Indian Solution to Global Health Problems
Globally Patented New Immunity Drug: NID/Receptol®

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Innovation Journey of New Immunity Drug (NID)/Receptol®

Dr. George Wald, Nobel laureate & Prof. Joseph Weizenbaum, father of artificial intelligence at MIT, USA brain stormed with the Biomix team.Poor Immunity was found to be the #1 reason for majority of diseases.

After 10 years of research , we have successfully isolated Nanopeptides from bovine colostrum and conducted global clinical studies on 25,301 Subjects suffering from HIV, Swine flu & other communicable / Immune disease via innovative oral spray drug delivery system.

What is NID/Receptol®

NID Active Pharmaceutical Ingredients (API) consist of Patented Nano – Informational Peptides extracted from mammalian/ bovine colostrum via Ultra Nano filtration Technology having sequence id 1-8 *(provided on next slide)* & Proline Rich Poly Peptides (PRPs)

PRPs & NID are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.

Innovation Journey of New Immunity Drug (NID)

- Dr. George Wald, Nobel laureate & Prof. Joseph Weizenbaum, father of artificial intelligence at MIT, USA brain stormed with the Biomix team.
- Poor Immunity was found to be the #1 reason for majority of diseases.
- Several immunity drugs existed, however none could ; “build body’s own immunity like mother’s first milk”. This was the insight & lead for the research team.
- After 10 years of research , we have successfully isolated Nanopeptides from bovine colostrum and conducted global clinical studies on 30000 patients suffering from communicable disease and Immune disorders via innovative oral spray drug delivery system.
- Radha 108 which also produces Biosimilars like IL, IFN & TNF, at the most affordable price creating a paradigm shift in the pharmaceutical industry.

Creating paradigm shift in health care from ‘ Prevention to Cure’

Fleming discovered Penicillin G, which saved millions from bacterial infections. Radha 108 will save billions from viral infections & immune disorders

Composition of NID

NID Consists of - Radha 108 Active Pharmaceutical Ingredients (API)

- **API consist of Patented Nano – Informational Peptides extracted from mammalian colostrum via Ultra Nano filtration Technology having sequence id 1-8** ***(provided on next slide)*** **& Proline Rich Poly Peptides (PRPs)**

- **PRPs & Radha-108 are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.**

- **Dosage - 3ml QDS via oral buccal spray (1 ml contains 0.03 grams of Patented Nano Peptides that can be synthetically manufactured also) and tablets, capsules & MMS drug delivery systems**

The 'Biggest' thing in Industry, just may be the 'Smallest' thing –
Radha 108 Nanopeptides

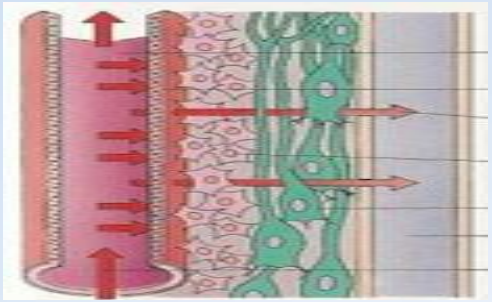
Patented Sequences of NID

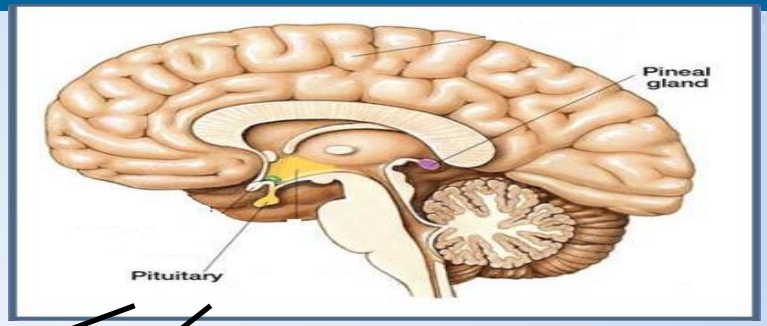
Radha 108 consists of Patented Sequence ID-8 that work in synergy with each other to build body's strong immune system even in totally immune compromised AIDS patients

S. No.	Peptide Sequence	Spectral Count	Protein name
1	ELVPGVPRGTQL	27	DNA-binding protein inhibitor ID-3 **(MW – 1265.48)**
2	VAIIQHMIKKLR	24	Epstein-Barr virus induced gene 2 (Lymphocyte-specific G protein-coupled rec **(MW – 1449.86)**
3	LPQEVLNENLLRF	22	Alpha-S1-casein **(MW – 1584.84)**
4	RLNARMAELR	21	S-adenosylmethionine synthetase isoform type-1 **(MW – 1229.47)**
5	SSLQVLNMSHN	21	Toll-like receptor 4 **(MW – 1229.37)**
6	EYQELMNVK	20	Keratin, type II cytoskeletal 59 kDa, component IV (Fragment) **(MW – 1153.32)**
7	VDTLNDEINFLR	20	Keratin, type II cytoskeletal 7 **(MW – 1448.6)**
8	DGIVNENLAER	20	Ribonucleoside-diphosphate reductase small chain **(MW – 1229.31)**

