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PATENT REVIEW ON NANOSPONGE: TARGETED DRUG DELIVERY SYSTEM

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ABSTRACT

Nanosponges are tiny mesh like novel class of hyper cross linked polymer based colloidal structures in which large variety of drug molecules encapsulated within its core. They are having the size of a virus with an average diameter below 1µm.Nanosponges are effective drug carriers which possess higher drug loading capacities compared to other nanocarriers. So they are useful to increase stability, solubility, bioavailability and delayed release of drug also it is helpful in solving toxicity problems of drugs. The nanosponges are able to load both hydrophilic and lipophilic drugs of various categories. Nanosponges are three dimensional network or scaffold with highly porous nature. It can deliver the drugs through various routes like oral, topical, parentral etc. and used as biocatalyst in the delivery of enzymes, proteins, vaccines and antibodies.

INTRODUCTION

Nanosponges are tiny mesh like novel class hyper cross linked polymer based colloidal structures in which large variety of drug molecules encapsulated within its core. They have been a proved spherical colloidal nature, reported to have a very high solubilization capacity for BCS class II (poorly soluble drugs) by their inclusion and noninclusion behavior. They have been recently developed and proposed for drug delivery. It can be solubilize poorly water soluble drugs and provide prolonged release as well as increasing drug bioavailability. Nansponges can load both hydrophilic and hydrophobic drug molecule because of their inner hydrophobic cavities and external hydroplilic branching, there by offering flexibility. They are more like a (3D) three dimensional network or scaffold. The backbone is a long length of polyester which is mixed in solution with small Molecules called cross linkers that act as tiny grappling hooks to fasten different parts of the polymer together. It shows a marked advantage in comparison with the common nanoparticles. They are water soluble but does not breakup chemically in water. They also mix with water and use it as a transport fluid. They are used to mask the unpleasant odour and taste, to convert liquid substances to solids. The chemical linkers enable the nanosponges to bind preferentially to the target site. They are solid in nature and have been found to be safe for oral and invasive routes of administration and so that they could serve as a potential carrier for drug delivery system. The small shape of nanosponges enables the pulmonary and parentral delivery successfully. For oral administration, the complexes may be dispersed in a matrix of excipients, diluents, lubricants and anti-cacking agents suitable

for the preparation of capsules or tablets, for parenteral administration the complex may be simply carried in sterile water, saline or other aqueous solution and for topical administration they can be effectively incorporated into hydrogel. They are encapsulating nanoparticles which encapsulate the drug molecules within its core and having the size of a virus with an average diameter below 1μm.

International Patents Of Nanosponge:

1. WO2006002814

Title: Ultrasound assisted synthesis of Cyclodextrin based nanosponge.

Inventors: Trotta, Francesco, Sea Marconi Technology, SAS Cavalli, Tumiatti.

Date of Publication: 09 .12.2009

Description: The present invention relates to nanosponges obtainable by reacting natural Cyclodextrin with organic carbonates and their use as carrier for pharmaceutical or cosmetic active ingredient or as decongestants. Oral administration represents the easiest and most convenient route for access to systematic circulation but may have some disadvantages, alongside problems linked to bioavailability, such as for example degradation by enzymes or by gastroenteric pH. The invention found that nanosponge having improved properties obtained by reacting natural Cyclodextrin with an organic dicarbonate in the absence of a solvent and under sonication. The nanosponges obtainable according to the present invention may be distinguished from the previously known material in a number of characteristics, namely in the particle shape which is substantially spherical as well as in the uniformity of particle size. The nanosponge of the invention in view of said structural features, may be used for applications previously not disclosed for this kind of material for example as a carrier for the aerosol administration of pharmaceutical active ingredient. The nanosponges of the invention could also carry simultaneously both lipophilic molecules in the hydrophobic cavity of the Cyclodextrin and hydrophilic molecules in the spaces between the single Cyclodextrin. The nanosponges of invention are useful for solving the intrinsic problems of the active ingredients such as the poor hydrosolubility, instability, degradation, protection and toxicity.

Nanosponges have colloidal dimensions and form clear and opalescent suspension in water.

2. WO2009003656

Title: Cyclodextrin based nanosponge as a vehicle for antitumoral drugs.

