Indian Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals for Small Extramural Grants - 2025

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Proposal Id: IIRPSG-2025-01-03362, **Version Id:** F1,
Proposal Title: Development and Characterization of Carrageenan- 6-Gingerol herbal based nanoparticles with a customized meter dose inhaler for lung cancer and chronic respiratory diseases.

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS) :	PROF GANESH KUMAR
Designation :	Professor
Email :	drganeshbhatt2@gmail.com
Contact No. :	9897435971
Gender :	Male
DOB :	13-12-1978
Date of Superannuation :	13-12-2038
Nature of Employment	Permanent
Institute	Swami Rama Himalayan University, Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , YES (01-Jan-1970) Dehradun, Uttarakhand

Proposal Details PART-A

Nature of employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs.	Permanent
Advertisement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2025

Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.
Rationale and Knowledge Gaps Current challenges in lung cancer and other respiratory diseases are poor drug delivery efficiency to affected areas via conventional routes, Limited bioavailability of therapeutic compounds, Lack of targeted delivery systems, Side effects of systemic chemotherapy, and Absence of predictive models for nanoparticle behavior. There are certain knowledge gaps, like Limited understanding of carrageenan-6-gingerol-based herbal nanoparticle interaction with lung tissue and the respiratory tract, insufficient data on 6-gingerol therapeutic potential via customized meter dose inhaler. Novelty The novelty of the proposed project is to introduce four innovative elements, such as the • Innovative idea of developing the customized (pressure-controlled) metered dose inhaler (MDI) of 6-gingerol with natural biocompatible carrageenan polymer (for controlled delivery) for synergistic targeted effect for lung cancer and chronic respiratory diseases like asthma and COPD. 6-Gingerol. Objectives • Characterize the physicochemical properties of the carrageenan-6-gingerol nanoparticles (size, morphology, stability, encapsulation efficiency). • Evaluate the in vitro efficacy against lung cancer cell lines and respiratory tract inflammatory models. Expected Outcomes Scientific studies will unleash the understanding of the development of a stable carrageenan-6-gingerol nanoparticle meter dose inhaler formulation with optimal size for pulmonary delivery. Design Demonstration of a pressure-controlled delivery mechanism for customizable dosing for synergistic cytotoxic effects of carrageenan and 6-gingerol against lung cancer cell lines and anti-inflammatory activity for respiratory tract diseases.

Priority Area/Priority Area diseases	Non-Communicable Diseases / Chronic respiratory illness
Keywords Six keywords separated by comma which best describe your project may be provided.	6- Gingerol, Lung Cancer, Meter Dose Inhalet, Carrageenan, synergistic, customized.
Abbreviations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	AI: Artificial Intelligent MDI: Meter Dose Inhaler SEM/TEM: Scanning Electron Microscope/ Transmission Electron Microscope DLS: Dynamic Light Scattering FTIR: Fourier Transform Infra-Red XRD: X-Ray Diffraction DSC: Differential Scanning Calorimetry DoE: Design of Experiment QbD: Quality by Design

Swami Rama Himalayan University Director Research

Problem Statement (up to 500 words): State the currently available information to present the problem adequately.

Globally, chronic respiratory diseases, including lung cancer, asthma, COPD, and pulmonary inflammation, pose a significant burden, accounting for a substantial number of deaths and disabilities worldwide, with conventional treatment methods often limited by poor drug bioavailability, systemic side effects, inadequate targeting of cancer cells, and lack of personalization in drug delivery. While 6-gingerol, a bioactive natural compound derived from ginger and natural polymer carrageenan has demonstrated promising anti- cancer anti-respiratory illness properties 1-2. Current delivery systems for lung cancer chronic respiratory diseases have face several challenges: • Conventional drug delivery methods often fail to achieve optimal drug concentrations in lung tissue, resulting in reduced therapeutic efficacy. • Existing metered-dose inhaler delivery systems lack the customizable controlled delivery depth mechanism depending on the disease required. • There is also need to prepare natural herbal preparation which will be shown promising synergistic anti-cancer anti- respiratory diseases activity with minimal side effects • The development of customized MDI formulations that maintain drug stability while achieving optimal aerodynamic properties remains a significant challenge. The project focuses on developing an innovative drug delivery system with several notable features. It involves creating nanoparticles containing Carrageenan (a polysaccharide derived from seaweed) and 6-Gingerol (an active compound naturally found in ginger with potential medicinal properties). • These herbal nanoparticles will be formulated as a customized meter dose inhaler (DPI) for direct delivery to the lungs and respiratory tract. • The system is designed to be customizable and pressure-controlled, likely allowing for adjustable dosing or delivery depth depending on disease requirement. • Integration of carrageenan-based nanoparticles as carriers for 6-gingerol, leveraging their biocompatibility and controlled release properties. • It's intended for treating lung cancer and various chronic respiratory tract diseases for a longer duration of time. • Development of DoE QbD optimization approach for nanoparticle formulation and characterization, ensuring precise control over particle size, morphology, and surface properties. • Confirmation of activities in lungs and chronic respiratory diseases by measuring the synergistic anticancer/respiratory disease activity of carrageenan and 6-gingerol herbal nanoparticles by human lung cancer cell line culture by respiratory airways model.

