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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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(54) **Title**: COMPOSITION COMPRISING CHITIN AND TINOSPORIN FOR USE IN THE TREATMENT OF VIRAL DISEASES

(57) **Abstract**: The present invention is based on an efficient natural compounds chitin and tinosporin for the treatment of HIV, HTLV thereof. The invention emphasize specially on the application of compounds chitin and tinosporin which is acts as an immunomodulator. It increases innate immunity of the host where as tinisporin selectively inhibit virus from establishing infection to target t helper cells. The exact mechanism by which it prevent infection of virus and host cell is not known but on analysing from cell culture incubated with virus doesn't show any series activation of host cell it suggest either virus is not entering in to the cell or,after entry it could not get activated. The concentration of tinosporin for prevention is 10% isolated in to active form from its natural source. The concentration of chitin >20 um size for prevention is 10% solution base also plant lectins are added to boost up the effect. The remedy is effective against all type of retroviruses and other viruses which enters in to the cell via receptor binding and then cell entry mechanism. Another advantage of this drug is that it is very cost effective and not toxic because all the substance is of natural origin as comparative to existing drug which is toxic and expensive and not 100% effective too. The unique feature of invention is that it is the first natural fusion inhibitor for HIV or retroviruses and thus these compounds have no side effect.

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COMPOSITION COMPRISING CHITIN AND TINOSPORIN FOR USE IN THE TREATMENT OF VIRAL DISEASES

FIELD OF INVENTION

This invention is based on natural and efficient compound Chitin and Tinosporin which are effective in the treatment of all group of HIV (human immunodeficiency virus).HTLV(human T cell Lymphotrophic Virus)as well as other viral diseases also.

PRIOR ART:

In the existing system as given in United States Patent 7498038 wherein The present invention relates to chitin microparticles and their medical uses, in particular in the treatment of allergy, or the treatment of conditions that would benefit from an upregulation of the cell mediated immune system, or an up-regulation of natural killer (NK) cell activity and/or the secretion of interferon-γ (IFN-γ).

In the existing system as given in United States Patent 5587292 wherein A novel method for detecting chitin, and for diagnosing fungal infections (including yeast infections), with a chitinase or other chitin-specific binding protein. This method should allow the convenient, broad spectrum diagnosis of fungal infections in tissue samples or in body fluids. Fungal infections are a particular problem in immunocompromised hosts such as AIDS patients, where they can cause opportunistic infections. This invention overcomes difficulties experienced by prior methods of diagnosing fungal infections.

In the existing system as given in U.S. Patent Number 6,303,118 wherein A new human chitinase having an amino acid sequence as shown in FIG. 1 or FIG. 2. Modified forms of it having a similar

chitin-hydrolyzing activity, and antigenic peptides representing one of its epitopes. Recombinant production of the human chitinase by genetically engineered hosts or host cells. Recombinant nucleic acid encoding it, and human chitinase-specific oligonucleotides. Use for therapeutic or prophylactic treatment of humans against infection by chitin-containing pathogens, or for decomposing chitin, e.g. from chitin-based articles. Antibodies binding to the human chitinase. Diagnostic test kits comprising the human chitinase, its antigenic peptides, human chitinase antibodies, recombinant nucleic acid or oligonucleotides.

In the existing system as given in United States Patent 6124273 wherein This invention is directed to the preparation and utilization of supplemented chitin hydrogels, such as chitosan hydrogels. Further provided are biomaterials comprising same. The particular supplement delivered by the chitin hydrogel is selected as a function of its intended use. In one embodiment, this invention provides a composition of matter, comprising a chitin hydrogel or chitin-derived hydrogel, wherein the hydrogel does not inhibit full-thickness skin wound healing.

In the existing system as given in US Patent 6399571 wherein The present invention provides chitin-binding fragments of human chitinase, fragment analogs, purified and isolated polynucleotide sequences encoding such fragments and analogs, and materials and methods for the recombinant production of human chitinase fragment products which are expected to be useful as in products for detecting chitin, binding chitin, and treating fungal infections or for development of products useful for treating the same.

In the existing system as given in United States Patent 6579978 wherein The present invention is directed to novel sulphated compounds of hyaluronic acid and derivatives thereof, optionally salified, wherein the glucosamines are partially N-sulphated or partially N-sulphated and partially or totally O-sulphated in position 6. The compounds of the invention have anticoagulant and antithrombotic activities and are useful in the preparation of pharmaceutical compositions and biomaterials and in the production of coatings for biomedical objects.

