FORM 2

THE PATENT ACT 1970

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AND

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COMPLETE SPECIFICATION

(See section 10: rule 13)

TITLE OF INVENTION

METHODOLOGY FOR FORMULATION OF NANOTECHNOLOGY BASED DELIVERY SYSTEM OF NANO CARRIERS TO CELL OF THE IMMUNE SYSTEM

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PREAMBLE TO THE DESCRIPTION

COMPLETE

Following specification particularly describes the invention and the manner in which it is to be performed.

TECHNICAL FILED OF INVENTION:

The present invention relates to nanoparticles for providing immune responses for the treatment of infection by infectious agents such as viruses, parasites, bacteria, prions and fungi. The invention more particularly relates to a vaccine formulation based on Nanotechnology delivery of Nano carriers to cell of the immune system and method thereof.

BACKGROUND OF THE INVENTION

In recent years, nanotechnology is uncovering growing applications in industry, biology, medicine and allied interdisciplinary. The clear benefits of using these nanosized products in various biological and medical applications are often challenged by concerns about the lack of adequate data regarding their toxicity. The new area of interest for researchers now a days which involves the interactions between nanoparticles and the components of the immune system. Nanoparticles and Nanocarriers can be engineered to either avoid immune system recognition or specifically prevent or enhance the immune responses.

The immune system preserves the host from infections and malignancies. The immune function is fine-tuned to meet the body's changing requirements for responding to the internal and external environment. The immune system can be perturbed at different levels, resulting in either its suppression or its overstimulation. Hence, all new chemical and biological entities need adequate investigations into their interactions with the immune system before their use in industry, biology, and medicine.

Nanoscaled or Nanocarrier based particles can be either engineered or can be naturally occurred in the environment. Engineered or human made nanoparticles can specifically be designed to either target or avoid interactions with the immune system. An interaction between a nanoparticle or Nanocarriers and the immune system is considered desirable when it may lead to various beneficial medical applications, such as vaccines or therapeutics for inflammatory and autoimmune disorders.

SUMMARY OF THE PRESENT INVENTION

The present invention provides patches, which has been the accessibility of biopharmaceuticals target sites for the treatment of specific pathological conditions and made

convenient through the use of the present invention. By providing the excellent characteristics of nanocarriers, the clinical translation and commercialization for biopharmaceutical delivery makes easy and simpler without any biological and technological complications. Various compositions are used, which is discussed in detailed in the next section, to scale up nanocarrier formulations and conduct the quality control to manage their physicochemical properties. The developed nanocarrier-based biopharmaceuticals involved in a particular therapy need to be assessed with enhanced efficacy and synergistic effects. Altogether, the developed nanocarrier-based delivery of biopharmaceuticals has great potential for the effective treatment of multiple pathological conditions including autoimmune disorders, and related diseases.

DETAILED DESCRIPTION OF THE INVENTION

The present invention discloses a formulation based on Nanotechnology delivery of Nano carriers to cell of the immune system and method thereof. The formulation is comprised of steps, but not limited to, a first Nano carrier ligand composition comprised of a carbohydrate and the like residue capable of stimulating an innate immune response for a cell system;

a second Nano carrier ligand composed of a T cell helper peptide; a third Nano carrier ligand comprising a danger signal selected from the group consisting of endotoxins, heat-shock proteins, nucleotides, reactive oxygen intermediates, extracellular-matrix breakdown products, neuromediators, cytokines and lipid moieties, wherein said danger signal is a toll-like receptor agonist. Further, the plurality of Nano carrier ligand compositions is covalently linked to the core, wherein at least one of the Nano carrier ligand compositions comprises a carbohydrate moiety.

In accordance with another exemplary embodiment of the present invention, a fraction of the T cell helper peptide bound is released from the nanoparticle upon contacting the nanoparticle with a physiological solution, which is consisting dissociation of bound peptide molecules from the nanoparticle over a period of predetermined time.

In accordance with another exemplary embodiment of the present invention, the T cell helper peptide bound is selected from the group comprised of: insulin, IGF1, IGF2, INSL5, INSL6, INSL7, pancreatic polypeptide(PP), peptide tyrosine tyrosine(PTT), oxytocin, vasopressin,

GnRH, TRH, CRH, GHRH/somatostatin, CGA, prolactin, ClIP, ACTH, MSH, enorphins, lipotropin, GH, calcitonin, PTH, inhibin, relaxin, hCG, HPL, glucagons, insulin, somatostatin, thymosin, thmulin, gastrin, ghrelin, CCK, GIP secretin, motin VIP, enteroglucagon, IGF-1, IGF-2, leptin, adiponectin, renin, EPO, calicitrol, ANP, BNP, chemokines, cytokines, adipokines and biologically active analogs thereof.

In accordance with another exemplary embodiment of the present invention, the plurality of Nano carrier ligand compositions having a carbohydrate moiety, which is selected from the group consisting of: 3′-thioethyl-α-D-galactopyranoside, 3′-thioethyl-β-D-glucopyranoside, 3′-thioethyl-3-acetamido-3-deoxy-β-D-glucopyranoside, 4′-thiopentanyl-3-deoxy-4-imidazolacetamido-α,β-D-glucopyranoside and 4′-thioethyl-α-D-glucopyranoside, and wherein further the plurality of Nano carrier ligand compositions is comprised of a carbohydrate moiety, which is covalently linked to the core via the thiol sulphur.

Further a core comprises a metal, which is further selected from the group consisting of: Ag, Cu, Pt,Au, Co, Gd, Pd, Fe, Zn or any combination thereof, and having an NMR active atom selected from the group consisting of, but not limited to: Mn, Gd, Eu, Cu, V, Co, Ni, Fe, Fe and lanthanides.

The nanocarriers comprise polymer selected from the group consisting of, but not limited to, polymers of glycolic acid, polylactide-co-glycolide PLGA, poly(ortho ester), poly(caprolactone), polylysine, copolymers and block copolymers of polyethylene glycol or polyoxyethyleneoxide with polymers of lactic acid, poly(ethylene imine), and copolymers and block copolymers thereof.

We Claims:

1. A formulation based on Nanotechnology delivery of Nano carriers to cell of the immune system, comprising:

   a first Nano carrier ligand composition comprised of a carbohydrate and the like residue capable of stimulating an innate immune response for a cell system;

   a second Nano carrier ligand composed of a T cell helper peptide;

   a third Nano carrier ligand comprising a danger signal consisting of endotoxins, heat-shock proteins, nucleotides, reactive oxygen intermediates, extracellular-matrix breakdown products; and

   wherein the Nano carrier ligand compositions is covalently linked to the core, wherein the Nano carrier ligand compositions comprises a carbohydrate moiety.

2. The formulation based on Nanotechnology delivery of Nano carriers to cell of the immune system, as claimed in claim 1, wherein a fraction of the T cell helper peptide bound is released from the nanoparticle upon contacting the nanoparticle with a physiological solution.

Abstract

The present invention relates to a formulation based on nanotechnology delivery of Nano carriers to cell of the immune system. The vaccine formulation includes, a first Nano carrier ligand composition comprised of a carbohydrate; a second Nano carrier ligand composed of a T cell helper peptide; a third Nano carrier ligand comprising a danger signal selected from the group consisting of endotoxins, heat-shock proteins, nucleotides, reactive oxygen intermediates, extracellular-matrix breakdown productsand wherein the plurality of Nano carrier ligand compositions is covalently linked to the core, wherein at least one of the Nano carrier ligand compositions comprises a carbohydrate moiety.