Rationale of the study (up to 500 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

Despite significant advances in therapy for lung cancer and chronic respiratory diseases, current treatment modalities face several critical limitations that hamper their effectiveness. Traditional therapy, while widely used, suffers from poor drug bioavailability, systemic side effects, inadequate targeting of cancer cells, and lack of personalization in drug delivery. These challenges represent a significant barrier in achieving optimal therapeutic outcomes for lung cancer and chronic respiratory illness patients. The critical barriers this research addresses include: Scientific Knowledge Barriers • Limited understanding of the synergistic effects between carrageenan (a marine polysaccharide) and 6-gingerol (an active compound from ginger) at the nano-scale for lung cancer respiratory illness applications. • Gaps in knowledge regarding optimal herbal nanoparticle formulations for deep lung delivery for cancer treatment shallow delivery for chronic respiratory diseases simultaneously. Technical Capability Barriers • Absence of pressure-controlled meter dose inhaler that can be customized to patient-specific respiratory illness. • Challenges in developing stable herbal nanoparticle formulations with consistent drug delivery profiles • Limited tools for real-time monitoring and adjustment of inhaler performance based on patient respiratory patterns • Difficulty in achieving targeted delivery to specific regions of the respiratory tract lungs requirement-wise. 1. Local Context: • Addresses the rising incidence of lung cancer and chronic respiratory diseases in local populations. • Utilizes locally available natural compounds (6-gingerol) and sustainable materials (carrageenan). • Promotes development of indigenous pharmaceutical capabilities. National Relevance • Addresses the growing burden of lung cancer and chronic respiratory diseases nationally. • Promotes innovation in pharmaceutical technology and drug delivery systems. • Aligns with national initiatives for integrating traditional medicine with modern technology • Potential for reducing healthcare costs through more effective local treatments International Relevance • Contributes to global efforts in developing alternative cancer treatments with fewer side effects • Addresses the worldwide need for improved respiratory disease management • Presents an innovative approach to personalized medicine through customizable delivery systems. • Creates potential for international collaboration on herbal nanoparticle technology. The AI component of this project will likely enhance formulation design, predict drug-polymer interactions, optimize delivery parameters, and enable personalized dosing regimens based on individual patient characteristics and disease states.

Hypothesis/ Research question (up to 100 words) : Carrageenan-6-gingerol herbal nanoparticles delivered via a customised pressure-controlled meter dose inhaler will provide targeted therapeutic effects with optimal amount of herbal drug for lung cancer and/or chronic respiratory diseases with improved bioavailability and reduced systemic side effects compared to conventional delivery methods.

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : • Selection Optimization of formulations using different AI models (4-6 Months).

Study Design : Computational Design and Optimization Using Design of Experiment (DoE) for developing carrageenan-6-gingerol herbal nanoparticle formulations. • Develop AI models for Predicting drug-polymer interactions. • Machine learning prediction of herbal nanoparticle characteristics.

Study Area : Laboratory

Sample Size : NA

Primary and secondary outcome measure : The best formulation will be forwarded to the next

Design of Statistical analysis : NA

Study Objective No. 2

Study Objective : • Development of customized pressure-controlled meter dose inhaler (10 Months).