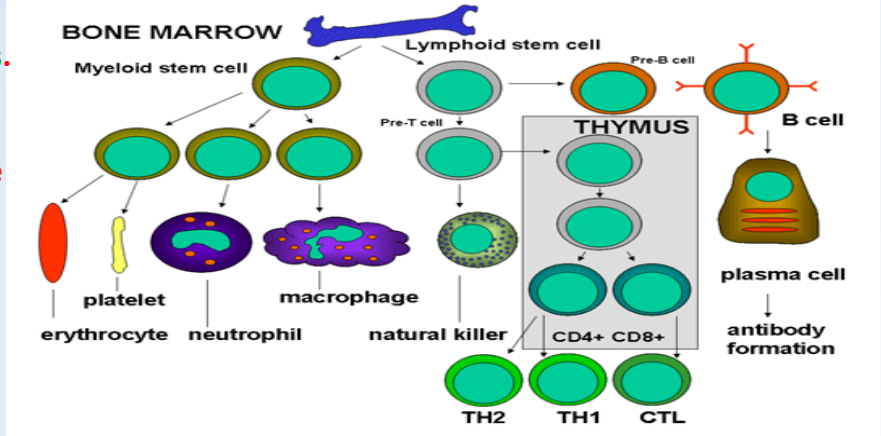
Mode of action: Science behind NID

PRPs get absorbed in the blood through buccal mucosa and crosses BBB





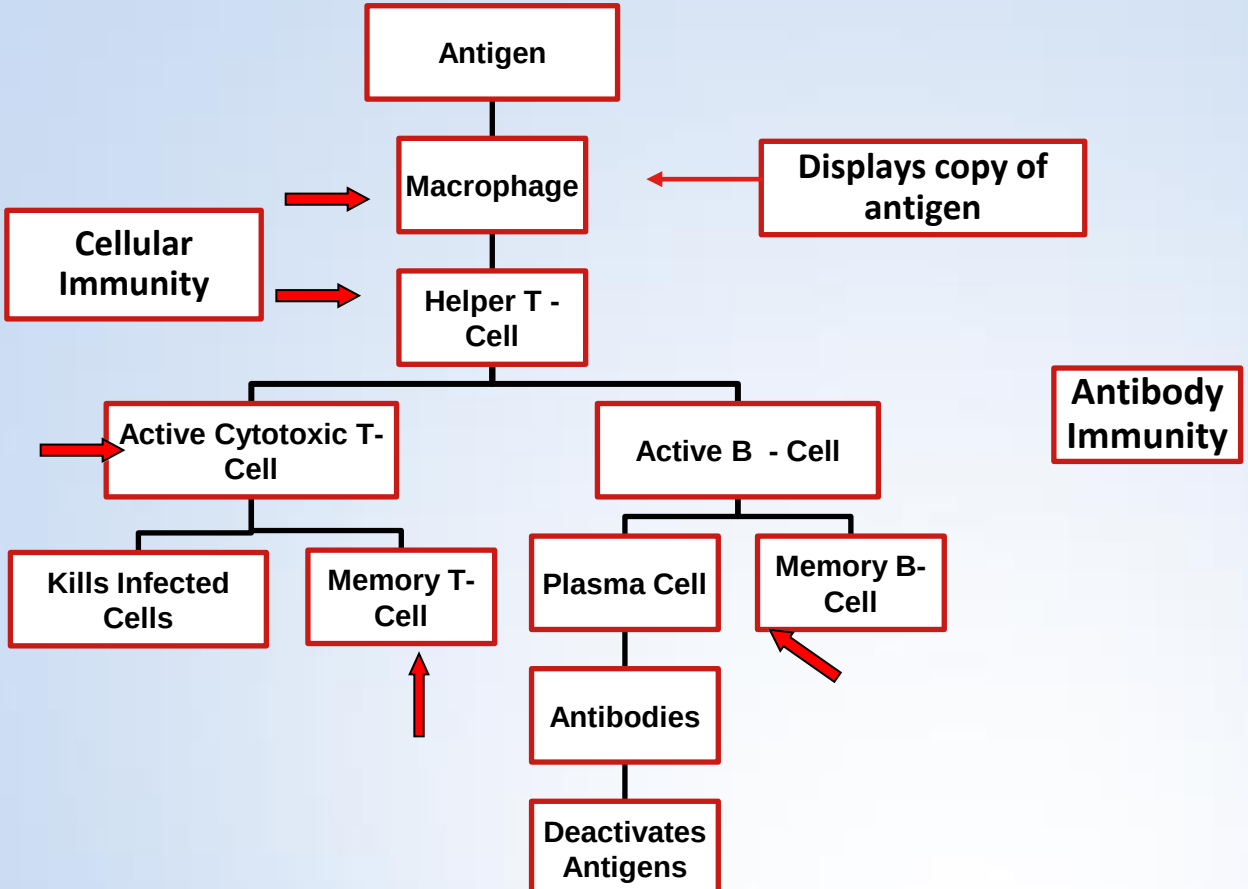
- Radha108 (PRP) promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180,160 and 41 mimicking receptor on the cell surface closing entry of viruses.



- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF–γ.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces

Mode of action - ↑Immuno Response Summary

Radha 108 ( )



PHARMACEUTICAL DATA ON FORMULATION

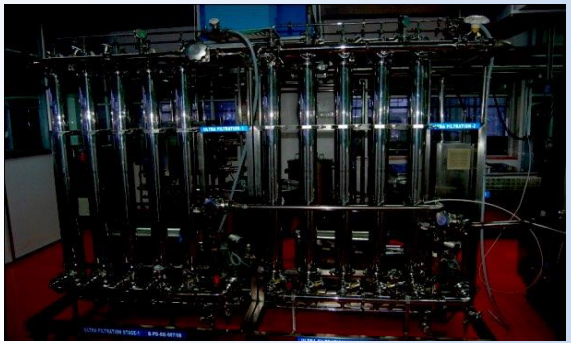
DOSAGE AND ADMINISTRATION	**4 Sprays of 0.75ml metered dose (3ml), two each on each side of inner cheek 4 times daily**
ROUTE OF ABSORPTION & DISTRIBUTION	• API (PRPs) absorbed through the buccal mucosa • Crosses blood brain barrier due to low mol. wt below 2kDa. • Distributed all over the body through the blood streams.
INDICATIONS	• Treatment of HIV as adjunct therapy & for associated recurrent infections. • Immunity enhancer for immune disorders like Asthma, Rheumatoid Arthritis & others
CONTRAINDICATIONS	•Proven to be safe in acute as well as chronic use. •No incompatibility along with any other medication. •No minor or serious contraindication reported.
WARNINGS & PRECAUTIONS	None, Since its over dose does not harm anyone even neonates
ADVERSE EFFECTS	No adverse effects observed.
STORAGE	Keep in cool & dry place. Keep under refrigeration once the bottle is opened and consume within 30 days after opening.

GMP Facility & Product Range

- **Radha108 Nano Peptide manufacturing plant is state of the art, nano biotech facility granted by TUV Nord Germany since 2012. GSK Consumer healthcare group UK & India due diligence done on product & the manufacturing facility**

- **Consistent raw material source : International quality from ISO/GMP certified, Amul, world's largest 75 year old dairy with stringent QC/QA checks & balances, right at the origin of Colostrum.**

- **Extraction of API, PRP (Radha108, Type of PRPs of molecular weight from 1800 to 500kDA) is done by Merck Millipore Molecular Exclusion Ultra filtration columns of 100 to 10 kDA at cGMP facility shown below.**



MHRA Approved Manufacturing facility for NID Powder & Tablet

Certificate No: UK GMP 33423 Insp GMP 33423/498770-0008

MHRA

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer: MILAN LABORATORIES (INDIA) PRIVATE LIMITED

Site address: PLOT NOS. 35/36/63/64/65/67/87 JAWAHAR CO-OP INDUSTRIAL ESTATE LTD
KAMOTHE
PANVEL (NAVI MUMBAI)
MUMBAI
IN 410 209
INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

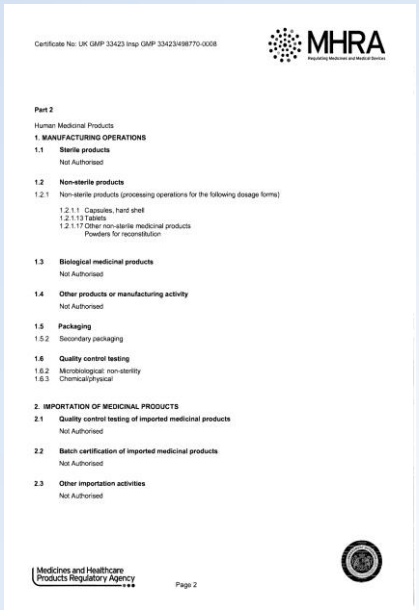
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20/06/2016, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