Inventors: Trotta, Francesco, Tumiatti, Vander, Cavalli, Roberta, Roggero, Carlo, Maria, Mognetti, Barbara, Giovanni, Nicolao.

Date of Publication: 08.01.2009

Description: The present invention relates to pharmaceutical composition comprising Cyclodextrin based nanosponge as a vehicle for antitumoral drugs which are insoluble in water, in particular paclitaxel and other taxanes, Camptothecin and Tamoxifen. The invention relates to pharmaceutical formulations which can be administered orally or parenterally and which use said complexes, mixed with suitable vehicles or excipients as active constituent. The complexes according to the invention are prepared by adding an excess of drug to an aqueous suspension of Cyclodextrin based nanosponge. The complexes obtained can be used directly to prepare oral or injectable formulations, using conventional techniques and experiments. For injectable formulations for example the complex may simply be carried in sterile water, saline or other aqueous solution for the parenteral administration. For oral administration, the complexes may be dispersed in a matrix of excipients, diluents, lubricants, and anticaking agents suitable for the preparation of capsules and tablets.

3. WO2009149883

Title: Cyclodextrin based nanosponge as a carrier for Biocatalysts and in the delivery and release of enzymes, proteins, vaccines and antibodies.

Inventors: Gilardi, Trotta, Cavalli, Fereuti, Ranucci, Di Nardo, Roggero, Tumiatti.

Date of Publication: 17.12.2009.

Description: It has now been found that Cyclodextrin based nanosponges is particularly suitable carrier to absorb proteins, enzymes, antibodies, and

macromolecules in general. In particular when enzymes are used, it is possible to maintain their activity and efficiency prolong their operation and extends the pH and temperature range of activity as well as allowing the conduct of continuous flow processes. The invention relates both to the immobilization process and to the enzymes immobilized on Cyclodextrin cross linked nanosponge. Example of enzymes which can be advantageously immobilized according to the invention include oxidoreductase, transferase, hydrolase, isomerase, lipase, protease and other enzymes of industrial interest. Cyclodextrin have been studied and present numerous application in various fields in which the characteristics of the inclusion compounds are exploited. Nanosponges are cross linked polymer of Cyclodextrin with various bonds which have proved very useful in various application ranging from environment decontamination to controlled drug delivery and release. The amount of enzyme immobilized on the nanosponges depends mainly on the incubation time of the polymer solution containing the nanosponge as well as their nature and temperature. The enzyme activity is maintained for several days and is more resistant to the temperature and pH conditions, thus allowing more efficient enzymatic reactions to be performed.

4. WO2009138998

Title: A template free and polymer free metal nanosponge and a process thereof

Inventors: Muthusamy, Katla

Date of Publication: 19.11.2009

Description: The present invention provides solution to the problem involved in preparation of metal nanosponge using template and polymer. The instant invention is successful in providing a simple, template free single step process for the preparation of metal nanosponges having porous low density and high surface area. These metal nanosponges were found to be good self supported substrates for surface enhanced Raman spectroscopy and have shown significant antibacterial activity.

In other embodiments of the present invention said metal is selected from a group comprising gold, silver, platinum, palladium and copper. In yet another embodiment of the present invention said metal nanosponges is porous, stable, black in color, has low density and high surface area. The present invention is in relation to a process for preparation of template free and polymer free metal nanosponge, said process comprising steps of mixing equimolar concentrations of one part of metal precursor and five parts of reducing agent solution to obtain a spongy solid; filtering and washing the spongy solid followed by drying to obtain the metal nanosponge. In another embodiment of the present invention said metal precursor is selected from a group comprising silver nitrate, chlorouric acid, dihydrogen hexachloroplatinate, palladium dichloride and cuprous nitrate. The present invention said processing steps of obtaining a spongy solid floating on reaction medium is complicated within a time period of about 5 min. The present invention is in relation to use of template free and polymer free metal nanosponge as substrate for surface enhanced Raman spectroscopy and for antibacterial activity.

5. WO2006121870

Title: Silicon nanosponge particles.

Inventors: Farrell, Limaye, Subramanian.

Date of Publication: 16.11.2011

Description: The present invention is related to porous silicon nanosponge particles prepared from metallurgical grade silicon powder, each particle comprising a plurality of nanocrystals with pores disposed between the nanocrystals and throughout the entire particle. The silicon nanosponge particles are unique in that each particle comprises a plurality of nanocrystals with pores disposed between the nanocrystals and throughout the entire nanosponge particles.