Study Design : • Formulation optimization of carrageenan-6-gingerol herbal nanoparticles • Physicochemical characterization (Particle size analysis (DLS), zeta potential measurement, morphology (SEM/TEM)) • Drug loading and encapsulation efficiency • In vitro release studies • Stability studies • Designing of customized pressure-controlled meter dose inhalation system. • Aerodynamic performance testing • Lung Deposition Pattern delivery efficiency

Study Area : Laboratory

Sample Size : NA

Primary and secondary outcome measure : • Particle size (target: 10-100 nm) • Polydispersity index (target: 0.3) • Zeta potential • Encapsulation efficiency (target: 70%) • In vitro release profile • Aerodynamic performance (fine particle fraction)

Design of Statistical analysis : NA

Study Objective No. 3

Study Objective : • Investigate the anticancer activity/chronic respiratory illness treatment of formulations by human lung cancer cell lines/ animal models (8-10 Months).

Study Design : In Vitro Studies • Cell culture studies using lung cancer cell lines. • Animal Model Studies for Asthma and COPD (at least four anatomic lesions) • Duration: 3-6 months

Study Area : invitro-Lab

Sample Size : NA

Primary and secondary outcome measure : i. Formulation Parameters • Powder flow properties • Aerodynamic performance • Stability under various storage conditions iii. Safety Parameters • Histopathological analysis • Blood chemistry • Inflammatory markers

Design of Statistical analysis : NA

Expected outcome/ Deliverables aligned with research question (up to 100 words): Customized pressure-controlled MDI development improved drug delivery efficiency by herbal nanoparticle, reduced systemic toxicity, and improved the therapeutic efficacy of herbal compounds, i.e., carrageenan and 6-gingerol.

Immediate next steps following the end of the project(up to 100 words): The next step of the project will involve detailed animal toxicological studies, focusing on various organs, particularly the lungs. The LD50 value will be determined during these studies and will serve as a key parameter for establishing the appropriate drug dosage.

Whether the study is going to generate new intellectual property: The proposed inhaler and the drug combination will represent a ground breaking advancement in drug development technology, designed to precisely control both the speed and concentration of medication administration with the display. This device will feature an adjustable airflow mechanism, allowing users or healthcare professionals to tailor the delivery parameters based on the targeted site within the respiratory system. For situations where the drug needs to reach the lungs, such as in cases of asthma, chronic obstructive pulmonary disease (COPD), or pulmonary infections, the inhaler will increase particle speed and pressure. This enhanced propulsion will ensure that the medication penetrates deeply into the lower respiratory tract, maximizing therapeutic efficacy. In cases where the treatment targets cancer cells, the inhaler will deliver the drug at a higher speed and concentration, enhancing its ability to penetrate deeply and reach the cancer cells. The linked carrageenan, known for its high selectivity towards cancer cells, will further aid in directing the drug specifically to the tumor site, improving therapeutic precision. Conversely, for conditions where the drug is intended to act primarily on the throat or upper respiratory region such as in sore throat, pharyngitis, or localized infections the device will reduce the particle velocity. This controlled, lower-speed delivery will allow the medication to remain suspended longer in the throat, promoting better absorption and localized effect. The device will be uniquely suited for administering naturally extracted compounds, ensuring that these sensitive materials retain their therapeutic integrity while achieving optimal deposition in the desired region. Additionally, the inhaler will offer user-friendly controls, empowering patients to adjust settings according to their condition, under medical guidance

Reference in (AMA style): 1. Kang DY, Park S, Song KS, et al. Anticancer effects of 6-gingerol through downregulating iron transport and PD-L1 expression in non-small cell lung cancer cells. Cells. 2023;12(22):2628. doi:10.3390/cells12222628 2. Liu L, Yu N, Leng W, Lu Y, Xia X, Yuan H. 6-Gingerol, a functional polyphenol of ginger, reduces pulmonary fibrosis by activating Sirtuin1. Allergol Immunopathol (Madr). 2022;50(2):104-114. 3. Ajayi BO, Olajide TA, Olayinka ET. 6-Gingerol attenuates pulmonary inflammation and oxidative stress in mice model of house dust mite-induced asthma. Adv Redox Res. 2022;5:100036. 4. Li Z, Liu Z, Uddandrao VS, et al. Asthma-alleviating potential of 6-gingerol: effect on cytokines, related mRNA and c-Myc, and NFAT1 expression in ovalbumin-sensitized asthma in rats. J Environ Pathol Toxicol Oncol. 2019;38(1):1-12. 5. Bhatt A, Nainwal N, Purohit P. The impact of carrageenan on pharmascience. Curr Tradit Med. 2024;10(6):206-223. 6. Shukla A, Kumar S, Bhatt A, et al. Iota carrageenan linked barium ion nanoparticle synthesis for the selective targeted imaging and inhibition of cancer cells. J Polym Eng. 2024;44(5):338-346. 7. Bhatt A, Kailkhura S, Shukla A, et al. Modulating ionic linkages in the heterocyclic sulfated polysaccharide carrageenan for enhanced selectivity against amelanotic melanoma cells. ChemistrySelect. 2024;9(20):e202400185.

