PARTICLE SCIENCES
DRUG DEVELOPMENT SERVICES

PRESS RELEASE

Update on Regulatory Approaches for Development and Evaluation of Topical Products

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April 26, 2013 Particle Sciences, Inc., (PSI) attended the 'Product Quality Research Institute (PQRI) Workshop on the Evaluation of New and Generic Topical Drug Products – Current Challenges in Bioequivalence, Quality and Novel Assessment Technologies', which was held at the U.S. Pharmacopeia in Rockville, MD, from 11 – 13 March 2013. The event was co-sponsored by the American Association of Pharmaceutical Scientists (AAPS), International Pharmaceutical Federation (FIP) and United States Pharmacopeia (USP) and was well attended by representatives from the U.S. Food and Drug Administration (FDA), innovator and generic pharmaceutical companies, CRO/CDMOs, as well as academia.

Topics included science-based regulatory approaches for development and evaluation of topical products. There was overview and critical discussion of the current techniques (dermatopharmacokinetics, skin stripping, microdialysis, and vasoconstriction) utilized for bioequivalence (BE) and strategic suggestions for methodologies that may be used by regulatory agencies to assess BE as part of product registrations. Additionally, there was discussion on product uniformity and stability along with their impact on BE for commercial products.

Of particular relevance to PSI Clients developing topical products, the value of *in-vitro* drug release performance testing of semi-solid dosage forms was further refined. Chapter <1724> for Semi-Solid Drug Products Performance Tests will officially be issued in the upcoming supplement to USP 36 – NF 1 (due 01Aug2013). During a working-group session of the USP workshop, Dr. Margareth R.C. Marques, Ph.D. (Senior Scientific Liaison, USP) and Dr. Tapash Ghosh (FDA) were present to discuss the chapter ramifications and field questions from pharmaceutical companies and academic institutions.

The general chapter will provide standardization of performance testing of semi-solid drug products, types of equipment and configuration as well as potential applications of the performance testing. Additional revisions will include required validation elements for *in-vitro* release testing (IVRT). IVRT is currently only required for the SUPAC-SS guidance (Non-sterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In-Vitro Release Testing and In Vivo Bioequivalence). However, Chapter <1724> directly impacts sponsors at much earlier stages of development in an effort to improve long-term quality control of topical products. Although not officially mandated at this time, IVRT is back as a relevant

performance test. Of note is that because IVRT is being viewed as a potential release test, synthetic membranes were called out as being preferable over natural alternatives because of the reproducibility of the synthetic. The agency is trying to promote and advocate using IVRT as a specification for product stability and release testing. Furthermore, data-driven and justified specification ranges for IVRT will be expected at filing.

Particle Sciences has been formulating topically applied products for over 20 years. Please contact us with any questions regarding their development or testing.

Particle Sciences is an integrated provider of drug development services. *Particle Sciences is an expert in formulating difficult to solublize API's using traditional and nano-based approaches. We bring that skill set to bear on a variety of dosage forms including topical, mucosal, oral and parenteral drug products. Particle Sciences is also a leader in combination drug/device product development. Through a full range of formulation, analytic, and manufacturing services, Particle Sciences provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic. The company was founded in 1991 and is headquartered in Bethlehem, Pennsylvania.*

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