Medicines and Healthcare Products Regulatory Agency



Certificate No: UK GMP 33423 Insp GMP 33423/498770-0008

MHRA

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products
Not Authorised

1.2 Non-sterile products
1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets
1.2.1.17 Other non-sterile medicinal products
Powders for reconstitution

1.3 Biological medicinal products
Not Authorised

1.4 Other products or manufacturing activity
Not Authorised

1.5 Packaging
1.5.2 Secondary packaging

1.6 Quality control testing
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products
Not Authorised

2.2 Batch certification of imported medicinal products
Not Authorised

2.3 Other importation activities
Not Authorised

Medicines and Healthcare Products Regulatory Agency

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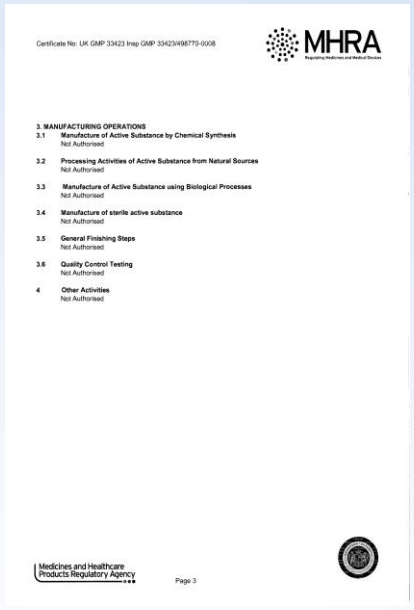

Certificate No: UK GMP 33423 Insp GMP 33423/498770-0008

MHRA

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Medicines and Healthcare Products Regulatory Agency

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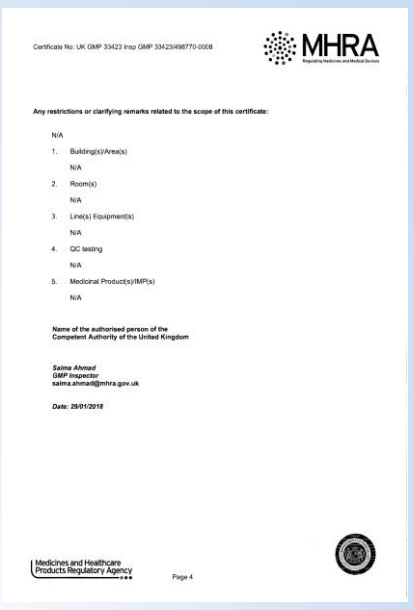


Certificate No: UK GMP 33423 Insp GMP 33423/498770-0008

MHRA

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)
N/A
2. Room(s)
N/A
3. Line(s) Equipment(s)
N/A
4. QC testing
N/A
5. Medicinal Product(s)/IMP(s)
N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Salma Ahmad
GMP Inspector
salma.ahmad@mhra.gov.uk

Date: 29/01/2018

Medicines and Healthcare Products Regulatory Agency

Page 4

NID – Product range

Oral spray

Oral liquid

Capsules & Tablets

Powder

REPORT

OF

ACUTE (14 DAYS) SUB – CHRONIC (60 DAYS – 45 days treatment, 15 days recovery) REPEATED DOSE TOXICITY STUDY OF COLOSTRUM MILK PRODUCT (RECEPTOL) THROUGH ORAL ROUTE IN SPRAGUE DAWLEY RATS

STUDY NO: 01 – 10

SPONSOR

BIOMIX NETWORK LTD.,
C/O KHEDA SATELLITE DAIRY,
NEAR KHATRAJ CROSS ROAD,
KHATRAJ–387130, GUJARAT, INDIA.
Email : biomix@amuldairy.com

STUDY CENTRE

CENTRE FOR ADVANCED RESEARCH IN PRE – CLINICAL TOXICOLOGY
NATIONAL INSTITUTE OF NUTRITION
INDIAN COUNCIL OF MEDICAL RESEARCH
Phone No. +91 (40) 27197322, Fax No. +91 (40) 2701 9074
HYDERABAD – 500 007, A.P INDIA

2011

Toxicology study at National institute of nutrition (NIN)

Pre-Clinical safety study has been undertaken as per schedule Y of DCGI guideline under the supervision of Dr. B. Dinesh Kumar, Asst. Director (Study director) at **National Institute of Nutrition, Hyderabad**.

Acute toxicity

RESULTS
No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route
All rats were found to be active and with normal body weight.
No Acute toxicity found.

