Signed details of the excellence in research work for which the Sun Pharma Research Award is claimed, including references and illustrations. The candidate should duly sign on the details (Max: 2.5 MB)

DESIGNING INNOVATIVE TOPICAL OCULAR NANOFIBROUS DOSAGE FOR LOCAL DRUG OF DRUGS USING NANOTECHNOLOGY APPROACH

A major challenge emanating in the design of topical ophthalmic preparations is their short precorneal residence time. Retention of a drug delivery system in the front of the eye is thus desirable. Due to advances in nanotechnological field, nanofibrous patch based retentive system has been proposed and developed that can preferably be delivered in a solid ultrathin patch and ultimately remain attached to the corneal/non corneal tissue owing to their inherent characteristics. Present invention relates to nano-ocular patch, particular nanofibers for the delivery of therapeutic entities via posterior and interior ocular route. Nano-patch of present invention provides comfortable and controlled delivery of encapsulated therapeutics constantly over a period of several days. Nanofibers can be used for ocular drug delivery carrier for the treatment of eye infections. Moreover, the formulation is capable of maintaining drug release at the site of administration. Positive Biocompatibility and toxicity studies have also demonstrated the potential and utility of nanofibrous ocular insert.

Outcomes of developed technology has been already patented (204/DEL/2014, 16/2014) and technology was transferred to Oniosomes Healthcare @ 5 Lacs (Rs.) + 3 % Royalty in association with NRDC, New Delhi. Pharmacokinetics studies proved the efficacy and safety of this nanopatch in the treatment of glaucoma. Now, company is trying to perform clinical efficacy and safety of this technology in human before mass commercialization of aforesaid technology (Project was funded from BIRAC). My two M. Pharm. student (supervisor) and one as co-guidance have completed their work on project on ocular delivery of using nanofibers as carrier systems. Further, more than 20 publications have been published in peer reviewed international journals in the field of nanofibers.

Furthermore, our team successfully delivered insulin via sublingual administration using composite nanofibers. The developed formulation exhibited pharmacokinetic and pharmacodynamics performance comparable to its marketed counterparts (intra peritoneal insulin). The patented technology was transferred to National Research Development Corporation, New Delhi, India. Some of the companies are touch with NRDC and are keen on the transfer of developed technology.

We are extensively indulges in the exploration of nanofiber technology pertaining to enhance permeability, solubility, drug loading, and drug release. We strongly believe that scientific outcomes of above study further supporting utility of nanofiber for ophthalmic drug delivery.

- Selection of solvent and polymer combination is crucial to achieve high drug loading efficacy.
- In general drug solubility is increased in nanofibers apart from the physiological aspect of nanofibers. Judicious selection of polymer and solvent seems to inevitable to achieve higher solubility of water insoluble drugs.
- Nanofiber exhibit excellent mucoadhesive properties make it particularly suitable for transmucosal drug delivery through various mucosal sites.
- Antimicrobial studies have conducted for various drugs clearly demonstrated higher efficacy against plain drug could be related to its ability to increased drug solubility and controlled release mechanism.
- Nanofiber exhibit sufficient tensile strength makes it suitable to withstand wear and tear experienced during packaging and transport.

The next step in the process is the design of formulation protocol for thermodynamically unstable biomolecules. We have also made significant augmentation in understanding, methods, application and theory of electrospun nanofibers for drug delivery applications. Our group is also exploring nanofibers for the topical delivery of pharmaceuticals and biopharmaceuticals in the treatment of buccal cancer, cervical cancer, mouth ulcer and eye problems.

1. INDIAN PATENT (Granted)

Title: A process for preparing medicated nano patch from nanofibre and its composition

Application No. 204/DEL/2014

Patent No. 311049 (Dated 09/04/2019)

Inventor Name: Shivani, Amit K. Goyal and Goutam Rath

Summary of the invention:

Present invention relates to medicated nano-patch prepared by nano-fibres comprising of biodegradable and non-biodegradable polymer for treating topical, intra-ocular and periocular pathological conditions of the eye. Nano-patch of present invention provides comfortable and controlled delivery of encapsulated therapeutics constantly over a period of several months. The nano-patches are formed of a composition comprising of biodegradable or non-

biodegradable polymer, a therapeutic active component and optionally, a plasticizer, and optional additive (s). The present invention relates to polymeric nano sized structures called nano-patch for delivery of therapeutic entities via ocular route. More particularly, the polymeric nanosized structures i.e. nanopatches prepared from nanofibres which are prepared from composition comprising of mucoadhesive polymer or polymeric composites to pass on a therapeutic active compound, thereby assuring a considerable permanence time in the area of application providing a controlled release of the therapeutic active compound.

