A critical analysis highlighting the most innovative contributions of the nominee that have made a difference.

Dr. Mohammad Owais is currently serving as a professor of biotechnology at Aligarh Muslim University, Aligarh. Besides active involvement in teaching modern biochemistry/biotechnology courses to M.Sc./Ph.D. students, Dr. Owais has successfully established a small but active research group with a focus on nano-particle-based novel delivery systems including dendrimers/virosomes for gene packaging and liposomes, niosomes, microspheres, and solid core lipid nano-particles for vaccine delivery, gene delivery, targeted drug delivery, *etc*; with a view to increasing the efficacy and safety of encapsulated chemo-therapeutic agents/sub-unit vaccines for some important infectious diseases.

The research focus of Dr. Owais's group has been on:

- Nanoparticles based antigen/DNA vaccine against various infectious diseases with special converges on intracellular pathogens.
- Novel nano-carriers for targeted delivery of encapsulated therapeutic agents (siRNA/drug of interest) for improved treatment of cancer and some imperative infectious diseases.
- Nanoparticles with assorted applications in the field of diagnostics, taste/odor masking, and treatment of hyper-bilirubinemia in model animals.

1. ***Nano-carrier based vaccines: prophylactic measures against major infectious diseases.***

Reckoning the limitations of conventional vaccines, the main focus of Dr. Owais's research endeavors has been to develop nano-vaccines against various infectious diseases of bacterial (tuberculosis, salmonellosis, listeriosis and brucellosis), protozoan (malaria, leishmaniasis) and fungal (candidiasis and cryptococcosis) origin.

(C. M. GUPTA)

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Professor of Molecular Biology
Nanobiopharm Biotechnology Unit
Aligarh Muslim University
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In general, specialized groups of pathogens adapt intracellular parasitism as a strategy to avoid antibody onslaught. Keeping into consideration the non-effectiveness of humoral immune response against intra-cellular pathogens, Dr. Owais evaluated potential of amyloid fibril based vaccines against various intracellular pathogens such as *M. tuberculosis* and *Brucella abortifacients, etc*. (Saba *et. al* JBC 2014, Faraz et al., Frontiers in Immunology and Tufail et. al. JBC 2018). Next, he assessed the prophylactic potential of fusogenic lipid-based vaccines as an alternative prophylactic strategy. In this regard, he has compared the lipid compositions of plasma membranes of both prokaryotic as well as eukaryotic cells. These studies established a correlation between the lipid compositions of plasma membranes of living organisms with evolutionary trend (Deba *et. al*. BBA 2005). Lipid isolated from lower organisms possesses strong fusogenic potential (Owais*et. al*. FEBS J 1999, Ahmad *et. al*. FEBS J 2000, Farah *et. al*. BBA 2005, Ansari *et. al*. Plos One 2011). He further established that model antigens entrapped in liposomes made up of fusogenic lipids can be delivered to the target cells including antigen presenting cells. This eventually facilitates both endo/lysosomal and cytosolic degradation pathways for antigen processing. The dual processing of antigens in the antigen presenting target cells activated both the CD4+ T helper as well as CD8+ T cytotoxic cells. Further, he established that immunization with fusogenic liposomes resulted in the expression of both IL-2 and IFN-γ, the two key cytokines that eventually help in protection against intracellular infections (Faisal *et. al* Vaccine 2003, Farah *et. al*, BBA 2005, Atif *et. al*, FEBS Letters 2006, Sharad *et. al*, Vaccine 2006).

Keeping in view that sperm-ova fusion during zygote formation is generally facilitated by specific lipid compositions of the two cell populations, he demonstrated the fusogenic attributes of sperm plasma membrane lipids (Atif *et. al*. Vaccine 2008) and established the prophylactic potential of Spermatosome based vaccines against various intracellular pathogens (Atif *et. al*. Vaccine 2010).

As conventional egg phosphatidyl-choline (PC) based liposomes are of limited application in activation of pathogen-specific CTL response, required for inhibiting intra-cellular pathogens, Dr. Owais developed non-PC liposome as a vehicle for delivery of antigens in the prophylactic treatment of experimental leishmaniasis (Sharad *et. al*. Vaccine 2006). Further, the liposome/niosome-based vaccines

were also found to be effective against malaria parasites (Sharma *et. al*. Vaccine 2006, Sharma *et. al*. Vaccine, 2007, Varun *et. al;* Pharmaceutical Research 2009). In addition, he has prepared Archae lipid based (Archaeosome) liposomes and demonstrated their immunoadjuvant potential in model animals. Of note, the archaeosome based vaccine was used to mount a long-lasting memory response against experimental listeriosis (Ansari *et. al*. I. J Nanomedicine 2012).

Further, Dr. Owais has highlighted interactions between two mycobacterial proteins viz. Rv3619 (RD9 family) and Rv3620 (CFP-10 analog). He demonstrated that the Rv3619 protein disrupted the biomembrane and also evoked a strong immunological response (Mahmood *et. al.* FEBS J 2010). Moreover, it was revealed that nano-particle mediated targeting of RD9 gene products to dendritic cells favors Th1 prototype of CD4+ T lymphocytes. Targeted delivery of encapsulated antigen to dendritic cells was achieved by coupling anti-DEC antibodies to the surface of archaeosome (archaebacteria lipid vesicles), which helped to cut down the antigen dose significantly thereby making the immunization protocol cost-effective (Ansari *et. al*. 2011).

He had successfully expressed L7/L12 ribosomal protein, SOD-IL-18 fusion protein of *Brucella sp*., and trypanothione-reductase of *Leishmania donavani*. The recombinant proteins were used as potent sub unit vaccines in protection studies (Sharad*et. al*. Vaccine 2006, Mallick *et. al* Vaccine 2007, Mallick *et. al*. Vaccine 2008). A liposome-based DNA vaccine developed by Dr. Owais has shown remarkable promise against experimental murine brucellosis (Singha *et. al*. Microbes & Infection 2008).

Besides introducing liposome, niosome and microsphere-based novel particulate vaccines; Dr. Owais has recently employed an autologous plasma bead-based dual antigen delivery system as a prophylactic strategy against intracellular infections (Ejaj *et. al*. Vaccine 2011). The liposome/microsphere entrapped

(C. M. GUPTA)

antigen further co-entrapped in dual core fibrin beads based vaccine was shown to eliminate intracellular pathogens from systemic circulation (Khan *et. al.* JAC 2012).

2. ***Targeted nano-delivery system***.

Targeted delivery of anticancer agents and antibiotics has been considered as one of the most coveted endeavors in the field of nano-vehicle based drug delivery technology employing adjunctive antimicrobial agents. Efforts from Dr. Owais research group to use a combination of nano-particles based formulations with immunomodulators have been highly successful in combating infectious diseases in experimental diseases (Khan *et. al*. FEMS Micro & Immunol.2003, Khan *et. al*. JDT 2004, Khan *et. al*. JAC 2004). His studies suggest that drug delivery potential of nano-particles can be increased considerably by co-entrapment of potential immunomodulators, such as picroliv, tetrapeptidetuftsin, protein A and various analogs of muramyl peptide, *etc*, in combination with the anti-microbial agents. The resulting formulations were found to be effective against treatment of a range of infectious diseases such as fungal (candidiasis, cryptococcosis, aspergillosis), bacterial (tuberculosis, leprosy, salmonellosis), protozoal (leishmaniasis, malaria) nematodes (filariasis) *etc* (Owais*et. al.* FEBS Letters 1993, Owais *et. al.*AAC 1995, Owais*et. al.* FEBS J 1999, Khan *et. al.* JACS 2002, Khan, *et. al.* FEMS Microb. & Immun. 2003, Deeba *et. al.* Biochimie 2005, Sharma, *et. al*. Vaccine 2006, Sharad, *et. al.* Vaccine 2006).

Liposomes have been widely considered useful as drug/enzyme/nucleic acid vehicles in therapy. However, their successful application was limited by their rapid lysis in blood, major uptake by the RES, and lack of availability of simple procedures for specific targeted delivery. The main emphasis of Dr Owais has been therefore on addressing some of the problems associated with the liposomes as drug delivery systems. He demonstrated that covalent attachment of anti-erythrocyte $F(ab')_2$ to the liposomes surface enables the liposomes to

(C. M. GUPTA)

specifically, recognize the erythrocytes in vivo and deliver their contents to these cells. It was further demonstrated that the entrapment of anti-malarial drugs like chloroquine (chq), in the antibody-coated liposomes increases the drug efficacy not only against the chq-sensitive but also against the chq-resistant malarial infections. Encouraged by these results, the liposomes were coated with $F(ab')_2$ fragments of a monoclonal antibody which specifically recognized the malaria-infected erythrocytes (Patent No. 182550). The monoclonal antibody bearing liposomes with encapsulated chq were found to be highly effective in the treatment of chq-resistant experimental malaria (Owais *et. al.*AAC 1995).

RNA interference is a newly discovered cellular mechanism for silencing genes in a sequence specific manner at the mRNA level. It involves introduction of cognate double stranded small interfering RNA (siRNA) to target desired mRNA and has been shown to have application in viral and cancer therapy. Administration of naked siRNA is susceptible to rapid degradation by plasma RNAses. Cationic lipids have been used as carrier of siRNA, however, not desirable due to innate toxicity of the RNA-lipid complex. To overcome this problem, Dr. Owais has developed a novel nano-particle based formulation encapsulating siRNA that down-regulates Polo like kinase 1(Plk1) and Fox O protein in treatment of skin, liver and breast cancer (Chauhan *et. al.* Nanomedicine 2014, Sherwani et. al. RSC Advances, 2015, Asif et. al. RSC Advances 2015).