NIN Study : Sub acute data

No mortality was observed & product is safe

1.	No. of Rats used	48
2.	Categories	Vehicle control (VC), Therapeutic dose (TD – 1.08ml), Average dose (AD – 5XTD), (five times of TD) and High Dose (HD – 10XTD), (ten times of TD)
3.	Days of trial	45
4.	Period of Observation	Biweekly for live phase, cage side, physical and neurological parameters. At 48hrs and 15th day hematology and biochemistry profile along with gross necropsy and histopathology of major organs were evaluated.

RESULTS
No significant difference in physical activity and neurological activity between control and test groups throughout the study period.
No significant abnormalities in hematology , clinical chemistry profile in blood/serum samples.
No gross lesions were found in any organ and no significant difference in histopathology of various organs.
No sub chronic toxicity found

Indian Safety & Efficacy Mono Therapy Clinical Trial

On immunocompromised HIV subjects used as the model

Preclinical Safety: as per **NIN** National Toxicology Panel

- **No Acute Toxicity & No Sub Chronic Toxicity**

Phase IIIIndian Safety & Efficacy Mono Therapy Clinical Trials- with Radha 108 Nano Peptide by Government of India, Ministry of Health/National AIDS Control and Monitored by Indian Council of Medical Research/NARI* by US PATH accredited org.

- **Study I** : 50 HIV Positive Patients at Tertiary Care LTMG Hospital Sion, Mumbai (Clinical trial registry No. : CTRI-2012-08-002931)
- **Study II** :51 HIV Positive Patients at Tertiary Care LTMG Hospital, Sion, Mumbai (Clinical Trial registry No. : CTRI-2012-09-002959)

Safety and Efficacy Achieved by Global Trials:

Phase I : 12 cohort 30 days (completely safe) in Ohio, USA
Phase II : 30 cohort 90 days (highly effective with no side effects)in Nairobi – Kenya
Phase III : 60 cohort for 365 days (highly effective with no side effects) in Rwanda, Africa

SUMMARY - GLOBAL SAFETY & EFFICACY STUDY DATA ON AIDS SUBJECTS

KEY DIMENSIONS	PHASE I, II & III INTERNATIONAL TRIALS	INDIA PAGE III STUDY 1	INDIA PAGE III STUDY 2
Phase	Phase I – HIV trial, US Phase II – HIV trial,Nairobi,Kenya Phase III – HIV trial, Rwanda	Phase III validation trial by GOI on HIV patients, Standalone monotherapy	Phase III validation trial by GOI on HIV patients, Standalone monotherapy
No. of patients	Phase I – 12 cohorts Phase II – 30 cohorts Phase III – 60 cohorts	50 HIV seropositive patients	51 HIV seropositive patients
Duration	30 to 365 days	180 days	180 days
Compliance	Very good	Very good	Very good
Side effect	None	None	None
Weight gain	6 lbs average gain	4.73 kg per patient, $p<0.05$	4.68 ± 1,9 kg per patient, $p<0.001$
Clinical symptoms	90 days relief from symptoms	Improved within 3 weeks from starting of therapy	Improved within 3 weeks from starting of therapy
CD4 cell count	Phase II: Average by 31	Average by 51, median CD4 cell count from 312 to 363 ($p = 0.06$)	On an average by 27 ($p = 0.042$)
HIV Viral load	Phase II: Mean HIV log viral load from 4.6 to 2.5	Mean HIV log viral load from 4.63 to 4.18 ($p = 0.001$)	Mean HIV log viral load from 4.41 to 4.02 ($p = 0.009$)

Summary of Mumbai, India phase III study on AIDS patients

- **Tertiary care, Sion Hospital, Mumbai 51 AIDS Patients Study**
  - Absolute CD4 cell count & HIV Viral Load – tested at IIH (ICMR)
  - Clinical & Physical symptoms study - at ART Center, Sion Hospital
  - **Inclusion criteria** – absolute CD4 cell count greater than 100 $cells/mm^3$ and 100% Symptomatic patients at basal.
  - **Exclusion criteria** – no pre- exposure to ART
  - Mean HIV log viral load has statistically significantly dropped ($p < 0.009$)
  - Statistically significant increase in CD4 cell count ($p < 0.042$)
  - Clinical symptoms disappeared in 3 weeks of treatment in All Patients ($p<0.001$)
  - Statistically significant weekly weight gain in All Patients ($p<0.001$).