The present invention basically relates to polymeric nano sized structures called nano-patch for delivery of therapeutic entities via ocular route. More particularly, the polymeric nanosized structures i.e. nanopatches prepared from nanofibres which are prepared from composition comprising of mucoadhesive polymer or polymeric composites to pass on a therapeutic active compound, thereby assuring a considerable permanence time in the area of application providing a controlled release of the therapeutic active compound.

Claims:

WE CLAIM

1. Polymeric nano-fiber based patchs for ocular delivery prepared from a composition comprising a polymer ranging from 5% to 15% (w/w) ; drug plasticizers from 0.01% (w/w) to 5% (w/w) , penetration enhancer, buffer system and tonicity reagent.

2. The nano patch as claimed in claim 1, wherein the polymer is poly vinyl alcohol having an average molecular weight in the range from about ranging from 9000 g/mol to 124,000 g/mol.

3. The nano patch as claimed in claim 1, wherein the polymer is sodium alginate of average molecular weight in the range from about ranging from 10000 g/mol to 600,000 g/mol.

4. The nano patch as claimed in claim 1, wherein the polymer is selected from group consisting of biodegradable and non-biodegrdable polymers consisting of agarose, chitosan, gelatin, Hyaluronic acid various gums (guar, hakea, xanthan, gellan, carragenan, pectin, and sodium alginate) Synthetic Cellulose derivatives, copolymer of acrylic acid, PEG, poly(alkylcyanoacrylate)and blends and copolymers thereof.

5. The nano patch as claimed in claim 1, wherein the composition comprises an additional therapeutically active agent selected from the group consisting of antibacterial antibiotic agent, synthetic antibacterial agent, antifungal antibiotic agent, synthetic antifungal agent,

antineoplastic agent, steroidal anti-inflammatory agent, nonsteroidal anti-inflammatory agent, anti-allergic agent, glaucoma-treating agent, antiviral agent and anti-mycotic agent.

6. The nanopatch as claimed in claim 1, wherein the composition comprises an additional antibiotics selected from a group aminoglycosides or a combination thereof.

7. The nanopatch as claimed in claim 1, wherein the composition comprises a polymer selected from the group of nondegradable polymers consisting of nylon, polyurethane, polycarbonate, polyacrylonitrile, polyethyleneoxide, polyaniline, polyvinyl carbazole, polystyrene and poly(vinyl phenol) and the group of biodegradable polymers consisting of polyhydroxyacids, poly(caprolactone, polyanhydrides, polyhydroxyalkanoates, polyurethanes, collagen, alginate, chitosan, and hyaluronic acid, blends and copolymers thereof.

8. The nanopatch as claimed in claim 1, wherein the composition comprising of plasticizers, preferably low volatile substances with average molecular weights between 200 and 400 such as diesters derived from dicarboxylic acids (e.g. sebacic acid, azelaic acid) or from ethylene glycol and propylene glycol, citric acid (tributylcitrate, triethylcitrate) or glycerol (triacetin, tributyrin) and a mixture thereof, in a range of 0.1 to 3 % w/w of total composition.

9. The nanopatch as claimed in claim 1, wherein the composition comprising penetration enhancer selected from the group consisting of β-cyclodextrin, sodium lauryl sulphate, sodium glycocholate, sodium deoxycholate, sodium laurate, glyceryl monolaurate peppermint oil, spearmint oil, menthol, pepper oil, eucalyptus oil, cinnamon oil, ginger oil, fennel oil, and dill oil, hydrochloric acid, phosphoric acid, acetic acid, citric acid, lactic acid, oleic acid, linoleic acid, lauric acid, palmitic acid, benzoic acid, poly(alkylene oxide), a polyvinyl alcohol, and a polycarboxylic acid

polymer and a mixture thereof in a range of 0.5 – 10 % wt by weight of total composition. 10. The nanopatch as claimed in claim 1, wherein the composition comprises a buffer system selected from the group consisting of borate buffers, phosphate buffers, citrate buffers, and combinations and mixtures thereof.

