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Regulatory challenges for nano therapeutics

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Nanomedicines are just beginning to enter drug regulatory processes, but within a few decades could comprise a dominant group within the class of innovative pharmaceuticals, the current thinking of government safety and cost-effectiveness regulators appearing to be that these products give rise to few if any nano-specific issues. There are also significant public good aspects to the regulation of nanotechnology, particularly with regard to ensuring that industry involvement in standard-setting does not become a means of reducing competition and that nanotechnology policy and regulation encourages new models of safe drug discovery and development more systematically targeted at the global burden of disease. There is no international regulation of nanoproducts or the underlying nanotechnology. Nor are there any internationally agreed definitions or terminology for nanotechnology, no internationally agreed protocols for toxicity testing of nanoparticles, and no standardized protocols for evaluating the environmental impacts of nanoparticles. In the US, the EPA's nanomaterials stewardship program (NMSP), launched in 2008 and due to be concluded in 2010, was split into two: the basic program, whereby companies were simply required to submit information about the materials they produce; and the in-depth program, which offered companies the opportunity to work with the EPA to identify what additional information might be useful in regulatory decision-making, and to devise methods to generate this information. The European Union has formed a group to study the implications of nanotechnology called the Scientific Committee on Emerging and Newly Identified Health Risks which has published a list of risks associated with nanoparticles.

Biography

Lakshmi Durga Vemuri is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed her B. Pharm from Chalapathi institute of pharmaceutical sciences,Guntur, Andhrapradesh during the year 2012. Presently she is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. She has attended various National and International Conferences. Her current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, GMP Auditing and analytical method development.

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RA-RR-A new approach for conversion of retinoic acid to retinyl retinoate using dehydroretinol

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Retinoic acid is highly effective against photo aging. But its carboxyl end group results in lots of side effects. To overcome this problem we have tried to get a derivative of retinoic acid without carboxyl group using 3, 4-didehydroretinol. 3, 4-didehydroretonol is collected from natural source *Wallago attu* fish liver. Both retinoic acid and dehydroretinol are allowed to react in presence of N, N-carbonyl diimidazole and dimethyl amino pyridine. The yield of the purified product Retinyl retinoate is 55% with respect to dehydroretinol. The purified product is analysed with the help of UV-visible spectrophotometer, HPLC and NMR spectra. It is a new hybrid compound containing both retinoic acid and dehydroretinol part.

Biography

L. Das is a Ph.D. Scholar in Department of Chemistry under Gauhati University, Guwahati, ASSAM. She has completed her final registration in 2011 and now preparing her Ph.D.Thesis. She has presented oral presentation, poster presentation in different National and International Seminar and Conference. She has a published paper entitled **an efficient condition of saponification of Lutein ester from marigold flower** in *Annals of Biological Research*, 2012, 3(3); 1461-1466. B. C. Goswami is senior Professor in Department of Chemistry under Gauhati University, Guwahati, Assam. She has fifteen papers published in different journals. His working field is mainly on Vitamin A and Carotenoids.

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