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Development and characterization of sterile nanoparticulate suspensions

Many active pharmaceutical ingredients are poorly water soluble and may suffer from low oral bioavailability, if formulated in unmodified form. These compounds are also challenging to formulate for other routes of administration, especially parenteral. The prevalence of low solubility compounds has led to intensive research and has generated many technologies to address formulation. For BCS II molecules, there are other drug delivery approaches besides Nanoparticulate Suspensions (NSs) used for oral administration but many feel the higher value of this technology is for parenteral delivery. This technology has been used for several marketed products including oral tablets, oral liquid NSs and parenteral liquid NSs. There continues to be a strong interest in employing NS formulations, particularly for parenteral dosage forms. An overview of the history and product development of NSs with an emphasis on sterile products will be presented.

Biography

Robert Lee is an Executive Vice President of Pharmaceutical Development Services at Particle Sciences, a Lubrizol Advanced Materials, Inc. company, a pharmaceutical contract development and manufacturing organization. He provides direction and is involved with product and business development. Before joining Particle Sciences, he has held Senior Management positions at Novavax, Inc., Lyotropic Therapeutics, Inc., and Imcor Pharmaceutical Co. He has completed his BSs in Biology and Chemistry from the University of Washington and a PhD in Physical Bioorganic Chemistry from the University of California, Santa Barbara. He has published articles in numerous peer-reviewed journals and five book chapters plus holds over two dozen issued patents or provisional patent applications.

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