11. The nanopatch as claimed in claim 1, wherein the composition comprises of tonicity agents selected from the group consisting of dextrose, NaCl, KCl, ZnCl2, CaCl2, and MgCl2.

12. The nanopatch as claimed in claim 1 wherein nanopatch has a length of from 1 mm to 30 mm, a width of from 1 mm to 30 mm and a thickness of from 0.001 mm to 2 mm.

13. Method of preparing nanopatch from nano-fibres forming polymers comprises: -electrospinning a solution comprising of polymer and active therapeutic component or with a carrier and pharmaceutically acceptable additives -cross-linking, phase separation, melt fibrillation, gas jet, melts blower or nano litrography.

14. The method of producing nano-fibres as claimed in 13 wherein the solution for electrospinning has a viscosity ranging from 200 – 1000 cps and a surface tension ranging from 43.5 – 46.5 mN/m.

15. The method of producing nano-fibres as claim 13, wherein the composition has a pH ranging from 5 to 8.5.

16. The method of producing nano-fibres as claim 13, wherein nano-fibers are produced by electrospinning a solution comprising of a polymer and active therapeutic agent.

2. **Development and characterization of nano-fiber patch for the treatment of glaucoma, T Garg, B Malik, G Rath, AK Goyal, European Journal of Pharmaceutical Sciences 2014, 53, 10-16**

(Impact Factor: 3.616, Citation Index: 112)

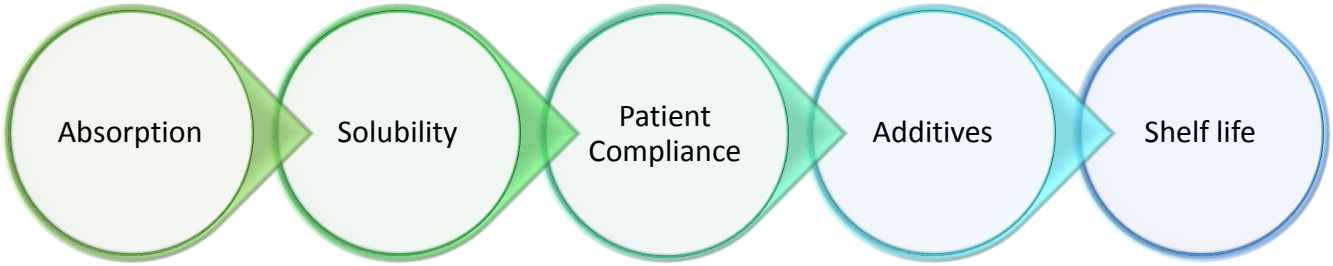
It was downloaded more than 1000 times within 6 month after coming online on 2014.

In the present work polymeric nano-fiber patches was developed for the effective treatment of glaucoma using timolol maleate and dorzolamide hydrochloride as model drugs. The nano-fibers were prepared by electrospinning technique and were characterized on the basis of fiber diameter, morphology, entrapment efficiency, mucoadhesive strength, and drug release behavior, etc. Final formulations were inserted in the cul-de-sac of glaucoma induced rabbits and the efficacy of the formulation was evaluated. The results clearly indicated the potential of the developed formulation for occur drug delivery. There was a significant fall in the intraocular pressure compared to commercial eye drops.

Prof. Amit K. Goyal

MAJOR CHALLENGES

The eye is the most accessible organ for the delivery of drugs directly at the site without introducing it into the systemic circulation. Topical medications remain the cornerstone of treatment for ocular diseases including infections, uveitis diseases, ocular hypertension and glaucoma, among other. However treatment of ocular diseases posses number of unique challenges



- Limited precorneal capacity
- Lachrymal and nasolachrymal drainage
- Biological barriers