Implementation strategy and milestone chart	Download

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): The work related to the carrageenan and its physicochemical and biological activity has been done by one of the PI Dr. Priyank purohit and published peer reviewed highly reputed journals, these research articles are Eclipsed conformational locking: exploring iota carrageenan's distinct behavior in ethanol–water systems via hydrogen bonding with the disulfate group." Chem. Pap. (2024).2) Modulating Ionic Linkages in the Heterocyclic Sulfated Polysaccharide Carrageenan for Enhanced Selectivity Against Amelanotic Melanoma Cells." Chemistry Select (2024). 3) Conversion of iota carrageenan hydrocolloids to hydrophobic hydrocolloids for the entrapment of water-insoluble drugs." Discov Appl Sci (2024). 4)Benzoylation of Iota Carrageenan: Development of a Stable, Conductive, and Hydrophobic Drug Carrier with Reduced Toxicity and Improved Gel-Forming Ability." Macromol. Chem. Phys. (2024). Iota carrageenan linked barium ion nanoparticle synthesis for targeted imaging and inhibition of cancer cells." J. Polymer Eng. (2024). Along with the carrageenan the PI Dr. Ganesh established a concept, that the nano particle formation enhances the bioavailability of 6-Gingerol and published research on "Development and Characterization of Gold Nanoparticles Conjugates to Increase Bioavailability of 6-Gingerol", Journal of Pharmaceutical Research International, 36(5), pp. 12–24. DOI: 10.9734/jpri/2024/v36i57513

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with quality.) **:** 1) Experience related to polymer chemistry: 1) Kailkhura, S., Purohit, P., Bhatt, A. et al. Eclipsed conformational locking: exploring iota carrageenan's distinct behavior in ethanol–water systems via hydrogen bonding with the disulfate group. Chem. Pap. (2024). https://doi.org/10.1007/s11696-024-03590-4. 2) A. Bhatt, S. Kailkhura, A. Shukla, S. Kumar, P. Purohit, M H. Abdellattif, Modulating Ionic Linkages in the Heterocyclic Sulfated Polysaccharide Carrageenan for Enhanced Selectivity Against Amelanotic Melanoma Cells. Chemistry Select, May 2024, 9, 20, https://doi.org/10.1002/slct.202400185 3) Shukla, A., Kumar, S., Bhatt, Purohit Priyank. Conversion of iota carrageenan hydrocolloids to hydrophobic hydrocolloids, by the replacement of potassium to barium ion, for the entrapment of water insoluble drugs. Discov Appl Sci 6, 244 (2024). https://doi.org/10.1007/s42452-024-05925-y 4) A. Bhatt, S. Kailkhura, P. Purohit Benzoylation of Iota Carrageenan: Development of a Stable, Conductive, and Hydrophobic Drug Carrier with Reduced Toxicity and Improved Gel-Forming Ability. Macromol. Chem. Phys. 2024, 2400017. https://doi.org/10.1002/macp.202400017 5) Shukla, Aman, Kumar, Sachin, Bhatt, Akanksha, Purohit, Priyank, Kailkhura, Shashank and Abdellattif, Magda H. "Iota carrageenan linked barium ion nanoparticle synthesis for the selective targeted imaging and inhibition of cancer cells" Journal of Polymer Engineering, 2024. https://doi.org/10.1515/polyeng-2023-0278 2) Experience related to nano particle formation and characterization and in vitro studies 1. Mittal, R.K., Purohit, P., Sankaranarayanan, M. et al. In-vitro antiviral activity and in-silico targeted study of quinoline-3-carboxylate derivatives against SARS-Cov-2 isolate. Mol Divers (2023). 2. Kumar, G., Nautiyal U., Bhatt M. and Dhyani A. (2024) "Development and Characterization of Gold Nanoparticles Conjugates to Increase Bioavailability of 6-Gingerol", Journal of Pharmaceutical Research International (Pubmed Indexed), 36(5), pp. 12–24. DOI: 10.9734/jpri/2024/v36i57513. 3. Priyanka Gauniya, Radheshyam, Sukirti Dobriyal, Mukesh Pandey, Ajay Semalty, Mona Semalty, Enhancing Acyclovir Permeability Using SLS Crosslinked β-Cyclodextrin Nanoparticles, Micro and Nanosystems. 2025, 17, In press. DOI: 10.2174/0118764029339726241208062307 4. Priyanka Gauniya, Radheshyam, Ajay Semalty, Mona Semalty, Curcumin Nanoparticles: Exploring Types and their Impact on Biopharmaceutical Performance, Micro and Nanosystems 2025, 17, e18764029339646. DOI: 10.2174/0118764029339646241003060231. 5. Mukesh Pandey, Priyanka Rani, Lokesh Adhikari, Mukul Gupta, Ajay Semalty, Mona Semalty, Preparation and characterization of cyclodextrin complexes of doxycycline hyclate for improved photostability in aqueous solution, Journal of Inclusion Phenomena and Macrocyclic Chemistry, 2022, 102, 271-78 ISSN: 1388-3127 https://doi.org/10.1007/s10847-021-01116-z

