

2nd International Conference and Exhibition on Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Nanoshell - A novel tool for cancer treatment

Spoorthy Paladi Gokaraju Rangaraju College of Pharmacy, India

Nanoshell plasmons are a novel type of composite spherical nanoparticles consisting of a dielectric core covered by a thin metallic shell which is typically gold. Nanoshells possess highly favorable optical and chemical properties for biomedical imaging and cancer treatment. By varying the relative dimensions of the core and shell the optical resonance of these nanoparticles can be precisely and systematically varied over a broad region ranging from the near U.V to the mid IR. This review article includes the synthesis and properties of gold nanoshells, transport mechanisms of nanoshells in to tumors and illustrate how the core/shell ratio and overall size of a nanoshell influences its scattering and absorption properties, and also describes several examples of nanoshell based diagnostic and therapeutic approaches including the development of nanoshell bioconjugates for molecular imaging, the use of scattering nanoshells as contrast agents for optical coherence tomography (OCT), and the use of absorbing nanoshells in NIR thermal therapy of tumors.

Biography

P. Spoorthy had completed B.Pharmacy from Vignan institute of pharmaceutical sciences. She is pursuing M.Pharmacy in Gokaraju Rangaraju College of Pharmacy.

spoorthy.paladi@gmail.com

Benefit-risk assessment in drug development

Sravani Angaru¹, Lakshmi Durga Vemuri, N.Vishal Gupta and H.V. Raghunandhan JSS University, India

Major regulatory agencies, for example, FDA and EMA, have started to request comprehensive benefit-risk analyses of pharmaceutical products prior to approval or labelling expansion. The purpose of this study is to develop a generally applicable and reliable data-driven benefit-risk assessment method, where two or more drugs/doses can be compared. Our aim is to formulate an approach that is simple to apply, allows direct comparison of different types of risks and benefits, and is tailored for application in different disease areas both during clinical development and in the marketing approval phase.

The method involves eight successive steps: 1) establishment of the decision context, 2) identification of benefit and risk criteria, 3) weighting, 4) scoring, 5) evaluation of uncertainty, 6) calculation of weighted scores, 7) visualisation, and 8) discussion and formulation of an overall conclusion. In order to reduce the impact of subjective judgments, scores are assigned to each criterion on the basis of objective information (data) wherever possible.

The method is comprehensive and supported by a qualitative framework with built-in quantitative measures. It employs descriptive statistical methods to highlight the clinically significant differences between drugs in clinical trials. The approach can be used in single as well as in multiple trials and provides clear diagrams as the basis for presentation and discussion of the results.

Biography

A. Sravani is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed her B.Pharm from M.S.Ramaiah College of Pharmacy, Bangalore during the year 2011. 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.

mahita3@gmail.com