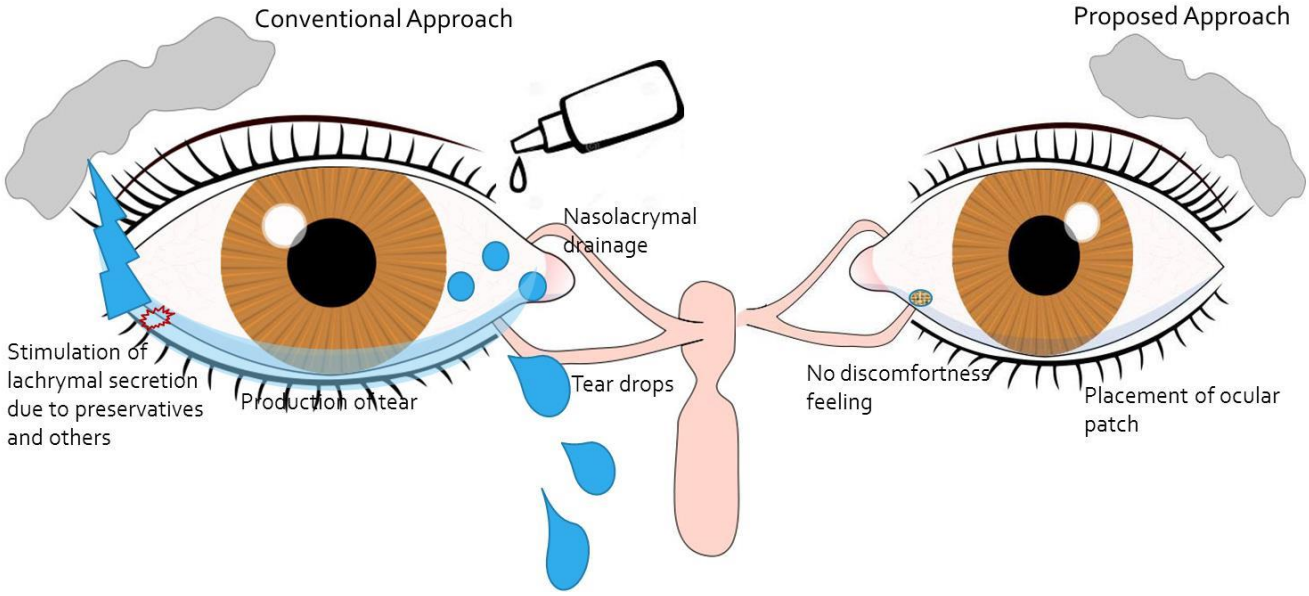
- Limited biological fluids
- Narrow Log P and Pka range
- Less contact time
- Particle size

- Multiple instillations
- Dose accuracy
- Burning
- Blurred Vision
- Invasive treatments

- Preservatives
- Viscosity of ophthalmic preparation
- pH and Tonicity Modifiers
- Surfactant