Institutional Support/ Facilities: The study's implementation requires strong inter-departmental and inter-institutional collaboration, combining expertise and resources from Swami Rama Himalayan University (SRHU), Hemwati Nandan Bahuguna Garhwal University (HNBGU), and the Himalayan Institute of Biological Sciences. SRHU, led by Dr. Ganesh Kumar (PI) and Dr. Priyank Purohit, (Co- PI) will oversee 6-gingerol extraction, nanoparticle synthesis, drug loading, in-vitro studies, aerodynamic performance testing, and lung cancer cell line culture, utilizing specialized equipment like a rheometer, IR spectrometer, ELISA plate reader, and a custom MDI device (to be procured). HNBGU, led by Dr. Ajay Simalty, (Co- PI) will optimize formulation using Design of Experiment (DoE) software and conduct physicochemical characterization, including DLS, Zeta potential, and SEM-TEM analysis. The Himalayan Institute of Biological Sciences will supply A549 lung cancer cell lines for biological evaluations. This collaborative effort integrates advanced techniques, ensuring efficient formulation development, thorough characterization, and reliable biological validation.

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc.	1) Extraction and Synthesis • Extraction Assembly for 6-Gingerol and Nano Synthesizer: o Lead: Dr. Ganesh Kumar (PI) o Institution: Swami Rama Himalayan University (SRHU) 2) Formulation Development • Design of Experiment (DoE) for Carrageenan-6-Gingerol Herbal Nanoparticles: o Lead: Dr. Ajay Simalty o Institution: Hemwati Nandan Bahuguna Garhwal University (HNBGU) o Software: To be utilized at HNBGU 3) Device Development • Customized Metered Dose Inhaler (MDI) Device: o Lead: Dr. Ganesh Kumar o Institution: Swami Rama Himalayan University 4) Physicochemical Characterization • Techniques: o Particle Size Analysis (DLS) o Zeta Potential Measurement o SEM-TEM Imaging o Lead: Dr. Ajay Simalty o Institution: HNBGU 5) Drug Loading and Release Studies • Parameters: o Drug Loading Encapsulation Efficiency o In-vitro Release Studies o Lead: Dr. Priyank Purohit o Institution: Swami Rama Himalayan University o Equipment: Rheometer, IR (to be purchased from project funds) 6) In-vitro Studies • Lead: Dr. Priyank Purohit • Institution: Swami Rama Himalayan University • Equipment: Elisa plate, enzymes, Elisa plate reader (to be purchased from project funds) 7) Aerodynamic Performance Lung Deposition Analysis • Tests: o Aerodynamic Performance o Lung Deposition Pattern Delivery Efficiency o Leads: Dr. Ganesh Kumar and Dr. Priyank Purohit o Institution: Swami Rama Himalayan University 8) Lung Cancer Cell Line Studies • Cell Line: A549 (Lung Cancer Cells) • Institution: SRHU (in collaboration with the Himalayan Institute of Biological Sciences
Conflict of Interest declaration (if any)	Not Any
Duration (in Months)	36 Months