Further, the nano-particle based formulations (*cf*. dendrimers, niosomes, liposomes and microspheres) of some important essential oils, viz. clove oil, perillyl alcohol, eugenol and various allyl-sulphide analogs, were first time developed by nominee's group and shown to be effective against drug resistant isolates of various fungal as well as bacterial pathogens (Arif *et. al.* Mol Medicine 2007, Arif, *et. al.* Mol Medicine 2009). Interestingly besides infectious diseases,

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(C. M. GUPTA)

the pH sensitive as well as fusogenic liposomes-based formulations of diallyl-sulphide were shown to be effective against skin carcinoma in model animals as well (Maroof *et. al*, Nanomedicine 2010, Khan *et. al.* JACS 2011). As evident from one of his studies that introduction of HIV-1 genome into PBMCs blocks the propagation of HIV-2 viruses, he developed gene therapy vector for transfecting HIV-2 infected PBMCs with HIV-1 genome using SCID mice (Al-Harathy *et. al*. AIDS RHV 1998). Several studies have defined a close relationship between the HIV-1 infection and the components of the immune system involving chemokines. Suppression of HIV by chemokines represents a special case in virology and immunology where soluble molecules other than antibodies inhibit infection by a specific virus. Consequently, studies by Dr. Owais have focused on the role of various domains of chemokines that are responsible for anti-HIV activity or help in inflammatory responses in the host. He cloned genes of important β chemokines such as RANTES and MIP-1α and expressed them in eukaryotic (HEK 293) and insect cells (SF-9 and SF-21). In order to develop chemokine as a future therapeutic agent in the treatment of HIV infection, it is necessary to establish their structure and function relationship. In this context, he successfully characterized the functional domains of β chemokine RANTES in relation to its anti-HIV activity (Owais & Arya J Hum Virol 1998).

3. Other applications of as-synthesized novel nano-particles

a) The research group of Dr. Owais group developed a liposome based mouthwash containing essential oil that binds to the mucus membrane inside the mouth. This enables the essential oils to remain in the mouth for extended time period to achieve long-lasting germ-killing and breath-freshening protection. Because liposomes have a tremendous amount of surface area, which may facilitate the transfer of the essential oils to the mucus membrane, thus affecting the efficacy of the oils. The encapsulation of the essential oils also protects them from hydrolysis or oxidation (Ahmad *et. al*. JDT, 2004).

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b) Bilirubin, a metabolic by-product of hemoglobin, has been considered as an effective biomarker of liver function. The elevated plasma level of bilirubin exerts deleterious effects on liver function. The liposome/microsphere-based nano-carriers developed by Dr. Owais have been found to be potential scavengers of bilirubin from experimental animals (Masood *et. al.* FEMS Micro & Immunol. 2004, Ahmad *et. al*. BBA 2004, Ahmad *et. al*. BBA 2006).

c) Nano-particles have been exploited as an effective tool for diagnostics in the detection of cancer as well as the presence of pathogens in various food products. The gold-nano-particle-based immunodiagnostic device developed by Dr. Owais has been found to be very effective in cancer diagnosis (Arun *et. al*. IJ Nanomedicine 2011). Besides, aptamer/antibody based biosensor devices developed by Dr. Owais have wide applications in the detection of food-borne pathogens in the meat and shrimps industry (Owais *et. al.* Plos One 2014).

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Awards & Honors

Name of the Award	Name of the Organization	Purpose of the Award	Nature of the Award/Frequency
National Bio-Science Award-2007	DBT, New Delhi Govt of India	To promote Scientific Research	National/ Annual
TATA Innovation Award-2013	DBT, New Delhi Govt of India	To promote Scientific Research	National/ Annual
YM Scientist Award-2002	MAAS (INDIA)	To promote Scientific Research	National/ Annual
Distinguished Research Scientist Award-2015	VIFRA FOUNDATION (INDIA)	To promote Scientific Research	Inter-National/ Annual
Research Excellence Award-2015	The Indus Foundation, NJ (USA)	To promote Scientific Research	Inter-National/ Annual
Best Teacher Award-2009	AMU, Aligarh	For outstanding Scientific/Teaching contributions	National/ University Level Annual
Rashtriya Gaurav Award	IIF, Society, New Delhi (INDIA)	To promote Scientific Research	National/ Annual
Merit Award	Delhi University, New Delhi	For securing Ist position in B. Pharm.	University Level Annual
Merit Award	DYEA, New Delhi	For outstanding perfor-mance in B. Pharm	National/ Annual

सत्यमेव जयते

Government of India
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PRESENTS

NATIONAL BIOSCIENCE AWARD FOR CAREER DEVELOPMENT 2007

TO

DR. OWAIS MOHAMMAD
ALIGARH MUSLIM UNIVERSITY, ALIGARH

in recognition of his pioneering work in development of nano-particles based delivery systems such as virosomes for gene packaging, liposomes and microspheres for vaccine development, gene therapy vectors and drug delivery systems. He has developed liposome based antigen delivery vehicles, which can elicit strong immune response against model antigens in animals.

Given this Day, the 17th of March 2008 at the function organized in connection with the Foundation Day of the Department.

Sibal

KAPIL SIBAL
MINISTER OF SCIENCE & TECHNOLOGY
AND EARTH SCIENCES

RASHTRIYA GAURAV AWARD

CERTIFICATE OF EXCELLENCE

Presented to

Dr M Owais

For Meritorious Services, Outstanding Performance And Remarkable Role

By

Dr. Bhishma Narain Singh

Former Governor of Tamilnadu & Assam

at a Seminar on

Economic Growth & National Integration

At New Delhi on 9th February, 2013.

Gurpreet Singh

Secretary General

India International Friendship Society

No. BT/HRD/35/01/03/2012
Government of India
Ministry of Science & Technology
Department of Biotechnology

Block No. 2, 6-8th Floors
CGO Complex, Lodi Road,
New Delhi – 110 003.

Dated: 15.04.2013

ORDER

In continuation of this Department's sanction order of even number dated 21.02.2013, sanction of the President of India is hereby accorded under Rule 18 of the delegation of Financial Powers Rules, 1978, for the release of a sum of **Rs. 7.40 lakhs** (Rupees Seven lakhs and forty thousand only) of Tata Innovation fellowship awarded to Dr. Mohammad Owais, Associate Professor, Interdisciplinary Biotechnology Unit, Aligarh Muslim University, Aligarh-202002, U.P. being the first release for the implementation of the project entitled "Targeted **delivery of promiscuous antigens to dendritic cells; Prophylactic implications against experimental brucellosis"** as per the break-up given below:

(₹ In Lakhs)

S. No.	Head	Amount
1.	Fellowship	2.40 @ Rs. 20,000/-per month
2.	Contingency	5.00
	Total	**7.40**

2. The other terms and conditions of the grant shall remain unaltered.

3. The amount of ₹ 7.40 lakhs (Rupees Seven lakhs and forty thousand only) will be drawn by Drawing and Disbursing Officer, DBT, from the Pay and Accounts Officer, DBT and disbursed to **the Registrar, Aligarh Muslim University, Aligarh-202002, UP** through RTGS as per following details:

Name of Bank : State Bank of India (SBI)
Branch Name : AMU Branch, Aligarh
A/c No. : 10512179411
IFSC Code : SBIN0005555
MICR Code : 202002003

4. The expenditure involved is debitable to

Demand No. 87	:	Department of Biotechnology
3425	:	Other Scientific Research 2013-14
3425.60	:	Others
3425.60.200	:	Assistance to other Scientific Bodies(Minor head)
3425.60.200.17	:	Human Resource Development
3425.60.200.17.08	:	Human Resource Development Programmes
3425.60.200.17.08.31	:	Grants in Aid General

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Dr. G.J. SAMATHANAM
Advisor/Scientist-G
06/TDT
Telefax : 011-26862512
Phone : 011-26590367
Email : samathan@nic.in

THE GREAT ARC

D O No. VII-PRDSF/103/05-

Date 22.06.2007

Dear Dr. Owais,

I am forwarding herewith the minutes of the first year monitoring committee meeting of the project titled "Evaluation of Tuftsin-bearing polyene nanoparticles in combating some systemic murine fungal infections" among Aligarh Muslim University, Aligarh / M/s Cadila Pharmaceuticals Ltd., Ahmedabad held on 18.06.2007 at Ahmedabad for favour of your information & compliance. As and when you receive the industry contribution the same may be communicated to us for taking action to release DST share. Please ensure the observations of the monitoring committee during the second year so that you are able to contribute still more.