- Schedule H
- Store at cool place
- Light sensitivity

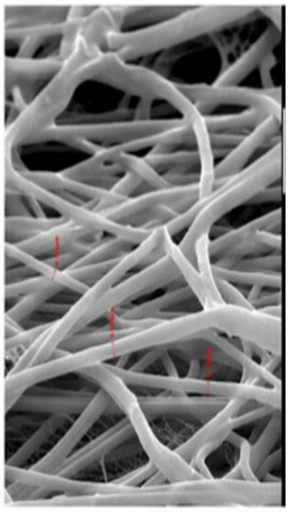
OVERVIEW OF ADMINISTRATION OF DIFFERENT DOSAGE FORMS AT OCULAR SITE



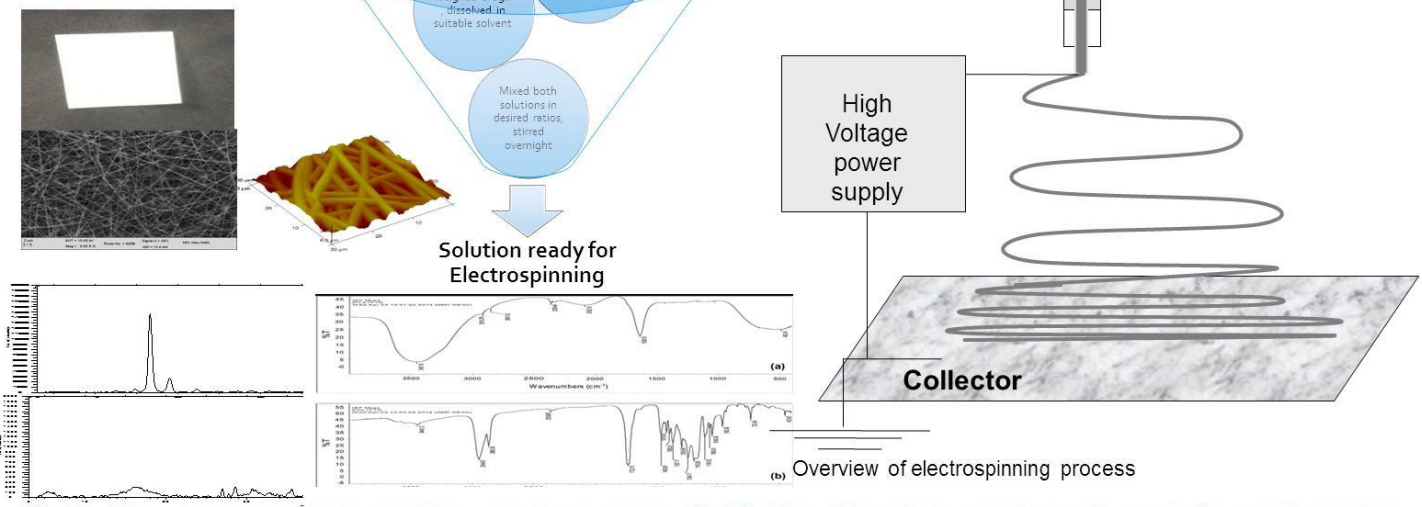
Nano-fibrous ocular patch may be described as single, sterile, thin, and multilayered, drug impregnated, solid unit dosage form designed for application in eye. The drug is either encapsulated or entrapped in the Nano-fibrous patch which have advantages as they increases the residence of the drug in the eye so a sustained release dosage form would be formulated. Both kind of polymers (Biodegradable and non-biodegradable) may be selected as per need.

WHY NANOFIBER OCULAR PATCH?

1. High surface area to volume ratio
2. 100 % transmittance
3. Increased mucoadhesion and retention time
4. Enhanced solubility
5. High drug loading
6. Sustained drug release
7. Fabrication under sterile condition
8. Nanoscale offers users friendly application
9. Easy to scaleup
10. Solid unit dosage forms improve product shelf life
11. Precise dosing



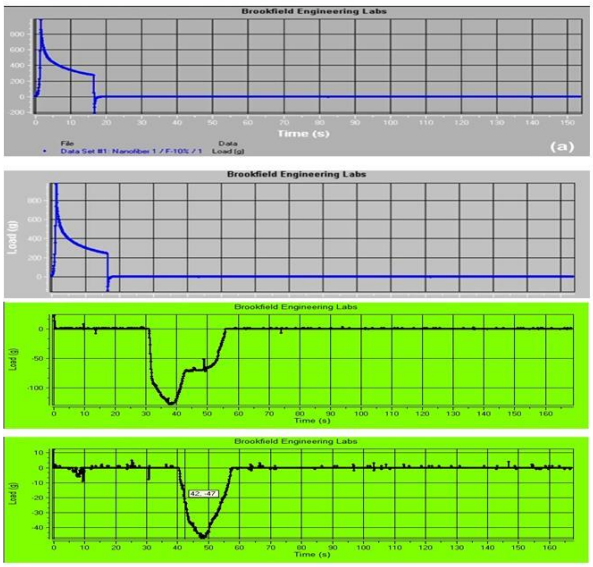
Background

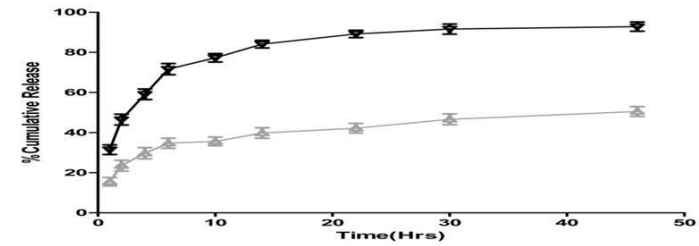


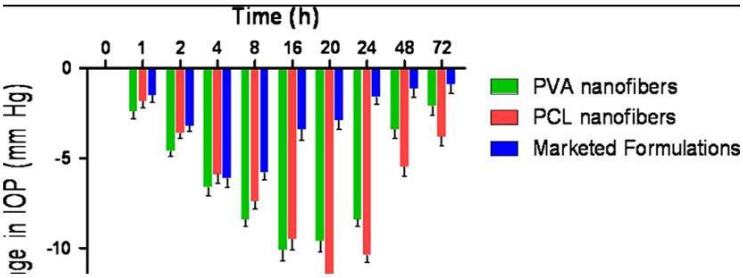
Highlights: Morphological studies confirms the nonwoven, uniform fibers. Fibers diameter found to be decreased after the addition of drugs