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Nature of Employment	Role in Proposal
1	Prof Ganesh kumar	Swami Rama Himalayan University	Professor	drganeshbhatt2@gmail.com	9897435971	Permanent	PI
2	Dr Priyank purohit	Swami Rama Himalayan University	Associate Professor	priyank.niper@gmail.com	9501549468	Permanent	Co-PI
3	Dr Ajay Semalty	HEMVATI NANDAN BAHUGUNA GARHWAL UNIVERSITY(A Central University)	Assistant Professor	semaltyajay@gmail.com	9412964614	Permanent	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Declaration and attestation
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	Device design generated through open source AI

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
HEMVATI NANDAN BAHUGUNA GARHWAL UNIVERSITY(A Central University)	1	0	0	0	0	0	0	0
Swami Rama Himalayan University	1	739200.00	24000.00	650000.00	1900000.00	150000.00	0	3463200
HEMVATI NANDAN BAHUGUNA GARHWAL UNIVERSITY(A Central University)	2	0	0	500000.00	0	0	0	500000
Swami Rama Himalayan University	2	369600.00	24000.00	0	700000.00	100000.00	0	1193600
HEMVATI NANDAN BAHUGUNA GARHWAL UNIVERSITY(A Central University)	3	0	0	0	0	0	0	0
Swami Rama Himalayan University	3	776160.00	50000.00	260000.00	0	0	0	1086160

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Total in (Rs.):		**1884960**	**98000**	**1410000**	**2600000**	**250000**	**0**	**6,242,960.00**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
1	**Year: 1**	Swami Rama Himalayan University	Project Technical Support - III	2	12	30,800	0.00	739,200.00

Justification : Technical Staff 1: Device Design and Performance Specialist • Role: This staff member will focus on the design, development, and optimization of the MDI device to ensure it supports efficient aerosolization, aerodynamic performance, and targeted lung deposition. Device customization requires continuous modifications, troubleshooting, and performance testing, making it crucial to have a dedicated staff member for uninterrupted progress. Technical Staff 2: Formulation and Bioactivity Specialist • Role: This staff member will start from day one with the extraction of 6-gingerol, nanoparticle synthesis, drug loading, and in-vitro bioactivity studies. Early-stage work is critical to generate optimized formulations for device testing, ensuring that the nanoparticles exhibit the required stability, drug release, and biological efficacy. Delays in formulation could stall the entire project timeline, making this role indispensable for early experimental success.

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
2	**Year: 2**	Swami Rama Himalayan University	Project Technical Support - III	1	12	30,800	0.00	369,600.00

Justification : Technical Staff 1: Device Design and Performance Specialist • Role: This staff member will focus on the design, development, and optimization of the MDI device to ensure it supports efficient aerosolization, aerodynamic performance, and targeted lung deposition. Device customization requires continuous modifications, troubleshooting, and performance testing, making it crucial to have a dedicated staff member for uninterrupted progress. Technical Staff 2: Formulation and Bioactivity Specialist • Role: This staff member will start from day one with the extraction of 6-gingerol, nanoparticle synthesis, drug loading, and in-vitro bioactivity studies. Early-stage work is critical to generate optimized formulations for device testing, ensuring that the nanoparticles exhibit the required stability, drug release, and biological efficacy. Delays in formulation could stall the entire project timeline, making this role indispensable for early experimental success.

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
3	**Year: 3**	Swami Rama Himalayan University	Project Technical Support - III	2	12	32,340	0.00	776,160.00

Justification : Technical Staff 1: Device Design and Performance Specialist • Role: This staff member will focus on the design, development, and optimization of the MDI device to ensure it supports efficient aerosolization, aerodynamic performance, and targeted lung deposition. Device customization requires continuous modifications, troubleshooting, and performance testing, making it crucial to have a dedicated staff member for uninterrupted progress. Technical Staff 2: Formulation and Bioactivity Specialist • Role: This staff member will start from day one with the extraction of 6-gingerol, nanoparticle synthesis, drug loading, and in-vitro bioactivity studies. Early-stage work is critical to generate optimized formulations for device testing, ensuring that the nanoparticles exhibit the required stability, drug release, and biological efficacy. Delays in formulation could stall the entire project timeline, making this role indispensable for early experimental success.