Summary of Mumbai, India phase III study on AIDS patients

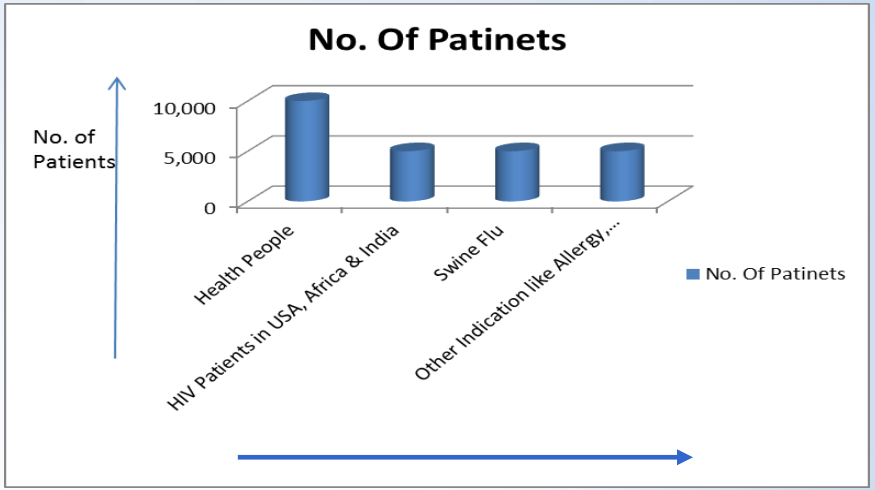
Clinical Symptoms	N	At Baseline	Responders At Week-2
Diarrhea	51	51(100%)	12(23.53%)
Nausea	51	51(100%)	3(5.9%)
Vomiting	51	51(100%)	17(33.3%)
Fever	51	51(100%)	13(25.5%)
Cough	51	51(100%)	13(25.5%)
Paraesthesia	51	51(100%)	16(31.4%)
Disturbed Sleep	51	51(100%)	0(0%)
Skin Rash	51	51(100%)	7(13.7%)
Fatigue/Malaise	51	51(100%)	51(100%)
Herpes Zoster	51	51(100%)	18(35.3%)
Hair Changes	51	51(100%)	16(31.4%)
Leukoplakia	51	51(100%)	0(0 %)
Oral Thrush	51	51(100%)	0(0 %)

Parameter	Baseline Mean ± SD	Week 12 Mean ± SD	Difference (Week 12- Baseline) Mean ± SD	P-value
CD4 Counts (cells/ cmm)	317.16 ± 128.67	344.24 ± 165.79	+ 27.08 ± 92.47	0.042
CD8 Counts (cells / cmm)	1037.06 ± 285.02	1139.75 ± 386.76	+102.69 ± 267.44	0.008

Meta Analysis on 25000 Patients

Meta Analysis is a combined Statistical analysis of 25,000 subjects across HIV, Swine Flu, Allergy/Asthma, Rheumatoid Arthritis , Endometriosis & NCD: Chronic Fatigue Syndrome showing increase in weight gain as an Indication of overall wellness showing Safety & Efficacy of Radha108 Nano Peptide.

Sr.No.	Stand Alone Receptol Therapy in Global clinical studies	No. of Patients
1	Healthy people	10,000
2	HIV Patient in USA, Africa, India	5000
3	Swine Flu	5000
4	Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.	5000