In the existing system as given in Application number: 12/433,960 wherein the present invention relates to the field of sterilization of items that are sensitive to e.g. temperature, pH, positive or

negative pressure, radiation or oxidation. More particularly, the invention concerns a method, the use of this method and an apparatus for sterilization or disinfection, comprising the steps of contacting one or more item or part of an item with a water-based fluid comprising at least one reductant, followed by the step of contacting with a gas having oxidative properties in a substantially water-free environment. According to the invention, items can be sterilized that are otherwise impaired by conventional sterilization procedures, such as laboratory items, medical items, dental items, military items, biological items, and food processing-related items

In the existing system as given in Patent application number: 20090270347 wherein Methods of producing microparticles, and especially chitin microparticles (CMP), are disclosed that involve reducing the size of (larger) particles using a (high shear) microfluidising instrument.

In the existing system as given in WO 1992/005196 A1 (patent application wherein The present invention provides therapy and prophylaxis against HIV-induced AIDS, as well as methods for ascertaining the susceptibility of an individual to HIV-induced AIDS, the invention being based on the discovery that AIDS results from gp120 of HIV mimicking the antigen-presenting component of the immune system, thereby spuriously activating certain CD4+ T cells in susceptible individuals, leading to a condition similar to graft versus host disease, the condition being treatable by eliminating the responsible T cells, for example.

In the existing system as given in WO 1992/005196 A1 (patent application) wherein The present invention provides therapy and prophylaxis against HIV-induced AIDS, as well as methods for ascertaining the susceptibility of an individual to HIV-induced AIDS, the invention being based on the discovery that AIDS results from gp120 of HIV mimicking the antigen-presenting component of the immune system, thereby spuriously activating certain CD4+ T cells in susceptible individuals, leading to a condition similar to graft versus host disease, the condition being treatable by eliminating the responsible T cells, for example.

In the existing system as given in US 7285566 (granted patent) wherein Resistance-repellent and multidrug resistant retroviral protease inhibitors are provided. Pharmaceutical composition comprising such compounds, and methods of using such compounds to treat HIV infections in mammals, are also provided.

In the existing system as given in AU 2003/230545 A1 (patent application)wherein Resistance-repellent and multidrug resistant retroviral protease inhibitors are provided. Pharmaceutical composition comprising such compounds, and methods of using such compounds to treat HIV infections in mammals, are also provided.

In the existing system as given in US 5935579 (granted patent) wherein The present invention provides therapy and prophylaxis against HIV-induced AIDS, as well as methods for ascertaining the susceptibility of an individual to HIV-induced AIDS, the invention being based on the discovery that AIDS results from gp120 of HIV mimicking the antigen-presenting component of the immune system, thereby spuriously activating certain CD4+ T cells in susceptible individuals, leading to a condition similar to graft versus host disease, the condition being treatable by eliminating the responsible T cells, for example

In the existing system as given in WO 1998/002742 A1 (patent application)wherein A novel method for detecting chitin, and for diagnosing fungal infections (including yeast infections), with a chitinase or other chitin-specific binding protein. This method allows the convenient, broad spectrum diagnosis of fungal infections in tissue samples, body fluids, and other samples. Fungal infections are a particular problem in immunocompromised hosts such as AIDS patients, where they can cause opportunistic infections. This invention overcomes difficulties experienced by prior methods of diagnosing fungal infections.

In the existing system as given in WO 2006/064376 A1 (patent application) wherein The present invention relates to peptides or derivatives thereof, pharmaceutical compositions comprising the same and uses thereof to treat or prevent a viral infection, in particular a retroviral infection, such as Hepatitis C Virus (HCV) or Human. Immunodeficiency Virus (HIV) infection. The invention specifically discloses novel chemical compounds as active ingredients to treat such infection.

In the existing system as given in WO 2008/115894 A1 (patent application)wherein Resistance-repellent and multidrug resistant retroviral protease inhibitors are provided. Pharmaceutical composition comprising such compounds, and methods of using such compounds to treat HIV infections in mammals, are also provided.