Total Cost (Rs.) **1,884,960.00**
including overhead

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	**Year: 1**	Swami Rama Himalayan University	0.00	24,000.00

Contingency Name : Covers unexpected costs in equipment setup, initial raw materials, calibration, and troubleshooting during nanoparticle formulation and device prototyping.

Justification : For smooth functioning of the project, with out any delay.

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
2	**Year: 2**	Swami Rama Himalayan University	0.00	24,000.00

Contingency Name : Need for the maintenance of instruments (like DLS, FTIR, and the MDI device), additional consumables like stationary, and unplanned expenses in biological evaluations or cell culture handling

Justification : For unexpected error of device

Total Cost (Rs.) **98,000.00**
including overhead

Contingency budget breakup details

3	**Year: 3**	Swami Rama Himalayan University	0.00	50,000.00

Contingency Name : Addresses final-stage needs like data validation, manuscript preparation, additional cost of intellectual property right

Justification : For final documentation related to patent, research paper and others.

Total Cost (Rs.)
including overhead **98,000.00**

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Swami Rama Himalayan University	• 6-Gingerol (Standard Bulk): ₹50,000 • Carrageenan (Different grades): ₹40,000 • Organic solvents (Methanol, ethanol, chloroform, etc.): ₹30,000 • Buffers (PBS, Tris, etc.) for stability studies: ₹20,000 • Nanoparticle synthesis reagents (Surfactants, crosslinkers): ₹50,000 • Cell culture media, FBS, antibiotics (for initial setup): ₹60,000 • Glassware, pipettes, microtips, and plasticware: ₹230,000 • ELISA plates, enzymes, assay kits (for initial in-vitro studies): ₹140,000 • Miscellaneous lab consumables (pH strips, gloves, masks, etc.): ₹30,000	0.00	650,000.00

Justification : For First Year: Formulation Development and Characterization

2	**Year: 2**	HEMVATI NANDAN BAHUGUNA GARHWAL UNIVERSITY(A Central University)	• Additional 6-Gingerol and carrageenan for formulation refinement: ₹60,000 • Consumables for MDI device optimization (tubing, nozzles): ₹10000 • Characterization.: ₹100,000 • for extended in-vitro studies: ₹100,000 • Consumables for NGI performance testing ₹100,000 • Miscellaneous lab consumables: ₹40,000	0.00	500,000.00

Justification : Second Year: Optimization, Characterization, and Bioactivity Studies

3	**Year: 3**	Swami Rama Himalayan University	• Reagents for long-term stability and accelerated stability studies: ₹10000 • Cell culture Study ₹60,000 • Materials for final device assembly and delivery testing: ₹40,000 • Data recording, documentation, and scientific poster printing: ₹90,000 • Miscellaneous consumables: ₹60,000	0.00	260,000.00

Justification : Third Year: Final Studies, Data Validation, and Documentation

Total Cost (Rs.)
including overhead **1,410,000.00**

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
1	**Year: 1**	Swami Rama Himalayan University	DLS			Domestic	400,000.00

Justification : Dynamic Light Scattering (DLS) is essential for this project to measure the particle size, size distribution, and zeta potential of the carrageenan-6-gingerol nanoparticles, ensuring they remain within the optimal size range (1-5 µm) for effective lung deposition. It also helps assess nanoparticle stability by evaluating aggregation behavior and surface charge, which are crucial for maintaining drug delivery efficiency and ensuring reproducibility in formulation development.

Mode of Proposed disposal :donate for training purposes.

2	**Year: 1**	Swami Rama Himalayan University	FTIR			Domestic	1,500,000.00

Justification :FTIR (Fourier Transform Infrared Spectroscopy) is essential for this project to confirm chemical interactions between carrageenan and 6-gingerol, ensuring successful nanoparticle formulation by identifying functional groups, tracking structural modifications, and verifying drug encapsulation. It also helps monitor formulation stability over time and supports physicochemical characterization, which is crucial for formulation's efficacy and safety.