With kind regards,

Yours sincerely,

(G.J. Samathanam)

Dr. Owais Mohammed,
Senior Lecturer,
Interdisciplinary Biotechnology Unit,
Aligarh Muslim University,
Aligarh-202002

Copy to:

1. Dr. Rajiv I. Modi, Managing Director, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Ahmedabad – 382 210.
2. Dr. Bakulesh M. Khamar, Executive Director – Research, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Ahmedabad – 382 210 – with a request to consider the release of Cadila's second year contribution to AMU as recorded in the minutes. Please take action on the issues industry has to provide information to DST.
3. Shri V.K. Sharma, Advisor (Corporate Affairs), Cadila Pharmaceuticals Ltd., D-1011, New Friends Colony, New Delhi – 110 065

(G.J. Samathanam)

डॉ.जी.जे. समाथानम/Dr.G.J.SAMATHAN
वैज्ञानिक 'जी'/Scientist 'G'
विज्ञान एवं प्रौ.विभाग/Dept.of Science & Tech
टेक्नोलॉजी भवन/Technology Bhawan
नया महरौली रोड, नई दिल्ली-110016
New Mehrauli Road, New Delhi-110016

Young Muslim Scientist Award

The Governing Council of
The Muslim Association for the Advancement of Science
confers Young Muslim Scientist Award for the year 2001 on

Dr. Mohammad Owais

with

Dr. Javed Ali

for his outstanding contribution in the field of Life Sciences.

Dr. Rais Ahmad
Hon'y Secretary

Prof. M.A. Roquib
President

THE INDUS FOUNDATION

Indo-Global Education Summit 2015

November 14 & 15, 2015, Hyderabad, India

AWARD FOR RESEARCH EXCELLENCE

Presented to

Dr. M. Owais

Professor, Interdisciplinary Biotechnology Unit

Aligarh Muslim University, Aligarh


Venus International Foundation
(Regd. Trust in India Vide No.18 / BK-IV / 2015)
Dr. Mohammad Omais
Award Winner
VIFRA 2015
Distinguished Scientist
We Congratulate You!
Dated: 19th December 2015
Chennai - 600088, Tamil Nadu, India.

FIRST ANNOUNCEMENT

12th INTERNATIONAL LIPOSOME RESEARCH DAYS
joint meeting with the 3rd conference on
LIPIDS, LIPOSOMES & MEMBRANE BIOPHYSICS

UBC Campus, Vancouver, Canada
August 4-8, 2010

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Conference topics will include:

Nanotoxicology

Ligand-targeted and combination therapeutics

Intracellular delivery

New technology developments

Roles of lipids in membranes

Self-organization of lipids

Lipid trafficking

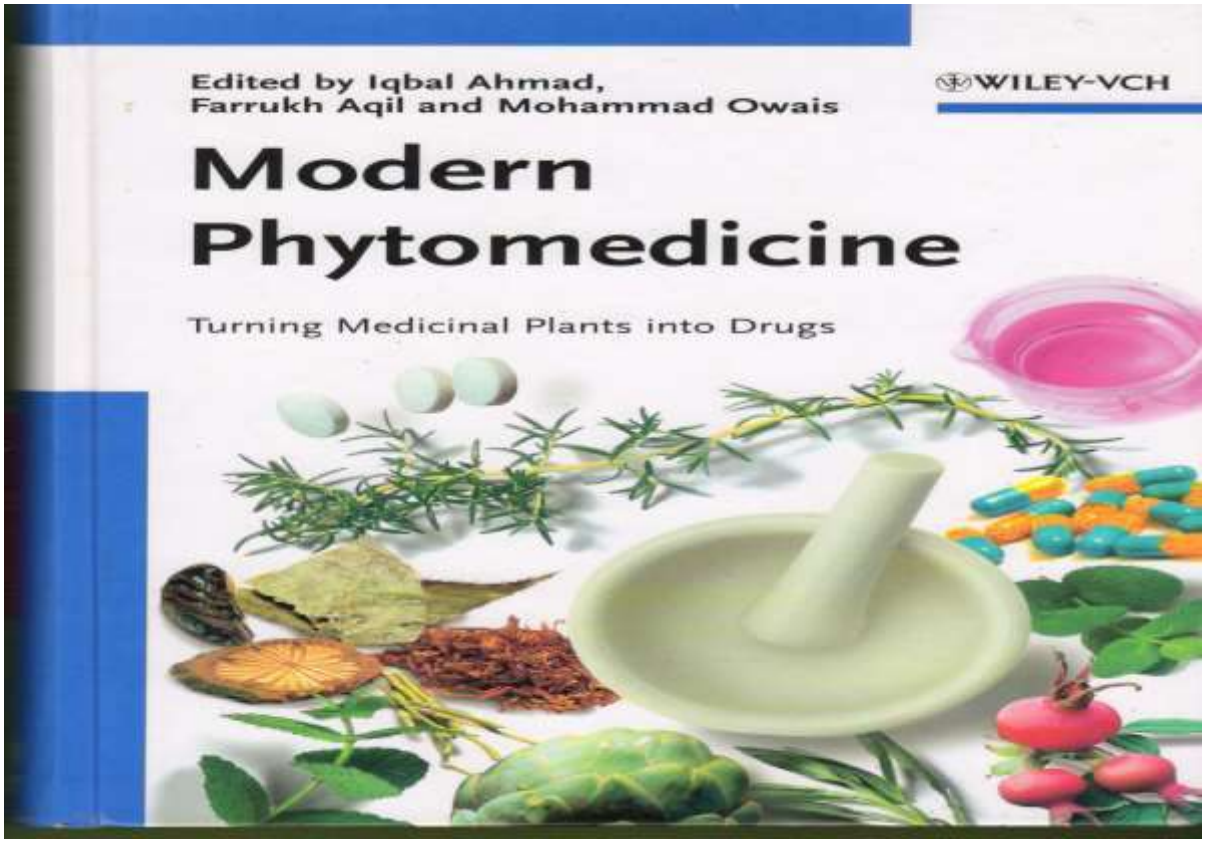
Membrane nanotechnology

PLUS workshops on
- commercialization of nanomedicines
- delivery of gene therapeutics (DNA, siRNA)
- recent clinical develoments

PLUS the International Alec Bangham Award, poster awards, and sponsor exhibits

All researchers with interests in liposomes, nanomedicines, lipids and biomembranes are invited to join us on the beautiful University of British Columbia campus for an exciting interdisciplinary conference.

Organizers: Theresa M Allen (terry.allen@ualberta.ca; Pieter R Cullis (pieterc@interchange.ubc.ca)


Edited by Iqbal Ahmad,
Farrukh Aqil and Mohammad Owais
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Modern
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Turning Medicinal Plants into Drugs

GENNOVA Biopharmaceuticals

To Whom it may concern

This letter is my personal recommendation for Dr. Mohammed Owais. I have seen the profile of Dr. Owais very closely who holds a distinguished record from his Ph.D. days till today specifically in the area of development of liposome-based formulations for the treatment of a range of infectious diseases. His pioneering work in development of nano-particle based delivery systems such as virosomes for gene packaging, liposomes and microspheres for vaccine development, gene therapy vectors and drug delivery systems are being currently exploited by some of the leading pharmaceutical and biotechnology companies to develop some novel drug formulations. Dr Owais work in the area of liposomes technology and nanoparticle has been featured as a cover page by reputed International journals (Molecular Medicine & FEMS-Immunology and Medical Microbiology). He has also developed liposome based antigen delivery vehicles, which can elicit strong immune response against model antigens in animals. Dr. Owais is also currently propagating idea of administering suitable drug formulation along with immunomodulators to combat infectious diseases.

Cadila Pharmaceuticals Ltd., India has sought help of Dr. Mohammed Owais in development of nanoparticle based novel antifungal formulations for treatment of opportunistic fungal infections under the PRDSF program of DST, Govt of India. This product is likely to have great market value and the formulations have been found to impart tremendous increase in efficacy of the drugs. Presently Gennova is evaluating liposome based vaccine delivery options for human phase I clinical trial which have been developed at Dr. Owais lab.

On a personal note, I would like to mention that it has been a pleasure to know a scientist like Dr. Owais, who has developed applied science area so well within academic environment. I wish him all the success in his endeavors and he may add more laurels to his illustrious career.

Yours Sincerely,

Sanjay Singh, Ph.D.
Chief Executive Officer

Gennova Biopharmaceuticals Limited
Plot No.: P-1, I.T. – B.T. Park, Phase – II, M.I.D.C., Hinjwadi, Pune – 411 057 (India) Phone Nos.: + 91 20 39821300 Fax: 91 20 – 39821441
Registered Office : Emcure house, T – 184, M.I.D.C., Bhosari, Pune – 411 026 (India)

एड्स: अमुवि के प्रोफेसर बनाएंगे दवा

बहुराष्ट्रीय दवा की कंपनी मेडीला से हुआ करार

अलीगढ़। अलीगढ़ मुस्लिम विश्वविद्यालय ने एड्स जैसी बीमारी के नियंत्रण पर दवा तैयार करने के लिए एक त्रिपक्षीय समझौता किया है। इस समझौते के अंतर्गत बहुराष्ट्रीय दवा कंपनी मेडीला और भारत सरकार के विज्ञान एवं प्रौद्योगिकी विभाग के बीच वैज्ञानिक शोध और विद्वता के क्षेत्र में आगे कदम बढ़ाएंगे।