The completely porous or nanosponge structure of each particle enables the silicone nanosponge particles of the present invention to be useful as a carrier material for a broad range of application such as catalysts and drugs, adsorbents, sensors explosives photosensitive, precursors for high surface area.

6. WO2012147069

Title: Method for preparing Dextrin Nanosponge.

Inventors: Trotta, Francesco, Shende Pravin, Biasizzo, Miriam.
Date of Publication: 01.11.2012
Description: The present invention regards a method for preparing Dextrin nanosponge comprising the steps of dissolving atleast one Dextrin in a basic aqueous solution having a pH higher than or equal to 10 to form a Dextrin solution, dissolving a polyfunctinal cross linking agents in a water immiscible organic solvent to obtain a solution, of cross linking agents and setting the Dextrin solution in a close contact with the solution of cross linking agents to precipitate the nanosponge. Moreover provided is a nanosponge that can be obtained by means of the method according to the present invention. The method of the present invention is a method interfacial polymerization in which the nanosponge is produced by precipitation at the interface between an organic phase and an aqueous phase that are immisible with one another.
According to the present invention, constituted by an aqueous solution of a Dextrin having a pH equal to or higher than 10, in particular comprised between 12 and 13. The emulsion polymerization methods known to the art and used for preparing polymer such as polycarbonate and poly amides, the method of the present invention does not require the use of a surfactant in solution.

Advantageously, the method according to the invention, unlike the methods known to the art for preparation Dextrin nanosponges, does not require the use of anhydrous Dextrin and extractions for a subsequent purification.
The TGA and the DSC analysis conducted on the nanosponges obtained by applying the method according to the invention have shown how these products present profiles different from those obtained from the corresponding nanosponge.

7. WO2013046165

Title: Use of functionalized nanosponges for the growth, conservation, protection and disinfection of vegetable organisms.
Inventors: Roggero, Carlo Maria, Di Carlo, Stefano, Tumiatti, vander.
Date of Publication: 04.04.2013
Description: The present invention relates to the functionalized nanosponges based upon a cross linked Cyclodextrin and contains atleast one functionalising agent, such as micro element, an active principle and or a magnetic material. The growth and development of vegetable organisms are mainly correlated to typical environment factors such as the quantity and quality of water, carbon dioxide, light, temperature, pH and essential active principles. More specifically, an element is defined essential when its absence prevents the completion of the biological cycle of a vegetable organism. On the basis of their concentration in the vegetable tissues, the essential growth and conservation elements are divided into macro and micro nutrients.

The main source of nutrients for vegetable organisms is the nutritive solution, in which the nutrients not only must be present, but also being found in a usable form, that is so that they can be taken by the organism itself and metabolized inside the tissues. The variations of the concentration of nutrients available cultures is one of the most limiting factors for agricultural production, the production of biomass in general and the one for algae. Nanosponge can be used in aqueous dispersion for radical administration in hydroponic cultivation, foliar application or directly mixed with solid supports making the growth bed, strengthening the effects of the circulating nutrient solution. Functionalized nanosponge are macro molecules synthesized through specific cross linking of Cyclodextrin and the trapping and or encapsulation of micro elements and ir active principles, functional for the application required.
Functionalized nanosponge provides the optimization of the management of the mineral nutrition of vegetable organisms, for the global sustainable development in industrial countries and in particular in the developing ones.

8. WO2016153892

Title: Detection of explosives using Raman spectroscopy with gold/silver nanosponge alloy
Inventors: Creasey, Guenther.
Date of Publication: 29.09.2016.

Description: This invention belongs to the field of detection of low concentration of explosives via Raman spectroscopy. More specifically it is a detection substrate design having a surface enhancement effect by using roughened glass with a gold/silver nanosponge alloy sputter deposited onto it. Sputtering is a method of thin film deposition that utilizes a high vacuum plasma phase to slowly and steadily eject a material from a bulk target onto a substrate opposite that target. Many different working gases and targets can be used. Gold and silver are known to have Raman surface enhancing effects with various compounds and one can co-sputter both of these metals at the same time. Silver is of course far less expensive than gold, so a silver target with gold foil strips overlaid over a portion of the area is used.