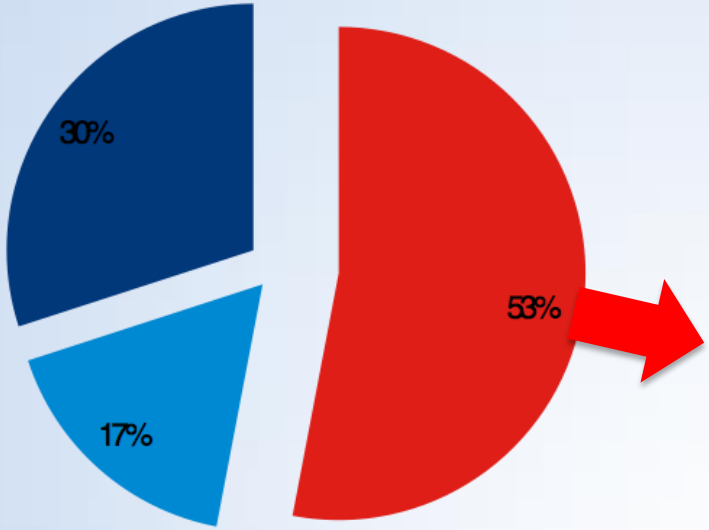


Stand Alone Radha 108 Therapy in Global Clinical Studies

Global Clinical Study

Data on Respiratory Disease - Allergies

Reporting Patients*	:	24
Duration of Treatment	:	6 months

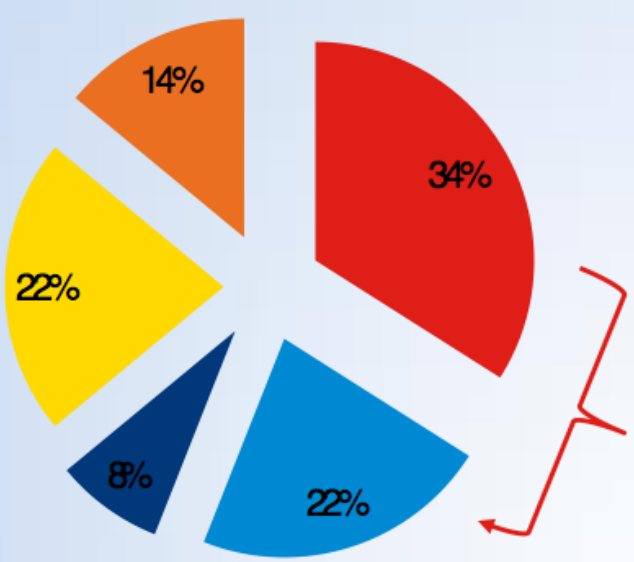


More than half the respondents experienced complete resolution of symptoms!

Data on Autoimmune Disease

Rheumetoid Arthritis

Reporting Patients*	:	63
Duration of Treatment	:	6 months



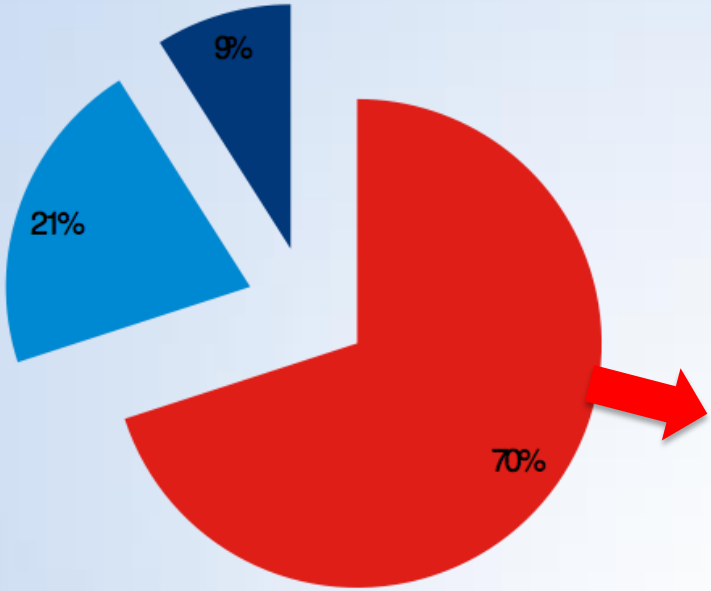
- Complete resolution of symptoms
- Significant benefits
- Some benefit
- Did not exhibit the same benefit
- Inconclusive

56% **of patients found the product to be highly effective!**

Data on General Immunity Disorder

Chronic Fatigue Syndrome

Reporting Patients*	:	108
Duration of Treatment	:	6 months

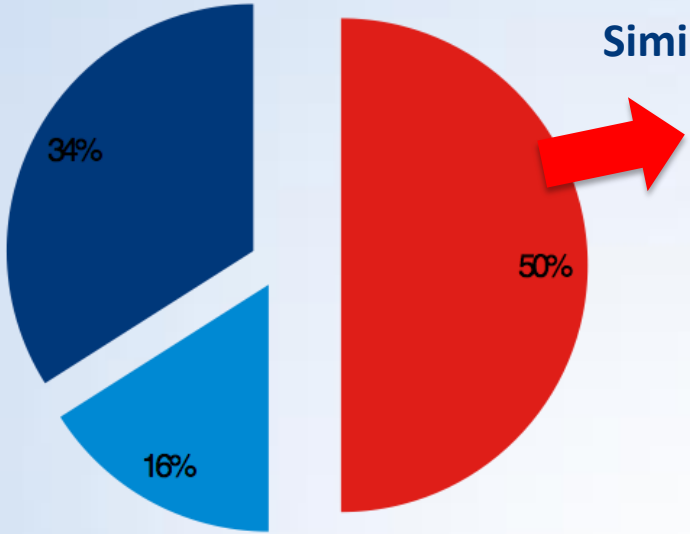


70% of patients received significant benefits!

Data on General Immunity Disorder

Endometriosis

Reporting Patients*	:	106
Duration of Treatment	:	6 months



Similarly for Endometriosis, complete resolution in most cases!