Highlights: Chemical and thermal analysis confirms the presence of drug and indicated the drug was present in amorphous state in the nanofiber

Background







Highlights: Lower fiber diameter of drug loaded nanofibers ensures higher fiber density per unit area leads high mucoadhesive strength and tensile strength

Highlights: Results indicated an initial burst release was followed by sustained drug release behaviour. Nano-fiber formulation showed the significant reduction in IOP for the prolonged time period

Information regarding IPR

Patent application filed covering nanofiber patch for ocular delivery of therapeutics. Since the technology is first time ever used for ocular drug delivery. Therefore it has immense potential to explore the drug delivery application of nanofibers using different route of drug administration.

Patent

- "Topical Non-fibrous ocular implants"
- Application No. 204/DEL/2014, Pub. No. 16/2014

Publication

- Development and characterization of nano-fiber patch for the treatment of glaucoma
- European Journal of Pharmaceutical Sciences, 53, pp.10-16. IF: 3.418
- Downloaded **more than 1000 times**

Market Response

- Marketing potential is evident by response from **Alcon Novartis, Lakeforest, CA, USA; International Eye Scientific Committee, Texas, USA; NRDC, Govt. of India and international consultant InnoCentive Inc., Onisomes Healthcare, Chandigarh**

Competitors technology

- **Currently no product on the proposed carrier is available for the treatment of glaucoma. However The ring, called Helios, is a silicone ring loaded with the bimatoprost was shown to reduce eye pressure during six-month trials, suggesting a more reliable treatment that is easier for patients to use and doctors to monitor**

More than 20 publications have been published in peer reviewed international journals in the field of nanofibers. In addition to this, Some of the hospital and research center have also consented for clinical trials of one of our nanofibrous product.

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GEOGRAPHICAL INDICATIONS

सत्यमेव जयते

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पेटेंट कार्यालय
THE PATENT OFFICE

पेटेंट प्रमाणपत्र
PATENT CERTIFICATE
(Rule 74 Of The Patents Rules)

पेटेंट सं. / Patent No.	:	311049
आवेदन सं. / Application No.	:	204/DEL/2014
फाइल करने की तारीख / Date of Filing	:	22/01/2014
पेटेंटी / Patentee	:	1.Shivani 2.Dr. Amit Kumar Goyal 3.Goutam Rath

प्रमाणित किया जाता है कि पेटेंटी को उपरोक्त आवेदन में यथाप्रकटित A PROCESS FOR PREPARATION MEDICATED NANO PATCH FROM NANOFIBRE AND ITS COMPOSITION नामक आविष्कार के लिए, पेटेंट अधिनियम, १९७० के उपबंधों के अनुसार आज तारीख 22nd day of January 2014 से बीस वर्ष की अवधि के लिए पेटेंट अनुदत्त किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled A PROCESS FOR PREPARATION MEDICATED NANO PATCH FROM NANOFIBRE AND ITS COMPOSITION as disclosed in the above mentioned application for the term of 20 years from the 22nd day of January 2014 in accordance with the provisions of the Patents Act,1970.

एकस्य कार्यालय THE PATENT OFFICE GOVT.OF INDIA भारत सरकार

अनुदान की तारीख : 09/04/2019
Date of Grant :

पेटेंट नियंत्रक
Controller of Patent

टिप्पणी - इस पेटेंट के नवीकरण के लिए फीस, यदि इसे बनाए रखा जाना है, **22nd day of January 2016**को और उसके पश्चात प्रत्येक वर्ष मे उसी दिन देय होगी।

Note. - The fees for renewal of this patent, if it is to be maintained will fall / has fallen due on **22nd day of January 2016** and on the same day in every year thereafter.

