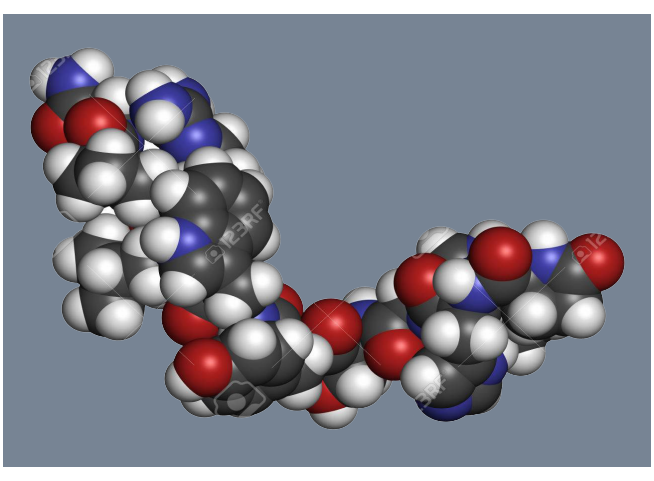
USP continues its leadership role in biologics with the pending release of new Triptorelin Pamoate Reference Standards, as well as Residual DNA Reference Standards validated with qPCR methods. See more details below.

Standards

Triptorelin

Triptorelin, a peptide hormone that is used to treat advanced prostate cancer, is widely administered at almost 7.5 standard units globally in 2015*. While only one manufacturer is approved in the US, there are many manufacturers globally in various stages of development, so the development of a public standard to support the quality of this therapy has high potential for utility by the industry. USP's Biologics Monographs 1 Expert Committee has collaborated with the US-approved sponsor to develop a new monograph, Triptorelin Pamoate, which has been published in Pharmacopeial Forum PF43(3). In line with USP's mission of promoting public health and ensuring quality of medicines, the monograph includes multiple orthogonal identification methods, as well as multiple chromatographic methods, to determine content and impurities. In parallel to publication of the monograph, USP has completed collaborative testing of four new Reference Standards that support the monographs, the API, and three related impurities.

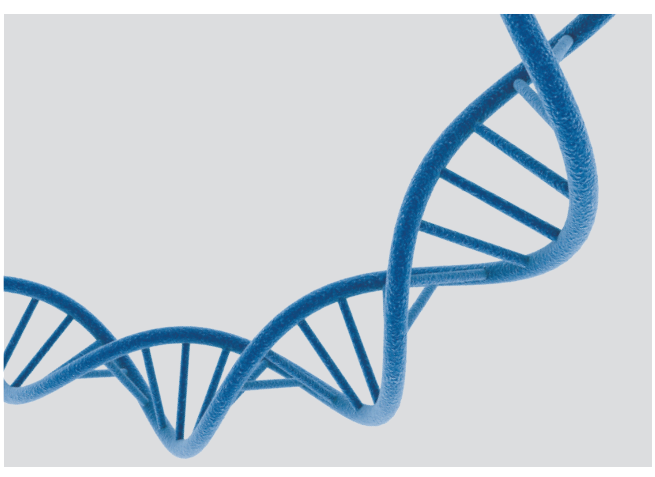


- Triptorelin Acetate RS (catalog #1696131);
- Triptorelin Related Compound A (catalog #1696110);
- Triptorelin Related Compound B (catalog #1696128); and,
- Triptorelin Related Compound C (catalog #1696142).

USP expects to release these new Reference Standards for the first time in the coming months.

More on these standards **Other USP Reference Standards**

Residual DNA Reference Standards



During downstream recombinant bio-processing, biologics manufacturers must ensure adequate removal of process impurities such as residual DNA remaining from the host cell. To support this purpose, USP is developing residual host cell DNA Reference Standards for both Chinese Hamster Ovary (CHO) and E.coli variants of Genomic DNA. These Reference Standards are associated with the validated qPCR methods which are detailed in the proposed USP General Chapter <509> Residual DNA Testing. With guidance from the USP Expert Panel on Residual DNA Measurement and support from laboratories participating in the collaborative study, testing for the Reference Standards is now largely completed. Data analysis is ongoing and findings will be reviewed with the USP Expert Committee of General Chapters – Biological Analysis. Look for updates in the next Newsletter!

Available Reference Standards
- CHO Genomic DNA RS (Catalog #1130710)
- E. coli Genomic DNA RS (Catalog #1231557)

Email us to be notified when USP biologics reference standards are released.

More on these standards

Download complimentary copy of USP General Chapter <509>

Donation of materials for development of performance standards for biologics

Help us continue to support the development and production of quality biotherapeutics with new quality standards. We welcome your donation of materials – drug substances that have been released for clinical use or other quality materials from manufacturing – to be used to develop performance standards which monitor performance of analytical methods and manufacturing processes. Please contact USP to determine if your materials can be used for development of performance standards. In addition to contributing to public standards and public health, your donation will also be recognized by the USP Donor Recognition Program.

Tell me more

Feature

USP focuses on biopharmaceuticals in South Korea

While other parts of Asia are hubs for small molecule active pharmaceutical ingredients (APIs) and finished formulations, South Korea has become a global leader in biopharmaceutical manufacturing. The following are just some of the ways that USP has increased its presence in South Korea to support their production of consistent, high-quality biotherapeutics.

- Early in 2018, USP met with Korean regulatory agency-Ministry of Food and Drug Safety (MFDS), Korea Drug Research Association (KDRA) and Korea Health Industry Development Institute (KhIDI) as well as local biologics manufacturers to explore potential collaborative opportunities to support stakeholders in the area.
- In May, a USP representative spoke on the "Role of Standards for Bio Therapeutics and USP Approach" at 7th Annual Biologics Manufacturing Korea 2018.
- 28 participants from more than 15 biopharmaceutical companies participated in a science forum in June to discuss USPs plans in the areas of vaccines, peptides, monoclonal antibodies (mAbs) and Heparin.
- Later in June, Ron Piervincenzi, USP's CEO, conducted a presentation on the USP Perspective in Biologics during the plenary session of the 2018 Global Bio Conference.

A User Forum in September is the first of many upcoming opportunities for biopharmaceutical manufacturers in South Korea to collaborate with USP to address the challenges of consistency and quality in biologics production.

Learn more and register

Ron Piervincenzi, USP's CEO

News

China Peptide workshop: April 2018

This year, USP achieved a major milestone in China with its first Biologics workshop in China, with more than 250 attendees. Experts from USP, US FDA, NIFDC, local peptide manufacturers, local biopharmaceutical manufacturers & academia participated. Select senior leaders participated in a Stakeholder Meeting to discuss the need for quality standards for peptide impurities and expressed an interest in collaborating with USP on standards for impurities. After the workshop, USP staff visited the Taiwan FDA to discuss potential training and collaboration opportunities.

CASSS

As more cell therapies fill the development pipeline, establishing standards is increasingly critical to ensure consistent quality for patients. Standards and quality for cell therapies were key topics at the inaugural 2018 CASSS Cell & Gene Therapy Products Symposium. USP's VP of Biologics, Dr. Fouad Atouf, spoke on the importance of the quality of raw materials in manufacturing of advanced therapies and Dr. Rebecca Potts, USP Associate Scientific Liaison discussed recent developments in standards for cell therapies.

USP IFPMA Roundtable on Performance Standards Development

This past May, USP and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) cosponsored a roundtable with analytical scientists and compendial representatives from eight major biopharmaceutical companies to discuss performance standards development. Performance standards are important to the industry as they support quality control, analytical development, process development and comparability of assays and materials between companies.

Read more

Meet us at these Events