- Complete resolution of symptoms
- Some benefit
- Inconclusive

Medical confirmation of NID for globally patented 58 indications (US Patent # 9,249,188 PCC# IN2009/000749 WO2010/079511)

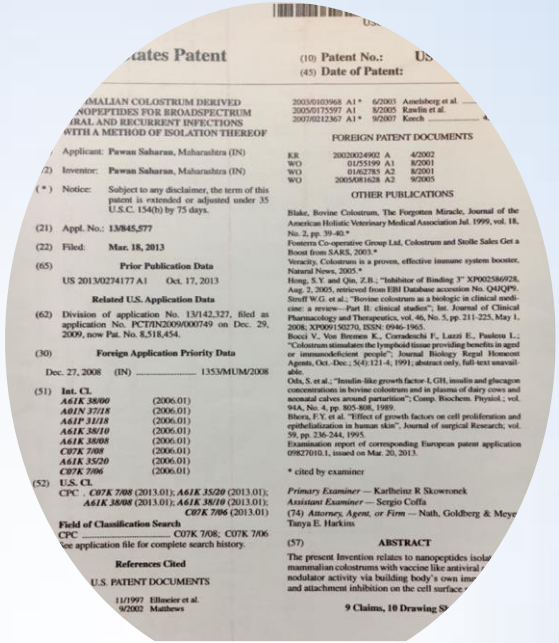
Allergies , Asthma, HIV, Autoimmune Disorders, Viral Respiratory Infection, Rheumatoid Arthritis, Endometriosis , Cancer, Lupus , Severe Acute Respiratory Syndrome (SARS), Cold & Flu, Benign Prostatic Hyperplasia , Premenstrual syndrome, & Alzheimer's, Hypertension, Thrush,Austism, Perthes disease, Prion disease, Psoriasis, Sjogren's syndrome, Spinal Muscular Atrophy, Thrombocytopenia, Burns, Infection, Insect bites, Daiper rash, Herpetic lesions, Pharangitis, Porphyria, Raynaud's phenomenon, Acute Viral Infection, Dengue fever, Shingles, Plantar Warts, Lymphoma , Herpes Simplex I & II, Parvo, Sarcoidosis, Celiac disease, Chronic Pancytopenia, Crohn's disease, Diabetes type II, Fibromyalgia Rheumatica, Mononucleosis, Multiple Sclerosis, Osteo Arthritis, Brown Recluse Spider Bite, Corneal Regeneration, Diarrhea, Guillain Barre Syndrome, Hemolytic Anemia, Idiopathic thrombocytopenia purpura, Myasthenia Gravis, Tuberculosis, Human Immunodeficiency Virus(HIV), Hepatitis A and C, Rabies in Dogs, Human Pappilloma Virus

Patents for Preventive Therapy

Current invention related to mammalian colostrum provides answers to current and pipeline vaccine conjugates for preventing majority of viral as well as bacterial communicable infections.

Abstract from US Patent 2016

The present Invention relates to nanopeptides isolated from mammalian colostrums with vaccine like antiviral and immunodulator activity via building body's own immune system and attachment inhibition on the cell surface receptors.


ates Patent

(10) Patent No.:

(45) Date of Patent:

MALIAN COLOSTRUM DERIVED
NOPEPTIDES FOR BROADSPECTRUM
RAL AND RECURRENT INFECTIONS
WITH A METHOD OF ISOLATION THEREOF

Applicant: Pawan Saharan, Maharashtra (IN)

(72) Inventor: Pawan Saharan, Maharashtra (IN)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 75 days.

(21) Appl. No.: 13/845,577

(22) Filed: Mar. 18, 2013

(65) Prior Publication Data

US 2013/0274177 A1 Oct. 17, 2013

Related U.S. Application Data

(62) Division of application No. 13/142,327, filed as application No. PCT/IN2009/000749 on Dec. 29, 2009, now Pat. No. 8,518,454.

(30) Foreign Application Priority Data

Dec. 27, 2008 (IN) 1353/MUM/2008

(51) Int. Cl.

A61K 38/00 (2006.01)
A01N 37/18 (2006.01)
A61P 31/18 (2006.01)
A61K 38/10 (2006.01)
A61K 38/08 (2006.01)
C07K 7/08 (2006.01)
A61K 35/20 (2006.01)
C07K 7/06 (2006.01)

(52) U.S. Cl.

CPC . C07K 7/08 (2013.01); A61K 35/20 (2013.01); A61K 38/08 (2013.01); A61K 38/10 (2013.01); C07K 7/06 (2013.01)

Field of Classification Search

CPC C07K 7/08; C07K 7/06

See application file for complete search history.

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(57) ABSTRACT

The present Invention relates to nanopeptides isolated from mammalian colostrums with vaccine like antiviral and nodulator activity via building body's own immune system and attachment inhibition on the cell surface

9 Claims, 10 Drawing Sheets