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Back to search | Total Document(s): 10 | Page: First << 1 >> Last

Application Number	Title	Application Date	Status	
2832/DEL/2014	COMPOSITE NANOFIBER BASED WATER FILTRATION ELEMENT AND ASSEMBLY	05/10/2014	Published	Application Status
2831/DEL/2014	DEVELOPMENT OF NANOFIBROUS CARRIER SYSTEM FOR MUCOSAL DELIVERY OF DIPTHERIA VACCINE IN GUINEA PIG	05/10/2014	Published	Application Status
949/DEL/2014	NOVEL TERPENOIDAL BASED ANALOGUE OF VASICINE OF FORMULA I WITH MULTIPLE THERAPEUTIC ACTIVITIES.	01/04/2014	Published	Application Status
3107/DEL/2013	FORMULATION AND EVALUATION OF ITRACONAZOLE LOADED NIOSOMAL GEL FOR THE TREATMENT OF ONYCHOMYCOSIS	18/10/2013	Published	Application Status
3106/DEL/2013	A TOPICAL FORMULATION DEVELOPMENT OF PREPARATION FOR HYPERPIGMENTATION	18/10/2013	Published	Application Status
1489/DEL/2013	A PARTICLE FRACTIONATOR FOR SPRAY DRYER	20/05/2013	Published	Application Status
3407/DEL/2012	"POLYSACCHARIDES BASED MUCOSAL VACCINES"	05/12/2012	Published	Application Status
3042/DEL/2012	A spermicidal herbal composition for prevention and control of infections and vaginal disorders.	28/09/2012	Published	Application Status
2574/DEL/2012	Transmucosal Delivery of Insulin using Polymeric Nanofibers	21/08/2012	Published	Application Status
1866/DEL/2012	"DEVELOPMENT AND CHARACTERIZATION OF NANO-CARRIER MODULES FOR MACROPHAGE TARGETED ANTIUBERCULAR MULTIDRUG THERAPY"	18/06/2012	Published	Application Status

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Re: International Eye Committee Member

1 message

frank.m@targetmeetingemail.com <frank.m@targetmeetingemail.com> Mon, Feb 17, 2014 at 12:45 PM
To: amitkumargoyal1979@gmail.com

February 17, 2014
Re: International Eye Committee Member

Dear Dr. Goyal

How are you doing? Based on your recent publications, such as Development and characterization of nano-fiber patch for the treatment of glaucoma. We are delighted to invite you to join the International Eye Scientific Committee. The committee is a focused and efficient communication platform for members to learn latest discoveries, solve academic questions, network with high-level experts, create more collaboration opportunities, receive constructive feed-backs on your works, or share your theory with other members.

With the persistent efforts, Target Meeting has achieved a well-respected reputation within life science community, based on the quality of organizers, speakers and scientific programs, as well as excellent experience. 2500+ international speakers gave oral presentations and tens of thousands of attendees joined the programs and conferences at Target Meeting. Please review hundreds of testimonials from previous participants (http://targetmeeting.com/files/pdf/testimonials.pdf).

Committee Composition and Annual Membership Fee
- Steering Members (Well-Known Professors or Ophthalmologists): For free.
- Full Members (Assistant Professors or Equivalent or above): 175 dollars.
- Member Associates (Junior Researchers or Ophthalmologists): 100 dollars.

Scientific Committee Activities
Target Meeting will work closely with committee members and provide conference servers, organizers, technical support, and all committee related works.

Committee Online Meetings (2 times annually): The 2014 1st Eye Committee Meeting will be held on June 3-5, 2014. The 2014 2nd Eye Committee Meeting will be held in November, 2014. Oral presentations (PPT slides with audio) and discussions are in real time. Headset with microphone is required. We encourage you to use webcam (optional). So members can see you. Target Meeting will try to provide all members comfortable time to join the committee meetings. The committee meeting will include:
- Member introduction & networking.
- Oral presentations and Q&A sessions.
- Panel discussion (academic questions, collaborations, etc.).

Collaboration Meetings: You can organize one or more members to hold specific session about common topic or collaboration. Target Meeting will provide you the full support, such as server, organizing, and so on. The session types will include:
- One (host member) to One (guest member) Meeting.
- One (host member) to More (guest members) Meeting.

Offline Communication: Target Meeting will provide members the detailed committee E-handbook, including names, positions, affiliates, contact information, research (clinical) focus, publications, etc. It is your valuable academic resource (or cycle). You can continue to communicate (offline) with other members based on E-handbook.

Please send us your confirmation before February 28, 2014. Do not miss the great opportunity to network with high-level committee members (your potential collaborators or friends) and get involved in eye committee activities. Feel free to email us if you have any questions.

Best wishes

Frank Ma, Ph.D
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