अमुवि बायोटेक्नोलॉजी इंस्टीट्यूट के डा. मुहम्मद उवैस एड्स से संबंधित नैनो पार्टिकल्स विकसित करने में अपने शोध से एक दवा तैयार करेंगे। डा. उवैस मोलिकुलर बायोलॉजी के क्षेत्र में 1998 से शोध कार्य कर रहे हैं। डा. उवैस ने अपना पोस्ट डाक्टरेट प्रशिक्षण अमेरिका स्थित एनआईएच के डा.आरती गैलो के ग्रुप के साथ किया है और एचआईवी सेकेंड को विकसित करने में महत्वपूर्ण भूमिका निभाई है। ताकि विश्वभर से एचआईवी से ग्रसित लोगों में आने वाले संक्रमण को समाप्त किया जा सके।

डा. उवैस के इस शोध से प्रभावित होकर ही कैडीला ने डा. उवैस से एड्स की रोकथाम के लिए दवा करने में उनका सहयोग मांगा है।

अमुवि द्वारा किये गये इस करार से औषधि कम्पनी और विद्वान के बीच सम्पर्क स्थापित होने से भारत की स्वास्थ्य सेवाओं में आत्म निर्भरता आएगी और मुकाबले के इस युग में भारत भूमण्डलीय बाजार में अपने को तैयार करेगा और स्वदेशी शोध कार्यों में अपनी पूंजी लगायेगा।

इस कार्य का श्रेय कुलपति प्रो. नसीम अहमद और रजिस्ट्रार प्रो. फैजान को जाता है। उन्होंने शोध कार्यों का रिश्ता सीधा कम्पनियों से जोड़ा है ताकि दोनों के बीच संवाद स्थापित हो जाए।

डा. उवैस ने बताया कि अमेरिका में डा. गैलो ग्रुप के साथ एड्स की रोकथाम के लिए विकसित की गई दवा अपने तृतीय चरण में है। उसके क्लीनिकल ट्रेट अंतिम चरण में है। इसके बाद यह दवा मार्केट में आ जाएगी।

AMU joins hands with Cadila in medical research

The Aligarh Muslim University has entered into an agreement with Cadila Pharmaceutical Industries, Ahmedabad, which is looking for the expertise of research scientists to develop more effective and modern medicines . AMU has developed excellent expertise and infrastructure in selected areas of drug development.

Pioneer 30/6/06

दैनिक प्रकाश

29 जून 2006

अमुवि द्वारा एड्स की दवा बनाने हेतु त्रिपक्षीय समझौता

अलीगढ़ २९ जून।

अलीगढ़ मुस्लिम विश्वविद्यालय ने एड्स जैसी बीमारी के नियंत्रण पर दवा तैयार करने के लिये एक त्रिपक्षीय समझौता किया है।इस समझौते के अन्तर्गत बहुराष्ट्रीय दवा कम्पनी कैडीला और भारत सरकार के विज्ञान और प्रौद्योगिकी विभाग के बीच वैज्ञानिक शोध और विद्वता के क्षेत्र में आगे कदम बढ़ायेंगे। अमुवि बायोटैक्नोलॉजी इंस्टीट्यूट के डा.मुहम्मद उवैस एड्स सम्बंधित नैनो पार्टिकल्स विकसित करने में अपने शोध से एक दवा तैयार करेंगे।डा.उवैस मोलिकुलर बायोलॉजी के क्षेत्र में १९९८ से शोध कार्य कर रहे हैं।डा.उवैस ने अपना पोस्ट डाक्टरेट प्रशिक्षण अमेरिका स्थित एम.आई.एच. के डा.आर.सी. गैलो के ग्रुप के साथ किया है और एच.आई.वी. सैकेंड को विकसित करने में महत्वपूर्ण भूमिका निभाई है।ताकि विश्व भर से एच.आई.वी. के खतरे को समाप्त किया जा सके।

डा.उवैस के इस अन्तर्राष्ट्रीय शोध से प्रभावित होकर ही कैडीला ने डाक्टर उवैस से एड्स की रोकथाम के लिये दवा करने में उनका सहयोग मांगा है। अमुवि द्वारा किये गये इस करार से औषधि कम्पनी और विद्वता के बीच सम्पर्क स्थापित होने से भारत की स्वास्थ्य सेवाओं में आत्म निर्भरता आयेगी और मुकाबले के इस युग में भारत भी भूमण्डलीय बाजार में अपने को तैयार करेगा और स्वदेशी शोध कार्यों में अपनी पूंजी लगायेगा।

इस कार्य का श्रेय कुलपति प्रो नसीम अहमद और रजिस्ट्रार और प्रोफैजान को जाता है कि उन्होंने शोध कार्यों का रिश्ता सीधा कम्पनियों से जोड़ा है ताकि दोनों के बीच संवाद स्थापित हो जाये।

राजपथ

अमुवि ने एड्स कि लिए त्रिपक्षीय समझ

अलीगढ़, २९ जून। अमुवि ने एड्स जैसी बीमारी के लिए नियंत्रण पर दवा तैयार करने के लिए त्रिपक्षीय समझौता किया है। इस समझौते के अन्तर्गत बहुराष्ट्रीय दवा कम्पनी कैडीला और भारत सरकार के विज्ञान एवं प्रौद्योगिकी विभाग के बीच वैज्ञानिक शोध और विद्वता में आगे कदम बढ़ायेंगे।

अमुवि बायोटैक्नालॉजी इंस्टीट्यूट के डा. मुहम्मद उवैस एड्स से संबंधित नैनो पार्टिकल्स विकसित करने में अपने शोध से एक दवा तैयार करेंगे। डा. उवैस मोलिकुलर बायोलॉजी के क्षेत्र में १९९८ से शोध कार्य कर रहे हैं। डा. उवैस ने अपना पोस्ट डाक्टरेट प्रशिक्षण अमेरिका स्थित एम.आई.एच. के डा. आर.सी. गैलो के ग्रुप के साथ किया है और एच.आई.वी. सैकेंड को विकसित करने में महत्वपूर्ण भूमिका निभाई है। ताकि विश्वभर से एच.आई.वी. के खतरे को समाप्त किया जा सके।

डा. उवैस के इस शोध से प्रभावित होकर ही कैडीला ने डाक्टर उवैस से एड्स की रोकथाम के लिये दवा करने में उनका सहयोग मांगा है।

अमुवि द्वारा किये गये इस करार से औषधि कम्पनी और विद्वता के बीच सम्पर्क स्थापित होने से भारत की स्वास्थ्य सेवाओं में आत्म निर्भरता आयेगी और मुकाबले के इस युग में भारत भूमण्डलीय बाजार में अपने को तैयार करेगा और स्वदेशी शोध कार्यों में अपनी पूंजी लगायेगा।

इस कार्य का श्रेय कुलपति प्रो नसीम अहमद और रजिस्ट्रार और प्रोफैजान को जाता है कि उन्होंने शोध कार्यों का रिश्ता सीधा कम्पनियों से जोड़ा है ताकि दोनों के बीच संवाद स्थापित हो जाये।

Shah Times

नई दिल्ली, शुक्रवार, 30 जून, 2006

एड्स पर नियंत्रण के लिए त्रिपक्षीय समझौता

सहारा न्यूज ब्यूरो

अलीगढ़, 29 जून। अलीगढ़ मुस्लिम विश्वविद्यालय ने एड्स के नियंत्रण पर दवा तैयार करने के लिए एक त्रिपक्षीय समझौता किया है। समझौते के अंतर्गत बहुराष्ट्रीय दवा कम्पनी और केंद्र सरकार के विज्ञान एवं प्रौद्योगिकी विभाग के बीच वैज्ञानिक शोध और विद्वता के क्षेत्र में आगे कदम बढ़ायेंगे।

अमुवि बायोटेकनोलॉजी इंस्टीट्यूट के डा. मोहम्मद उवैस एड्स से संबंधित नैनो पार्टिकल्स विकसित करने में अपने शोध से एक दवा तैयार करेंगे। डा. उवैस मोलिकुलर बायोलॉजी के क्षेत्र में 1998 से शोध कार्य कर रहे हैं। डा. उवैस ने अपना पोस्ट डाक्टर प्रशिक्षण अमेरिका स्थित एनआईएच के डा. आरती गैलो के ग्रुप के साथ किया है और एचआईवी सैकेंड को विकसित करने में महत्वपूर्ण भूमिका निभायी है ताकि विश्व से एचआईवी के खतरे को समाप्त किया जा सके।

डा. उवैस के इस शोध से प्रभावित होकर ही कैडीला ने डा. उवैस से एड्स की रोकथाम के लिए दवा करने में उनका सहयोग चाहा है।

अमुवि द्वारा किये गये इस करार से औषधि कम्पनी और विद्वान के बीच सम्पर्क स्थापित होने से भारत की स्वास्थ्य सेवाओं में आत्म निर्भरता आएगी और मुकाबले के इस युग में भारत भूमण्डलीय बाजार में अपने को तैयार करेगा।

इस कार्य का श्रेय कुलपति नसीम अहमद और रजिस्ट्रार प्रो. फैजान को जाता है कि उन्होंने शोध कार्यों का रिश्ता सीधा कम्पनियों से जोड़ा है ताकि दोनों के बीच संवाद स्थापित हो जाए।