9. WO2020101085

Title: Method for preparing nanosponge structured graphene dot-palladium hybrid and graphene dot-palladium hybrid catalyst prepared thereby.

Inventors: CHOI, HO- SUK, NGUYEN, VAN TOAN.

Date of Publication: 22.05.2020

Description: The present invention to a method for preparing a palladium nanocatalyst which has a large effective surface area, is stable, and has large effective surface area, is stable and has high catalytic activity and to a palladium nanocatalyst prepared thereby. More specifically, the present invention relates to a method for producing a nanosponge structured graphene dot-palladium hybrid characterized by reducing a palladium precursor while mixed with carbon dots and sodium bromide and to a graphene dot-palladium hybrid catalyst prepared thereby.

10. WO2020011197

Title: Cross linked nanosponge saccharin based material and methods for fabrication thereof.

Inventors: O Wingnien Wylie, LI, Tin Lok LIN, Zhijian, CHENG, Dan LI, Jifan.

Date of Publication: 16.01.2020

Description: The present invention discloses a cross linked nanosponge saccharin based material comprising saccharine as building blocks, also referred as nanoporous nanosponge materials. The reaction of saccharides with cross linked at different saccharides to cross linker ratios in one point shall allow formation of nanoporous nanosponge material. This method further allows introduction of new functional groups on this material by the use of suitable cross linkers and surface grafting agents and these functional group shall be able to provide different interaction forces with water, volatile organic vapour and metal ions. Along with larger inner surface area owing to the presence of nanoporous in comparison to porous materials, saccharin based nanoporous nanosponge materials shall find broad applications in thermal insulation, water retention hydrophobic finishes, odour removal properties and metal ions exchange or absorption from water or soil. The nanoporous nanosponge materials shall be eco-friendly, biodegradable and allowing recycle or reuse of spent materials.

11. WO2021053039

Title: Process for preparing Nanosponge.

Inventors: Trotta, Francesco, Rubin Pedrazzo.

Date of Publication: 25. 03. 2020.

Description: The present invention relates to a process for preparing nanosponge. The applicant has found out that the process according to the invention, by avoiding the use of solvents appears safer and more efficient, reducing costs and the use of energy, compared to the prior art processes for preparing nanosponge. The applicant has indeed unexpectedly found that by having recourse to ball milling, it is possible to include said mechanochemical cross linking reaction through high energy collisions of the plurality of milling bakls with the atleast one Dextrin and atleast one crosslinker in a particularly controlled and repeatable way, thus obtaining in a simple and economic way of nanosponge. The applicant found that the use of a single or multi screw extruded for carrying out the mechanochemical reaction between the least one Dextrin and the atleast one crosslinker is particularly advantageous, in view of the very short reaction time needed, and in view of the fact that the reaction is easily

managed even at large scale, thus reducing the overall process costs. The applicant has found out that the possibility to easily functionalized the nanosponge thus obtained improve the possibility of using the nanosponge according to the invention in field of chemical sensors, in the pharmacological area and image guided therapies. For example, for preparing biological markers.

Patent issued in USA:

1. US20160190558

Title: Sulfur nanosponge cathode for lithium sulfur battery and methods of manufacturing thereof.

Inventors: Junjie Niu, Akihiro Kushima, Chao Wanf, Ju Li.

Date of Publication: 30.06.2016

Description: The present invention is directed to lithium sulfur batteries exhibiting a high capacity, high cycle life with low production cost and improved safety.

This invention was made with government support under contract No. FA9550-08-1-0325 awarded by the U. S. Air force and contract No. DMR. 1120901 awarded by the National Science Foundation. The government has certain rights in the invention. The various embodiments provide a cheap and simple approach to manufacture sulfur based electrodes with Carbon additives for high capacity lithium ion batteries with long cycle life. In various embodiments, the present invention comprises liquid based, low cost and reliable synthetic methods for lithium sulfur composite cathode containing an open network of conductive carbon black nanoparticles(Cnet), infused with sulfur(Snet) to form sponge like network(Cnet + Snet).

Without limitation to a specific mechanism, it is believed that Snet has open access to the outside, allowing liquid electrolyte to infiltrate and impart Snet Li. Conductivity.

