT CHEMISTRY SERVICES

Synomics Pharma Services routinely provides contract product chemistry services to meet the requirements of GMP or GLP guidelines, or both. Services include:

- Adsorption/desorption
- Boiling point
- Color (Munsell System)
- Corrosion
- Density (pycnometer method)
- Dissociation constant
- Explodability
- Flammability (solids)
- Flash-point (liquids)
- Freezing point
- Hydrolysis
- Melting point
- Odor
- Oxidation/reduction
- Particle size
- Partition coefficient (water-octanol)
- pH
- Physical state
- Surface tension
- UV/Visible absorption
- Vapor pressure
- Viscosity
- Water solubility

EQUIPMENT AND INSTRUMENTATION

Synomics Pharma Services is committed to investing in state-of-the-art equipment and instrumentation. Our qualified scientists work closely with clients to develop methods that will deliver efficient and quality data. Relevant equipment and instrumentation includes:

- DuNouy Tensiometer CSC-70535
- Brookfield Viscometer LVDV II
- Boekel Model 152800 – Pensky Martins Flashpoint
- GC Agilent 6890/5890 (FID, FPD, μ ECD, NPD, TCD)
- HPLC Waters 2695 (PDA)
- Packard Radiometric 525TR
- Potentiometric Titrator – Dissociation Constant
- Thomas Hoover Melting Point Apparatus
- Validated Explodability Apparatus

REGULATORY COMPLIANCE

Synomics Pharma Services maintains the highest standards of regulatory compliance in facilities, validated instrumentation and quality systems to meet both GLP and GMP requirements for FDA, EPA and ICH. Our facility maintains active licenses for DEA Schedule II and IV controlled substances and for radioactive materials use.

CONTACT INFORMATION

VP Business Development
Synomics Pharmaceutical Services LLC
790 Main Street
Wareham, MA 02571-1037
Tel: (508) 273-0450
Fax: (508) 273-0452
info@synomicspharma.com
www.synomicspharma.com