आज

आगरा

29 जून 2006

अमुवि वैज्ञानिक एड्स की दवा तैयार करने में जुटे

अलीगढ़। अलीगढ़ मुस्लिम विश्वविद्यालय ने एड्स जैसी खतरनाक बीमारी के नियंत्रण पर एक दवा तैयार करने के लिये एक त्रिपक्षीय समझौता किया है। इस समझौते के अंतर्गत बहुराष्ट्रीय दवा कम्पनी कैडीला और भारत सरकार के विज्ञान एवं प्रौद्योगिकी विभाग के बीच वैज्ञानिक शोध और विद्वता के क्षेत्र में आगे कदम बढ़ायेंगे। ज च ि य

बायोटेक इंस्टीट्यूट के डा. मुहम्मद उवैस एड्स से सम्बंधित नैनो पार्टिकल्स विकसित करने में अपने शोध से एक दवा तैयार करेंगे। डा. उवैस मोलिकुलर बायोलॉजी के क्षेत्र में 1998 से शोध कार्य कर रहे हैं। डा. उवैस ने अपना पोस्ट डाक्टरल प्रशिक्षण अमेरिका स्थित एनआईएच के डा. आर.सी. गैलो के ग्रुप के साथ किया है और एचआईवी सेकेंड को विकसित करने में महत्वपूर्ण भूमिका निभाई है। ताकि विश्वभर से एचआईवी के खतरे को समाप्त किया जा सके। डा. उ वैस के इस शोधसे प्रभावित होकर कैडीला ने डा. उवैस से एड्स की रोकथाम के लिये दवा विकसित करने में उनका सहयोग मांगा है। अमुवि द्वारा किये गये इस करार से औषधि कम्पनी और विद्वान के बीच सम्पर्क स्थापित होने से भारत की स्वास्थ्य सेवाओं में आत्मनिर्भरता आयेगी और मुकाबले के इस युग में भारत भी भूमंडलीय बाजार में अपने को तैयार करेगा और भारतीय उद्योग शोध कार्यों में अपनी पूंजी लगायेगा। इस शोध का श्रेय कुलपति नसीम अहमद और रजिस्ट्रार प्रो. फैजान को जाता है। कि उन्होंने शोध कार्यों का रिश्ता सीधा कम्पनियों से जोड़ा है ताकि दोनों के बीच संवाद स्थापित हो सके।

Biotechnology in the Service of Humanity

Message

Biotechnology is a frontier area of science with a high promise for the welfare of humanity. New generation of biotechnology developed as a result of intensive work in India has opened up research of national relevance. I am confident that fruits of biotechnology would be harnessed for the benefit of millions of our poor people as we move into the next millennium.

(Atal Bihari Vajpayee)
Prime Minister

Message

India is well poised to leapfrog towards a bio-industrial development by conserving and using the precious biodiversity of the country on a sustainable basis with the application of biotechnological tools.

(Dr. Murli Manohar Joshi)
Minister for HRD & Science and Technology

Significant Achievements

- A novel targetec gene delivery system dedicated for liver cells developed and patented in US.
- Identification of a mutation conferring resistance to HIV infection in Indian population.
- Cloning and sequencing of atleast six genes achieved, specially the seed storage, amino acids, biosynthetics and genes for plant defence, for enhancing the nutritional quality. A US patent granted for the seed storage protein gene.
- Plant tissue culture established as an industrial activity. 45lakh plants of forest and horticulture species field planted in 4000 ha.; 40% increase in yield achieved in tissue cultured cardamom plants.
- Biobeneficiation and desulphurisation technologies perfected and transferred to industry, bioremediation field tested for wasteland recovery.
- Transgenic silkworm with bacterius gene can act as a bioreactor for producing proteins of agricultural and therapeutic importance.
- Bio-fertilizers and biopesticide formulations demonstrated on large scale in farmers' field; production units set up.
- 1000 genetically superior calves born through Embryo Transfer Technology (ETT), including 100 buffalo calves.
- Specific primers developed for sex determination of embryos, being used as a customerised service for farmers.
- Record production of over 10 tonnes/ha./year in two crops of prawns through semi-intensive aquaculture attained.
- Through intensive carp farming production level of 18 tonnes/ha./ year achieved.
- First indigenous recombinant vaccine strain for oral cholera, VA 1.3 and Rotavirat diarrhoea enter clinical trials.
- Three indigenous test systems perfected for detection of HIV-I and II, and Streptococcal infections, transferred to industry.
- Low cost nutritious food supplement for the school children being produced.
- Liposome encapsulated Amphotericin B, a drug for curing systemic fungal infections and leishmaniasis commercialised.
- Skin culture technology for burn, new vitiligo, cord blood and bone marrow preservation technologies transferred to hospitals.
- Centres for DNA Fingerprinting; Plant Genome; Brain Research; a Golden Jubilee Women's Biotechnology Park and a BioVillage being established.
- Human resource development in 17 States and UTs; produced about 4000 trained students.
- A wide spread bioinformatics network with INTERNET based Biotechnology Service Provider established.
- Large number of biotechnology based programmes to benefit rural population, SC/ST and women successfully conducted.

Department of Biotechnology , Ministry of Science and Technology

Current area of Research:

Among various novel drug delivery systems, Nanoparticles have emerged as a suitable drug vehicle in regulating pharmacokinetics, pharmacodynamics and eventually the bioactivity of the active core compound. Nanoparticles entail en-route shielding of the associated drug molecules and eventually facilitate their targeted delivery to the active site. Nano-particles with corona have been reported to preferentially accumulate at site of injury, infection and inflammation, mostly because of endothelial dysfunction and blood vessel fenestration at such sites.

In spite of their widely acclaimed potential for sustained drug release and potential to accumulate at the desired site, Nanoparticles do come across with series of barriers that prevent achievement of desirable therapeutic outcome. The main emphasis of Dr Owais has therefore been on addressing some of such problems. He has developed siRNA (*cf*. phosphoinositide 3-kinase, Polo like kinase-1 and, E6 of HPV) bearing nano-particles as a delivery vehicle for treatment of skin, liver, breast and lung cancer in model animals. In another study, he demonstrated that liposome prepared with lipid (from *E. coli* or Archae bacteria) can specifically prime dendritic cells to activate both $CD4^+$ T helper as well as $CD8^+$ T cytotoxic cells of the host. He has also demonstrated that exosomes as well as in-side-out erythrocyte vesicles can deliver encapsulated antigen to cytoplasm of the target cells and find application in development o f prophylactic vaccine against murine malaria. Recently, he demonstrated that **nano-particle/amyloid** mediated targeting (mannose/anti-DC-SIGN antibody based) of RD9 gene products of *Mycobacterium sps* to dendritic cells favors Th1 phenotype of elicited $CD4^+$ T lymphocytes against tuberculosis, thereby help to cut down the antigen dose by several folds. Besides, he developed nanoparticles based DNA (SOD/IL-18) and L_7/L_{12} ribosomal protein bearing vaccines against experimental brucellosis and escheriosome based subunit vaccines against experimental malaria and leishmaniasis in BALB/c mice.

He has successfully transferred technologies pertaining to development of biomimetically synthesized nanoparticles to industries viz. Cadilla Pharma, Ahmedabad and Gennova, Pune for treatment of cancer and opportunistic infections.

Traditional pharmaceutical approaches, implied in the synthesis of Nano-formulation are obscure, owing to the incompatible physico-chemical properties of the drug as well as various undesirable attributes of the excipients used in synthesis of the formulations. In general, the usage of excipients is curtailed by issues like non-optimal biodegradability, short shelf life, toxicity and non-specific activation of user's immune system. Such issues necessitate strategies that lead to development of excipient free drug delivery systems. Plant based extracts have great potential to induce biomimetic synthesis of Nanoparticles. Generally appreciated for medicinal importance of its antioxidant contents, orange juice is likely to play a role in the fight with cancer. Considering this fact, Dr. Owais proposed a prototype employing orange juice that facilitates biomimetic synthesis of Nano-sized supra-molecular assemblies of 5-fluorouracil (5-FU), a potent anticancer drug. The as-synthesized 5-FU Nanoparticles retained the anti-neoplastic efficacy of the parent compound and induced apoptosis of cancer cells. Excipient-free, biomimetically engineered 5-FU Nanoparticles demonstrated enhanced efficacy against DMBA induced fibrosarcoma in the experimental mouse model when compared to the free form of the drug. Nominee has extended similar biomimetic approach to fabricate amphotericin B, nystatin, cis-platinum, doxorubicin and plethora of anti-fungals as well as anticancer agents-based nanoparticles and established their efficacy in model animals.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/133,412	03/15/2015		80			

CONFIRMATION NO. 7816

UPDATED FILING RECEIPT

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OC000000075420950

Date Mailed: 05/28/2015

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

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Power of Attorney: None

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** **MICRO ENTITY** **

Title

PRODUCTION OF BISPECIFIC ANTIBODIES FOR RAPID DETECTION OF FOOD BORNE PATHOGENS

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Patents:

1. Gupta, C.M., **Owais, M**., and Varshney, G.C. A process for the preparation of the drug encapsulated target specific immuno-liposomes for the treatment of drug resistant disease. Patent No. 182550 (Indian Patent).

2. **Owais**, **M**., Verma J. N., Development of liposome based herbal formulations Patent No. 318455 (Indian Patent).

3. **Owais**,**M**.,Swaleha Z, Shadab K. Production of bispecific antibodies for rapid detection of food borne parhogens. Appln. No US 62/133,412 (US Patent).

