Safety of iron oxide nanoparticles - a regulatory perspective

The ample domain of clinical as well as theranostic applications of super paramagnetic iron oxide nanoparticles demands the need for establishing a complete toxicological profile of these nano particles in a regulatory perspective prior to its intended usage to ensure safety and to minimize the potential health hazards upon its exposure. In house synthesized Dextran stabilized iron oxide nanoparticles (DINP) were physicochemically characterized and subjected to various in vitro and *in vivo* evaluations through various routes of exposure, to elucidate its associated molecular, immune, genotoxic, carcinogenic effects and bio distribution profile.

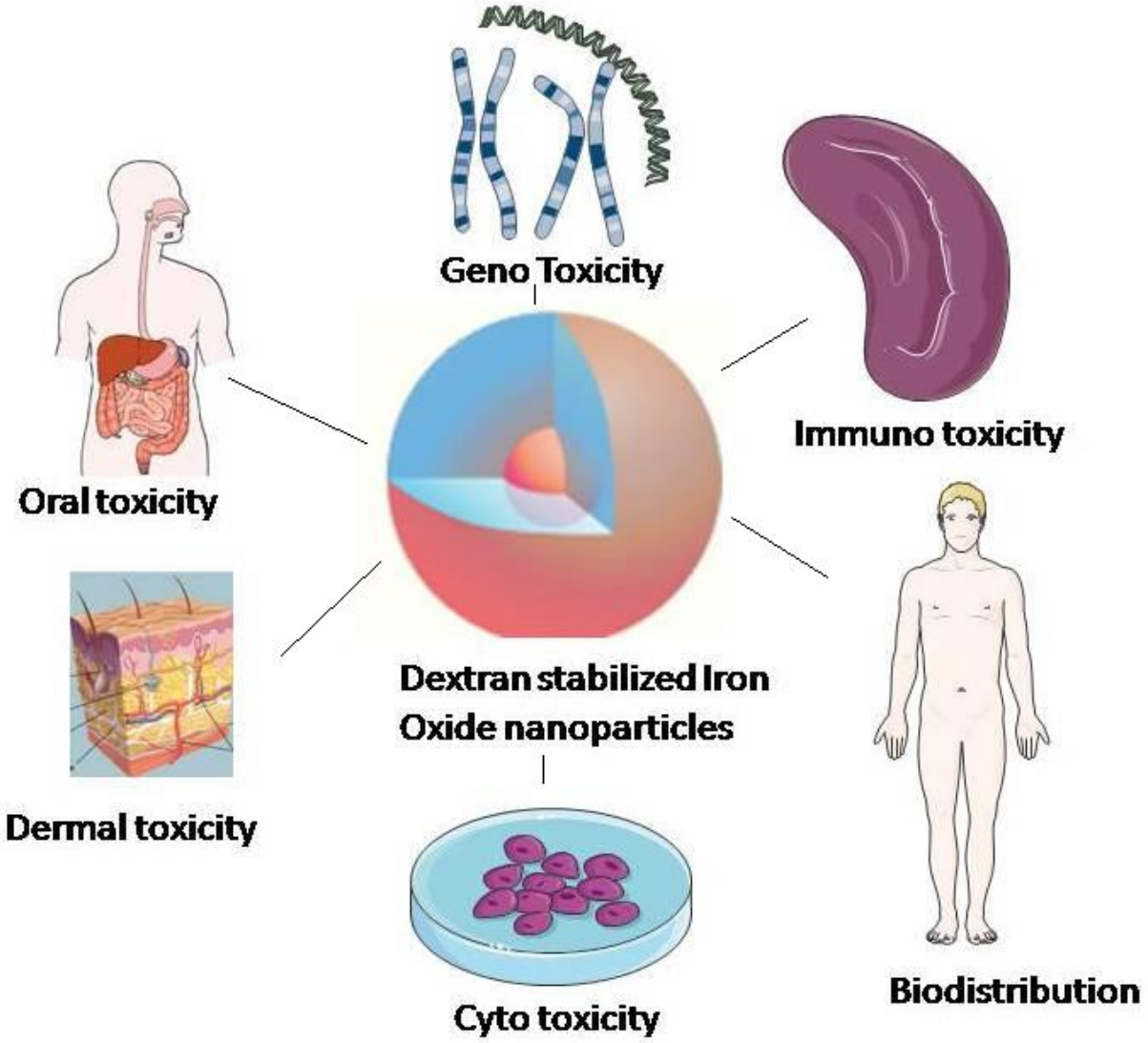

Fig. 1.

The results suggest that the potential adverse effects of metal and metal oxide nanoparticles are mitigated/ eliminated by surface coating with dextran. The size of the polymer functionalized iron oxide nanoparticle core was within the range of less than 25 nm with an average core diameter of 15.4±4.5 nm. The synthesized nanoparticles were nontoxic when exposed to laboratory experimental animals under various exposure conditions. Dextran stabilized magnetic iron oxide nanoparticles do not seem to induce oxidative stress mediated toxicological effects, nor altered physiological process or behavior changes or visible pathological lesions. Absence of any molecular toxicity authenticates the development of safe nanomaterials to be intended for biomedical applications. These nanoparticles therefore can be considered as unclassified compounds as per globally harmonized system for classification (category 5) for chemical substances and mixtures.

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