2. US20170152439

Title: Nanoparticles, Nanosponges, method of synthesis and method of use.

Inventors: Kun Lian.

Date of Publication: 01.01.2007

Description: The invention pertains to metal core carbon shell nanoparticles and nano metallic sponges, methods of making metal core carbon shell nanoparticles and nano metallic sponges and methods for using metal core carbon shell nanoparticles.

We have discovered nano metallic materials coated with a thin carbon layer. Prototypes have been made with metallic particle sizes less than 10um, and preferably less than 50nm, and more preferably less than 10nm, where in the metal typically exists in a zero oxidation state. We have also discovered a novel process for making these nano metallic carbon coated particles. The process comprises loading metal ions into fibers of biological origin, and then harmonizing the fibers. The carbonization temperature will differ for different metals and for different fibers.

The patents issued in USA

Patent No.	Date of Publication	Inventors	Title
US20080213384	04.09.2008	Francesco Trotta, Roberta Cavalli, Wander Tumiatti, Orfeo Zerbinati.	Ultrasound assisted synthesis of Cyclodextrin based Nanosponge.
US20110014300	20. 01.2011	Muthusamy, Eswaramoorthy, Katla, Sai Krishna.	Template free and polymer free metal nanosponge and a process thereof.
US20060251561	09.11.2006	Farrell, Limaye, Subramanian.	Silicon nanosponge particles.
US20170205352	20.07.2017	David, Creasey, Derek, Guenther.	Detection of explosives using Raman spectroscopy with gold/silver nanosponge alloy.
US201900066630	03.01.2019	Junjie, NIU, Akihiro	Sulfur nanosponge

		Kushima, Chao Wang, Ju Li.	cathode for lithium sulfur battery and methods of manufacturing.

Patent issued in Europe:

Patent No.	Date of Publication	Inventors	Title
EP1632503	08.03.2006	Trotta, Francesco, Cavalli, Roberta, Tumiatti, Vander, Zerbinati, Orfeo, Roggero, Carlo, Vallero, Roberta.	08.03.2006
EP1786841	23.05.2007	Cavalli R, Tumiatti Wander, Zerbinati Orfeo, Roggero Carlo, Vallero Roberto.	Ultrasound assisted synthesis of Cyclodextrin based nanosponge.
EP2276691	26.01.2011	Muthusamy, Katla.	A template free and polymer free metal nanosponge and a process for preparation thereof.
EP1888459	16.11.2011	Farrell, Limaye, Subramanian.	Silicon nanosponge particles.

Patent issued in Korea:

Patent No.	Date of Publication	Inventors	Title
KR1020190011210	01.02.2019	CHOI HO SUK, NGUYEN VAN TOAN	Method of manufacturing graphene dot-palladium hybrid with nanosponge structure and graphene dot-palladium hybrid catalyst manufacturing by same.
KR1020200031581	24.03.2020	CHOI WON IL, LEE JIN SIL	Thermosensitive nanosponge platform for simultaneous delivery of multidrug and used thereof.

Patent issued in India:

Patent No.	Date of Publication	Inventors	Title
IN201821029366	24.08.2018	Dhamane Suchita Prabhakar, Sonar Sagar Suresh.	Reconstituable hydrogel powder of Dapsone nanosponge useful in treatment of Acne.
IN201741029843	01.03.2019	Mahima Mathur, Kusumdevi Vemula.	Nanosponge and process of preparation.
IN3880/KOLNP/2006	22.06.2007	Trotta, Francesco Cavalli, Roberta, Tumiatti, Vander	Ultrasound assisted synthesis of Cyclodextrin based

		Zerbinati, Orfeo Roggero, Carlo Vallero Roberto	nanosponge.
IN202011051492	04.12.2020	Kaur, Singh, Sharma, Sobti, Thakur, Chopra, Prakash, Mittal, Mohan.	Novel nanosponge of felodipine and process.
IN2071/MUM/2014	29.01.2016	Caviar Pradeep Ratilal, Jadhav Nitin Vitthalrao.	Supercritical processed starch nanosponge for dissolution enhancement and flow properties improvement of poorly water soluble and allowable drugs.
IN1105/CHE/2008	13.11.2009	Eswaramoorthy, Muthusamy, Sai Krishna, Katla.	A template free metal nanosponge and a process thereof.

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