4. **Owais, M**., Swaleha Z. siRNA LOADED SUBTILOSOME FOR INHIBITING THE GROWTH OF HEPATOCELLULAR CARCINOMA AND METHOD OF PREPARATION THEREOF. Application No: 202111060743

5. Owais M, Khamar BK. Nano particle based polyene anti-fungal formulations (technology development).

6. Owais M, Zubair S, Umair SM, Shazia. A herbal composition for treating viral infections. (International patent No. PBT/2022/070168)

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(57) Abstract :
The present invention generally relates to the field of delivery vehicles. More particularly, the present invention relates to COX-2 specific siRNA loaded subtilosome for inhibiting the growth of hepatocellular carcinoma and method of preparation of the same. The subtilosome-based formulation is stable, releasing COX-2 specific siRNA in a sustained manner which helps in inhibiting TNF-a expression in experimental animals. The siRNA entrapped in B. subtilis plasma membrane lipids based subtilosome help in delivering entrapped COX-2 specific siRNA to the cytosol of the target cells.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
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(57) Abstract: The present invention provides a herbal composition for the management of microbial infections. More particularly, the present invention provides a herbal composition for the management of viral infections and the composition helps in reducing the activity of virus and prevents or manages the virus-associated diseases.

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"A HERBAL COMPOSITION FOR TREATING VIRAL INFECTIONS"

FIELD OF THE INVENTION

The present invention provides a herbal composition for the management of microbial infections. More particularly, the present invention provides a herbal composition for the management of viral infections.

BACKGROUND OF THE INVENTION

Coronaviruses are large, enveloped, plus-stranded RNA viruses. They cause the common cold in all age groups accounting for approximately 15% of all colds. Coronaviruses have been implicated in the etiology of gastrointestinal disease in infants. They also cause economically important diseases in animals (e.g. avian infectious bronchitis and porcine transmissible gastroenteritis). Coronaviruses get their name because in electron micrographs the envelope glycoproteins appear to form a halo or corona around the periphery of the virion. The coronaviruses are also interesting because they are the only plus-strand RNA viruses with a helical nucleocapsid. Coronaviruses are a major cause of common cold in the winter season. The virus is found throughout the world. Antibodies begin to appear in childhood, and are found in more than 90% of adults. The frequency of coronavirus respiratory infections is highly variable from year to year. The highest incidents occur in years when the cases of rhinovirus colds are lowest. Coronavirus colds tend to occur in defined outbreaks.

Coronaviruses have the largest genomes of all RNA viruses and replicate by a unique mechanism which results in a high frequency of recombination. Virions mature by budding at intracellular membranes, and coronavirus infection induces cell fusion.

Coronaviruses are transmitted by aerosols of respiratory secretions, by the fecal-oral route, and by mechanical transmission. Most viral growth occurs in epithelial cells. Occasionally the liver, kidneys, heart or eyes may be infected, as well as other cell types such as macrophages. In cold-type respiratory infections, growth appears to be localized to the epithelium of the upper respiratory tract, but there is currently no adequate animal model for the human respiratory coronaviruses. Clinically, most infections cause a mild, self-

limited disease (classical "cold" or upset stomach), but there may be rare neurological complications.

Emerging infectious diseases, such as severe acute respiratory syndrome (SARS) and Zika virus disease, present a major threat to public health. Despite intense research efforts, how, when and where new diseases appear are still a source of considerable uncertainty. A severe respiratory disease was recently reported in Wuhan, Hubei province, China.

To date, 2019-nCoV has been detected in human clinical specimens by next-generation sequencing, real-time RT-PCR, cell culture, and electron microscopy (Zhu et al., 2020). CDC recommends that clinical virology laboratories should not attempt viral isolation from specimens collected from 2019-nCoV patients under investigation (PUI). Because 2019-nCoV is a newly discovered virus, the spectrum of the available diagnostic tools is tight. At present, there are several commercially available multiplex NAAT tests for the detection of pathogenic organisms in respiratory specimens in clinical virology laboratories (Beckmann et al., 2016; Huang et al., 2018, Babady et al., 2018). They can detect HCoV-229E, -NL63, -OC43, and -HKU1. In addition, the BioFire FilmArray Respiratory Panel 2 plus and the BioFire FilmArray Pneumonia Panel plus can detect MERS-CoV in human clinical specimens.

Influenza virus is a common viral infection that can cause deadly disease in a person suffering from it, especially in high-risk groups i.e., the people who develop severe influenza viral infection. This virus is known to affect the respiratory system in children and adults, thereby leading to substantial morbidity and mortality. The people suffering from chronic disease or have weak immune systems are at high risk of developing the influenza virus in them.

Though there are several drugs and vaccines which are being tested against the pandemic caused due to the virus but a large population still doesn't have easy reach to these expensive drugs especially in developing countries. Moreover, to successfully launch a vaccine, minimum of 20 months of time is required. Therefore, keeping in mind the real threat looming over the whole world, the present invention provides a herbal formulation modified from an age-old drug used in Unani system of medicine to ward off and to control the epidemics caused due to viruses.

OBJECT OF THE INVENTION

The main object of the present invention is to provide a herbal composition for microbial infections.

Another object of the present invention is to provide a herbal composition for the management of microbial infections, particularly viral infections.

Still another object of the present invention is to provide a herbal composition which provides synergistic effect in the management of the viral infections.

Yet another object of the present invention is to provide a herbal composition which is given to reduce the activity of virus in affected subject and to prevent or manage virus-associated diseases.

SUMMARY OF THE INVENTION

The present invention provides a herbal composition for the management of microbial infections. More particularly, the present invention provides a herbal composition for the management of viral infections and the composition helps to reduce the activity of virus in affected patients and prevents or manages virus-associated diseases.

In an embodiment, the present invention provides a herbal composition for the management of viral infections comprising of Kadam or Pincushion fruit (*Neolamarckia cadamba* Roxb.) Mur makki or Myrrh (*Commiphora myrrha*), Aelwa or Aloe (Aloe vera), Habbul ghar (*Paurus nobils* Linn. Lourd.), Gilo neem or Giloy (*Tinospora cardifolia*), Jadwar or Delphinium denudatum powder, kalonji or Black cumin (*Nigella sativa*) and sat e Afsanteen or Artemisia absinthium dry extract in a defined amount/ratio. The said composition is obtained from part of medicinal plants from a group comprising gum, fruits, seeds and aerial parts.

DETAILED DESCRIPTION OF THE INVENTION

The present invention will now be described hereinafter with reference to the accompanying drawings in which a preferred embodiment of the invention is shown. This invention may, however, be embodied in many different forms and should not be construed as being limited to the embodiment set forth herein. Rather, the embodiment is

provided so that this disclosure will be thorough, and will fully convey the scope of the invention to those skilled in the art.

The present invention now will be described hereinafter with reference to the detailed description, in which some, but not all embodiments of the invention are indicated. Indeed, the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout. The present invention is described fully herein with non-limiting embodiments and exemplary experimentation.

The present invention provides a herbal composition for the management of microbial infections. More particularly, the present invention provides a herbal composition for the management of viral infections and the composition helps in reducing the activity of virus in affected subjects and prevents or manages virus-associated diseases.

In the preferred embodiment, the present invention provides a herbal composition for the management of viral infections comprising of Kadam or Pincushion fruit (*Neolamarckia cadamba* Roxb.) Mur makki or Myrrh (*Commiphora myrrha*), Aelwa or Aloe (Aloe vera), Habbul ghar (*Paurus nobils* Linn. Lourd.), Gilo neem or Giloy (*Tinospora cardifolia*), Jadwar or Delphinium denudatum powder, kalonji or Black cumin (*Nigella sativa*) and sat e Afsanteen or Artemisia absinthium dry extract in a defined amount. The composition is in an oral dosage form particularly, a tablet or capsule and the composition provides synergistic effect in the management of viral infections and reduces the activity of virus as well as prevents or manages the viral infections. The novel herbal composition is composed of plants gums, resins, minerals, barks, stems and seeds in specific proportion given below in **Table 1**.

Table 1

Herbal composition and form of use

Plant	Part/form of use	Actions
1) Mur makki or Myrrh (Commiphora myrrha)	Gum	Antimicrobial, antioxidant, respiratory disorders

2) Aelwa or Aloe (Aloe vera)	Dried sap	Antiviral, antioxidant, laxative
3) Habbul ghar (Paurus nobils Linn. Lourd.)	Berries	Antiviral, antioxidant
4) Gilo neem or Giloy (Tinospora cardifolia)	Dry extract	Antipyretic, antiviral, antioxidant, immunomodulator
5) Jadwar or Delphinium denudatum	Powder	Antidote to aconite poisoning, analgesic, astringent, brain diseases
6) kalonji or Black cumin (Nigella sativa)	Seeds	Antimicrobial, antioxidant, respiratory disorders
7) Sat e afsanteen or Artemisia absinthium	Dry extract	Ails digestive problems and worm infections, Anti-inflammatory, immunomodulatory, hepatoprotective, anti-helminthic and anti-depressant activity
8) Kadam or Pincushion fruit (Neolamarckia cadamba Roxb.)	Powder	Expectorant, antidote to venoms, antioxidant, rich mineral source

Neolamarckia cadamba (Roxb.) Bosser (Rubiaceae), known as Kodom in the Bengali language, is grown commonly in different parts of Bangladesh. It is an evergreen tropical tree found in Bangladesh, Nepal, India, Myanmar, Sri Lanka, the Philippines, Indonesia, and Papua New Guinea. Various parts of the plant have traditional uses as an anti-diuretic, and for the treatment of fever, anaemia and tumor. It is an herb mentioned in the Ayurvedic pharmacopoeia for the treatment of wounds, conjunctivitis, mouth ulcers, diarrhea, irritable bowel syndrome and diseases related to the urinary tract. Also, the herb is known to show anti-venom activity, anti-oxidant activity, anti-fungal, anti-bacterial activity, anti-malarial and anti-filarial activity. The fruit is used as expectorant in lung ailments and found very effective in mucoid cough.