In the existing system as given in AU 2006/222057 A1 (patent application) wherein The present invention concerns 2-(4-cyanophenyl)-6-hydroxylaminopyrimidines having HIV (Human Immunodeficiency Virus) replication inhibiting properties. The invention further relates to methods for the preparation of these pyrimidines and pharmaceutical compositions comprising these compounds and the use thereof in the prevention or the treatment of HIV infection

In the existing system as given in AU 2005/298637 A1 (patent application)wherein The present invention is concerned with pyrimidine derivatives having HIV (Human Immunodeficiency Virus) replication inhibiting properties. The invention further relates to methods for their preparation and pharmaceutical compositions comprising them. The invention also relates to the use of said compounds in the prevention or the treatment of HIV infection.

In the existing system as given in AU 1999/044150 A1 (patent application) wherein The present invention relates to methods of inhibiting viral entry and spread in vivo and in vitro. The invention further relates to isolated peptides from a mammalian Rho protein which have been found by the inventors to be useful for inhibiting entry of enveloped viruses, specifically paramyxoviruses and lentiviruses, into susceptible cells. In particular embodiments, the invention also relates to methods of preventing infection by enveloped viruses. These methods utilize the inhibitory effect of specific RhoA peptides or specific peptides isolated from the fusion glycoproteins of respiratory syncytial virus (RSV) or human immunodeficiency virus (HIV) on the viral entry mechanism of enveloped viruses.

OBJECT OF THE INVENTION

The main object of the invention is to introduce the application of therapy based on natural compound Chitin and Tinosporin which are effective for the treatment of the targeted viruses (Retroviruses) (HIV-I,HIV-II)all subgroups ,HTLV and other viral disease. The main advantage

of this invention is that it can be apply on all kind of virus which enters in to the cell via receptor binding and then cell entry mechanism. Another advantage of this drug is that it is very cost effective and not toxic because all the substance is of natural origin as comparative to existing drug which is toxic and expensive and not 100% effective too. The unique feature of invention is that it is a first natural fusion inhibitor for HIV or retroviruses.Thats why these compounds have no side effect.

STATEMENT OF INVENTION

This invention is based on natural compound Chitin and Tinosporin which are efficient for treatment various viral diseases like HIV, HTLV and other viral disease. It has no side effect, cost effective.

DETAILED DESCRIPTION OF THE INVENTION:

This invention is based on natural compound Chitin and Tinosporin which are efficient for the treatment of HIV. It is useful for all group of retrovirus which causes infection in human, all group of HIV (human immunodeficiency virus). HTLV (human T cell Lymphotrophic Virus). As well as

all type of virus which enters in to the cell via receptor binding and then cell entry mechanism. These are harmless for any kind of allergy because they are naturally occurring compounds.

Tinosporin:

Tinosporin is an immunomodulatory agent. It increases the white cell count in pathological states to increase the phagocytes of the foreign material. This leads to the destruction of microbes in infections. Liver enzymes are positively influenced. It has anti-diabetic (hypoglycemic) actions. Tinospora cardifolia helps to reverse the fatty degeneration of liver. Anti-oxidant, anti-pyretic and anti-inflammatory functions of ***Tinospora cardifolia*** are well studied scientifically and documented.

Chitin:

Chitin may play a role in a possible pathway in human allergic disease. Specifically, mice treated with chitin develop an allergic response, characterized by a build-up of interleukin-4 expressing innate immune cells. In these treated mice, additional treatment with a chitinase enzyme abolishes the response.

Human immunodeficiency virus (HIV)

It is a lentivirus (a member of the retrovirus family) that causes acquired immunodeficiency syndrome (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections.

Mechanism of AIDS

When CD4+ T cell numbers decline below a critical level of 200 cells per μL, cell-mediated immunity is lost, and infections with a variety of opportunistic microbes appear. Common opportunistic infections and tumors, most of which are normally controlled by robust CD4+ T cell-mediated immunity then start to affect the patient. Typically, resistance is lost early on to oral Candida species and to Mycobacterium tuberculosis, which leads to an increased susceptibility to oral candidiasis (thrush) and tuberculosis. Later, reactivation of latent herpes viruses may cause worsening recurrences of herpes simplex eruptions, shingles, Epstein-Barr virus-induced B-cell lymphomas, or Kaposi's sarcoma.

Mechanism of HTLV:

The Human T-lymphotropic virus Type I (HTLV-1) is a human RNA retrovirus that causes T-cell leukemia and T-cell lymphoma in adults and may also be involved in certain demyelinating diseases, including tropical spastic paraparesis. The HTLV-1 genome is diploid, composed of two

copies of a single-stranded RNA virus whose genome is copied into a double-stranded DNA form that integrates into the host cell genome, at which point the virus is referred to as a provirus. Adult T-lymphotropic virus (ATLV) is a strain of this disease that affects primarily adults. A closely related virus is bovine leukemia virus BLV.