L. nobilis originates from the eastern Mediterranean and Asia Minor, where natural stands still provide a considerable part of the laurel leaf production. A chemically distinct form is native to China. *L. nobilis* is grown and occasionally naturalized throughout the drier tropics, subtropics and warm temperate areas. It is also cultivated as a garden and pot plant worldwide. It has expectorant, bronchial and anti-flu properties. In case of respiratory diseases, it offers a beneficial effect against flu, bronchitis, cough, respiratory tract illness.

Aelwa or Aloe (Aloe vera) is known to keep *h*ealing properties, anti-inflammatory action, antiviral and antitumor activity, Laxative effects, Moisturizing, Antiseptic effect and anti-aging effect. The majority of Aloe species occur naturally on mainland Africa, in tropical and subtropical latitudes. The genus is found almost throughout the African continent south of the Sahara Desert, except for the moist lowland forest zones and the western end of West Africa.

Tinospora cordifolia is a shrub that is native to India. Its root, stems, and leaves are used in Ayurvedic medicine. *Tinospora cordifolia* is used for diabetes, high cholesterol, allergic rhinitis (hay fever), upset stomach, gout, lymphoma and other cancers, rheumatoid arthritis (RA), hepatitis, peptic ulcer disease (PUD), fever, gonorrhea, syphilis, and to boost the immune system.

Nigella sativa is a small black seed that has been used for centuries in herbal medicine. The seed comes from a flowering plant (part of the Ranunculacea family) native to southwest Asia and the Mediterranean. The plant now grows throughout India, the Middle East, and Europe. It has been widely used as antihypertensive, liver tonics, diuretics, digestive, anti-diarrheal, appetite stimulant, analgesics, anti-bacterial and in skin disorders. Extensive studies on *N. sativa* have been carried out by various researchers and a wide spectrum of its pharmacological actions have been explored which include antidiabetic, anticancer, immunomodulator, analgesic, antimicrobial, anti-inflammatory, spasmolytic, bronchodilator, hepato-protective, renal protective, gastro-protective, antioxidant properties, etc.

Further, the primary physical virtue of white serpentine stone is to prevent headaches. It soothes tension and relaxes the mind after a confrontation, stress or anxiety. It also has recognized healing effects, both at the cardiac and digestive levels. It is also known to be

antidote of snake bites and keep anti-hypertensive, antibacterial and antimicrobial properties.

Myrrh is a spiny, deciduous shrub or small tree growing about five meters tall. It usually has a small but distinct bole. An oleo-resin gum exudes from the bark of this species and various other members of the Commiphora genus. It is one of the oldest recorded medicines, having been extensively used in ancient Egypt. Myrrh is not usually cultivated, most of it being harvested from the wild. They are native to Africa, eastern Mediterranean countries, and southern Arabia. A pale yellow-white viscous liquid exudes from natural cracks or fissures in the bark or from fissures cut intentionally to harvest the material. The resin obtained from the bark of myrrh is a pungent, astringent, aromatic herb that is strongly stimulant, antiseptic and expectorant. It relieves spasms, inflammation and digestive discomfort, and encourages healing. It is particularly associated with women's health and purification rituals. The resin is taken internally in the treatment of dyspepsia, bronchial and ear infections, glandular fever, tonsillitis, pharyngitis, gingivitis, menstrual and circulatory problems. It is used in chest ailments as an expectorant in respiratory tract infections especially asthma chronic cough and also in diphtheria, tonsillitis, pharyngitis, common cold, bronchitis. It is used in chest ailments as an expectorant in respiratory tract infections especially asthma chronic cough, and also in diphtheria, tonsillitis, pharyngitis, common cold, bronchitis.

Therefore, the present invention provides a combination of an effective antiviral ingredient kadam with other ingredients helps to control the infections associated with virus infections, has great utility and represents an additional management option where, currently, effective management options are limited.

EXAMPLE 1

Viruses

Influenza (A/H1N1and A/H3N2) viruses were kind gift from Dr. Gunasekaran, P from King Institute of Preventive Medicine & Research, Chennai, India. The virus was cultured by nasal/throat swabs into Madin Darby Canine Kidney (MDCK) cells.

The Madin Darby Canine Kidney (MDCK) cells, obtained from the American Type Culture Collection (Manassas, VA) were used for virus inhibition assay. The cells were grown at 37°C with 5% CO_2 in Roswell Park Memorial Institute medium (RPMI;

Invitrogen, No: 22400-105), supplemented with 10% foetal bovine serum (FBS; Invitrogen, No: 16140-071) and 1% Penicillin-Streptomycin (Invitrogen, No: 15140-122). The monolayers were thoroughly washed with phosphate buffered-saline (PBS, pH 7.4 at room temperature), before adding the compounds or the virus, or when quantifying the results. The various experimental setups were including appropriate cell control (cells that were not infected with the virus or treated with the plant extracts), virus control (cells that were infected only with the virus but not treated with the plant extracts in the antiviral assays), and the positive controls (virus-infected cells treated with amanatidine or Oseltamivir).

Anti-viral activity

The influenza strain A/H3N2 subtype viruses had IC 50 values 3.67 nM against the drug oseltamivir and had IC 50 values 1.32 nM against amanatidine. The other influenza strain A/H1N1 had IC 50 value 2.65 against amanatidine and IC 50 values 4.32 nM against oseltamivir respectively.

EXAMPLE 2

Protocol for Cytotoxicity studies of extract

Briefly, MDCK cells were seeded into 96-well flat-bottomed microtitre plates (Costar) at 4×10^3 cells per well. Following overnight incubation, the media of MDCK cells were aspirated, followed by addition of 100 µL of plant extract solution diluted in RPMI medium (two-fold dilutions, ranging from 0.78–100 µg/mL) and another 100 µL of growth medium (supplemented RPMI) were then added to each well. After incubation at 37°C/5% CO_2 for further 3 days, the results were quantified using 3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyltetrazolium bromide (MTT, Invitrogen, No: M-6494) as per the manufacturer's instructions. The optical density (OD) was measured at 540 nm using a Bio-Rad iMark TM microplate reader. The percentages of cell viability were based on the amount of living cells in compound-treated cells relative to cell controls (defined as 100% viability). Cytotoxicity graphs were then generated by plotting percentage of cell viability versus concentration of extracts. Using regression analysis of cytotoxicity curves (in Microsoft excel), a trend line that best suited the curve was selected and the corresponding equation was used to calculate 50% cytotoxic concentrations (CC50).

EXAMPLE 3

In vitro micro-inhibition assay

The activity of plant extracts against influenza viruses was evaluated according to a method described elsewhere. Briefly, 96-well plates were seeded with 3×10^4 cells/well and incubated for 24 h at 37°C with 5% CO_2 until a confluent monolayer was attained. The cells were washed twice with PBS, and two-fold serial dilutions of plant extracts (0.78–100 µg/ml) in RPMI medium were challenged with 100 TCID50 of either of the two virus strains. To all wells, 100 µL of RPMI medium supplemented with 2 µg/mL trypsin (virus growth medium) were added. After incubation for three days at 37°C/5% CO_2, the results were quantified as previously described. The antiviral activity curve was then generated by plotting percentages of virus inhibition against concentrations of extracts. IC50, the concentration of extract essential to reduce virus-induced CPE by 50%, was expressed relative to the virus control employing dose-response curves. Using regression analysis of antiviral activity curves (in Microsoft excel), a trend line that best suited the curve was selected and the corresponding equation was used to calculate IC50 values.

EXAMPLE 4

Time-of-addition assay

The antiviral effects of extract was evaluated at different times of viral infection as described earlier. Briefly, 100 µL/well of the plant extract, serially diluted in RPMI at four concentrations (1-10 µg /mL), was added to 80% confluent MDCK cells at either 1 or 2 hours prior to infection (-1 and -2, respectively), at the time of infection (0), or 1 or 2 hours after viral infection (+1 and +2, respectively). The infection was performed by adding 100 µL/well of either H1N1 or H3N1 (100 TCID50). The various time points (−1, −2, 0, +1, +2) were tested independently in separate plates. 100 µL of virus growth medium was added to each well and the plates were then incubated for three days at 37°C/5% CO_2, after which the virus inhibition was quantified as described earlier.