Mode of action chitin and tinisporin on retrovirus

The invention emphasize specially on the application of compounds chitin and tinosporin which is acts as aa immunomodulator it increases innate immunity of the host where as tinisporin selectively inhibit virus from establishing infection to target t helper cells. The exact mechanism by which it prevent infection of virus and host cell is not known but on analysing from cell culture incubated with virus doesn't show any series activation of host cell it suggest either virus is not entering in to the cell or after entry it could not get activated .the concentration of tinosporin for prevention is 10% isolated in to active form from its natural source. and chitin >20 um size in 10% solution base also plant lectins are added to boost up the effect.

Advantages of compounds-

The remedy is effective against all type of retroviruses and other viruses which enters in to the cell via receptor binding and then cell entry mechanism. Another advantage of this drug is that it is very cost effective and not toxic because all the substance is of natural origin as comparative to existing drug which is toxic and expensive and not 100% effective too. The unique feature of invention is that It's first natural fusion inhibitor for HIV or retroviruses.Thats why these compounds have no side effect. The unique feature of invention is that It's first natural fusion inhibitor for HIV or retroviruses.Thats why these compounds have no side effect.

CLAIMS:

We claim:

1 The application of therapy of natural compounds such as Chitin and Tinosporin effective for the treatment of the targeted viruses (Retroviruses) (HIV-I,HIV-II) all subgroups ,HTLV and other viral diseases.

2 An effective treatment of the targeted virus as recited as claimed in Claim 1 wherein it increases innate immunity of the host where as tinisporin selectively inhibits virus from establishing infection to target t helper cells

3 An effective treatment of the targeted virus as recited in Claim 2 wherein the exact mechanism by which it prevents infection of virus and host cell is not known but on analysing from cell culture incubated with virus doesn't show any series activation of host cell which suggests either virus is not entering in to the cell or after entry it could not get activated.

4 An effective treatment of the targeted virus as recited in Claims 1, 2 & 3 wherein the concentration of tinosporin for prevention is 10% isolated in to active form from its natural source.

5 An effective treatment of the targeted virus as recited in Claims 1, 2 & 3 wherein the concentration of chitin >20 um size for prevention is 10% solution base also plant lectins are added to boost up the effect.

6 An effective treatment of the targeted virus as recited in Claim 1 wherein the remedy is effective against all type of retroviruses and other viruses which enter in to the cell via receptor binding and then cell entry mechanism.

7 An effective treatment of the targeted virus as recited in Claim 1 wherein advantage of this drug is that it is very cost effective and not toxic because all the substance is of natural origin as comparative to existing drugs which are toxic and expensive and not 100% effective too.

8 An effective treatment of the targeted virus as recited in Claim 1 wherein the unique feature of invention is that it is the first natural fusion inhibitor for HIV or retroviruses and thus these compounds have no side effects.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2010/000606

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/366 A61K31/722 A61K36/59 A61P31/12 A61P31/14 A61P31/18
ADD.
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 practical, search terms used)
EPO-Internal, BIOSIS, EMBASE, WPI Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 101 461 849 A (YI QU [CN]) 24 June 2009 (2009-06-24) the whole document & DATABASE EPODOC EUROPEAN PATENT OFFICE, THE HAGUE, NL; 24 June 2009 (2009-06-24), Database accession no. CN101461849 abstract ----- -/--	1-8

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2010/000606

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KALIKAR M V ET AL: "Immunomodulatory effect of Tinospora cordifolia extract in human immuno-deficiency virus positive patients.", INDIAN JOURNAL OF PHARMACOLOGY JUN 2008 LNKD- PUBMED:20040936, vol. 40, no. 3, June 2008 (2008-06), pages 107-110, XP009145114, ISSN: 1998-3751 the whole document page 109, left-hand column, last paragraph page 108, right-hand column, paragraph 1 -----	1-8
Y	WO 03/015744 A1 (MEDICAL RES COUNCIL [GB]; STRONG PETER [GB]) 27 February 2003 (2003-02-27) cited in the application claims 10, 11,13,14,24, -----	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IN2010/000606

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CN 101461849 A	24-06-2009	NONE	
WO 03015744 A1	27-02-2003	AT 375786 T	15-11-2007
		CA 2457027 A1	27-02-2003
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		DE 60223037 T2	24-07-2008
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		PT 1416916 E	25-01-2008
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