EXAMPLE 5

Virus binding (attachment) assay

To assess the activity of the compounds in inhibiting viral binding, an attachment assay was employed. Briefly, 80% confluent cells were chilled at 4°C for 1 hour followed by infection with 50 µL/well of H1N1 or H3N1 (200 TCID50) and simultaneous supplementation with 100 µL/well of each plant extract at four concentrations (0.78, 12.5, 25, 50 µg/ml). All plates were held at 4°C for a further 3 h, after which the supernatant was removed; cells were washed twice with ice-cold PBS and the medium was replaced with an equal volume of RPMI and virus growth medium, and incubated for a further three days at 37°C/5% CO_2. MTT was employed to evaluate cell viability and the percentage of viral inhibition was calculated in relation to the virus control wells.

EXAMPLE 6

Penetration assay

The effect of plant extracts on viral penetration was studied according to a method described elsewhere. Briefly, 80% confluent cells were chilled at 4°C for 1 hour prior to infection with H1N1 or H3N1 (200 TCID50) in virus growth medium and held at 4°C for further three hours. After the incubation period, specific concentrations of extracts (0.78, 12.5, 25 or 50 µg/mL) were added in triplicates to the wells with virus. The activity was studied at three time intervals (30, 60 and 120 min) employing one plate per interval at 37°C/5% CO_2. After the specified time interval, the supernatant was removed and treated with acidic PBS (pH 3) for 1 min to inactivate unpenetrated virus, and finally treated with alkaline PBS (pH 11) for neutralization. Cells were washed once with PBS (pH 7.4) and overlaid with an equal volume of RPMI and virus growth media. After three days' incubation at 37°C/5% CO_2, cell viability was evaluated using MTT.

EXAMPLE 7

RESULTS

The IC50 of the plant extract (in DMSO) against MDCK cell line **(Table 2)** and **(Table 3)** was found out to be:

IC50 against Influenza A/H1N1 : 66±04 µg/mL

IC50 against Influenza A/H3N2 : 42±3.2 µg/Ml

Table 2

The plant extract inhibited virus yield in dose dependent manner. MDCK cells were treated with DMSA or plant extract employing increasing concentration of extract followed by infection with virus (Influenza A/H1N1). Viral RNA copies in cell lysate were quantified by qRT-PCR

Concentration of extract µg/mL	Relative viral copy number (%) in cell lysate against A/H1N1
1	97±3.2
20	85±2.4
40	71±2.8
60	54±4.5
80	39±4.5
100	18±3.2
DMSO	96±2.4

Table 3

The plant extract inhibited virus yield in dose dependant manner. MDCK cells were treated with DMSA or plant extract employing increasing concentration of extract followed by infection with virus (Influenza A/ A/H3N2). Viral RNA copies in cell lysate were quantified by qRT-PCR

Concentration of extract µg/mL	Relative viral copy number (%) in cell lysate against Influenza A/H3N2
1	98±2.2
20	69±2.4
40	51±3.8
60	34±4.2
80	21±2.8
100	4±1.2
DMSO	96±2.4

Individual studies of individual ingredients is however known, however the novel herbal composition provided by the present invention is synergistic and exhibits effective results

in treating viral infections. Therefore, the present invention provides a herbal formulation improvised from an age-old Unani drug to ward off and to control the epidemics caused due to viruses.

Many modifications and other embodiments of the invention set forth herein will readily occur to one skilled in the art to which the invention pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

CLAIMS

I claim:

1. A herbal composition for the management of viral infections, comprising of Kadam or Pincushion fruit (*Neolamarckia cadamba* Roxb.) Mur makki or Myrrh (*Commiphora myrrha*), Aelwa or Aloe (Aloe vera), Habbul ghar (*Paurus nobils* Linn. Lourd.), Gilo neem or Giloy (*Tinospora cardifolia*), Jadwar or Delphinium denudatum powder, kalonji or Black cumin (*Nigella sativa*) and sat e Afsanteen or Artemisia absinthium dry extract in a defined amount/ratio.

2. The herbal composition as claimed in claim **1**, wherein said composition is in an oral dosage form particularly, a tablet or capsule.

3. The herbal composition as claimed in claim **1**, wherein said composition provides synergistic effect in the management of said viral infections and reduces the activity of virus as well as prevents or manages said viral infections.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2021/059092

A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSeer, IPO Internal Database, TKDL Database

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Khandelwal, Vishal, et al. "Cytokines modulating potential of Neolamarckia cadamba (Roxb.) Bosser." Indian Journal of Traditional Knowledge 18.1 (2019): 88-93. page 92, left column, para 01, lines 19-26	1-3
Y	Alyafei, Najat. "Can Myrrh Combat COVID-19?." Iberoamerican Journal of Medicine 03 (2020): 223-229. 16 May 2020 (16-05-2020) abstract; page 226, right column, para 5.EFFECT OF MYRRH	1-3
Y	KR20200013005A (LG HOUSEHOLD & HEALTHCARE LTD [KR]) 05 Feb 2020 (05-02-2020) claim 1, 8	1-3
Y	Aurori, Adriana C., et al. "Bay laurel (Laurus nobilis) as potential antiviral treatment in naturally BQCV infected honeybees." Virus research 222 (2016): 29-33. 15 Aug 2016 (15-08-2016). title; abstract	1-3
Y	Sachan, Swati, et al. "Immunomodulatory potential of Tinospora cordifolia and CpG ODN (TLR21	

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04-02-2022	04-02-2022
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Suresh Kumar Telephone No. +91-1125300200

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	agonist) against the very virulent, infectious bursal disease virus in SPF chicks." Vaccines 7.3 (2019): 106. 04 Sep 2019 (04-09-2019). title; abstract	1-3
Y	US5725859A (OMER OSAMA L.M. [DE]) 10 Mar 1998 (10-03-1998) abstract; claims; column 2, Group 1, 3 and 5, lines 32-36, 56-62	1-3
Y	Shamim Molla, Md, et al. "A review on antiviral effects of Nigella sativa L." Pharmacology Online, Newsletter 2 (2019): 47-53. 30 Aug 2019 (30-08-2019). title; abstract	1-3
Y	TKDL RS6/342A, Kadamba Guna, knowledge known since 500 years The Whole Document	1-3
Y	TKDL MH2/207D, Dawa Baraae Zeequn Nafas, knowledge known since 1000 years The Whole Document	1-3
Y	TKDL RS15/177, Kumari Guna, knowledge known since 500 years The Whole Document	1-3
Y	TKDL JA6/622, Laarch Bark, knowledge known since 100 years The Whole Document	1-3
Y	TKDL JA6/556B, Arq-e-gilo-brae-cough, knowledge known since 100 years The Whole Document	1-3
Y	TKDL BA3/1096A, Safoof Jadwar, knowledge known since 100 years The Whole Document	1-3
Y	TKDL MH6/96J2, Dawa-e- Shooneez Deegar, knowledge known since 1000 years The Whole Document	1-3
Y	TKDL NA2/141A, Joshanda-e- Afsanteen, knowledge known since 100 years The Whole Document	1-3

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2021/059092

Citation	Pub.Date	Family	Pub.Date
US 5725859 A	10-03-1998	EP 0708652 B1	25-08-1999
		WO 9529688 A1	09-11-1995
		CA 2168410 A1	09-11-1995
		DE 4415539 A1	17-11-1994

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/133,412	03/15/2015		80			

CONFIRMATION NO. 7816

UPDATED FILING RECEIPT

Dr. Mohammad Owais
Interdisciplinary Biotechnology Unit
Aligarh Muslim University
Aligarh, 262201
INDIA

Date Mailed: 05/28/2015

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Mohammad Owais, Aligarh, INDIA;
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Applicant(s)

Mohammad Owais, Aligarh, INDIA;
Swaleha Zubair, Aligarh, INDIA;
Shadab Kazmi, Aligarh, INDIA;

Power of Attorney: None

If Required, Foreign Filing License Granted: 03/25/2015

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/133,412**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
**** MICRO ENTITY ****
Title

PRODUCTION OF BISPECIFIC ANTIBODIES FOR RAPID DETECTION OF FOOD BORNE PATHOGENS

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

भारत सरकार
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THE GREAT ARC
200 YEARS

D O No. VII-PRDSF/103/05-

Date: 22.06.2007

Dear Dr. Owais,

I am forwarding herewith the minutes of the first year monitoring committee meeting of the project titled "Evaluation of Tuftsin-bearing polyene nanoparticles in combating some systemic murine fungal infections" among Aligarh Muslim University, Aligarh / M/s Cadila Pharmaceuticals Ltd., Ahmedabad held on 18.06.2007 at Ahmedabad for favour of your information & compliance. As and when you receive the industry contribution the same may be communicated to us for taking action to release DST share. Please ensure the observations of the monitoring committee during the second year so that you are able to contribute still more.

With kind regards,

Yours sincerely,

(G.J. Samathanam)

Dr. Owais Mohammed,
Senior Lecturer,
Interdisciplinary Biotechnology Unit,
Aligarh Muslim University,
Aligarh-202002

Copy to:

1. Dr. Rajiv I. Modi, Managing Director, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Ahmedabad – 382 210.
2. Dr. Bakulesh M. Khamar, Executive Director – Research, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Ahmedabad – 382 210 – with a request to consider the release of Cadila's second year contribution to AMU as recorded in the minutes. Please take action on the issues industry has to provide information to DST.
3. Shri V.K. Sharma, Advisor (Corporate Affairs), Cadila Pharmaceuticals Ltd., D-1011, New Friends Colony, New Delhi – 110 065

(G.J. Samathanam)

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