Mode of Proposed disposal :donate for training purposes.

Total (Rs.): 2,600,000.00

Equipment Budget Breakup Details

3	**Year: 2**	Swami Rama Himalayan University	Next Generation impactor	Domestic	700,000.00

Justification : The Next Generation Impactor (NGI) is essential for this project as it accurately simulates the respiratory tract, providing detailed data on particle size distribution and lung deposition — crucial for ensuring the Carrageenan-6-Gingerol Herbal Nanoparticle formulation reaches deep lung regions (1-5 µm range) where lung cancer cells reside. It evaluates the aerodynamic performance of the customized MDI device, ensuring consistent dose delivery, optimizing spray patterns, and preventing drug loss in the upper airways. Additionally, NGI data supports formulation refinement, ensuring nanoparticles remain stable during inhalation.

Mode of Proposed disposal :donate for training purposes.

Total (Rs.): 2,600,000.00

Travel Justification

#	Year	Amount(Rs.)
1	**Year: 1**	100000.00

Justification : It is for the setup and calibration of newly purchased instruments, ensuring uninterrupted project progress and high-quality outcomes.

2	**Year: 1**	50000.00

Justification : The travel allowance is essential across all three years to ensure smooth inter-institutional collaboration, enabling regular visits between Swami Rama Himalayan University and HNBGU for coordinating experiments, accessing advanced equipment like DLS, SEM-TEM, and NGI, and ensuring device optimization.

3	**Year: 2**	100000.00

Justification : It supports participation in specialized workshops to enhance technical expertise in cell culture handling, aerosol performance testing, and nanoparticle characterization. Additionally, travel is crucial for presenting findings at national and international conferences to gain expert feedback, fostering scientific recognition

Total: **250,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academies	Role in Proposal
Dr Ajay Semalty	1979-01-26	Pharmaceutics, Nanoparticles, Cyclodextrin, Herbal Drug dellvery, Obesity	49	23	NA	

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator (completed projects)

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

All Ongoing research projects

Project Id	Title	Grant Amount	Funding Agency	Start Date	End Date	Duration

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academies	Role in Proposal
Dr Priyank purohit	1988-02-16	Polymer medicinal chemistry	30	14	NA	Co-PI

Short resume PI/Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Kumar R, Saha N, Purohit P, Garg SK, Seth K, Meena VS, Dubey S, et al. Cyclic enaminone as new chemotype for selective cyclooxygenase-2 inhibitory, anti-inflammatory, and analgesic activities. Eur J Med Chem. 201915:111601.	6.1	coauthor	In-vitro enzyme assay.
Bhatt A, Kailkhura S, Purohit P. Benzoylation of iota carrageenan: development of a stable, conductive, and hydrophobic drug carrier with reduced toxicity and improved gel-forming ability. Macromol Chem Phys. 20242400017. doi:10.1002/macp.202400017	2	CORRESPONDING	Research journal
Seth K, Garg SK, Kumar R, Purohit P, Meena VS, Goyal R, Banerjee UC, Chakraborti AK. 2-(2-Arylphenyl) benzoxazole as a novel anti-inflammatory scaffold: synthesis and biological evaluation. ACS Med Chem Lett. 20145(5):512-516. doi:10.1021/ml500067d.	4.4	coauthor	In-vitro enzyme assay.
Bhatt A, Kailkhura S, Purohit P. Benzoylation of iota carrageenan: development of a stable, conductive, and hydrophobic drug carrier with reduced toxicity and improved gel-forming ability. Macromol Chem Phys. 20242400017. doi:10.1002/macp.202400017	2.5	CORRESPONDING	Research journal
Shukla A, Kumar S, Bhatt A, Purohit P, Kailkhura S, Abdellattif MH. Iota carrageenan linked barium ion nanoparticle synthesis for the selective targeted imaging and inhibition of cancer cells. J Polym Eng. 2024.	2.1	CORRESPONDING	Barium ion linked carrageenan for cancer selectivity.
Kailkhura S, Purohit P, Bhatt A, et al. Eclipsed conformational locking: exploring iota carrageenan's distinct behavior in ethanol–water systems via hydrogen bonding with the disulfate group. Chem Pap. 2024.	2.1	CORRESPONDING	Research journal
Bhatt A, Kailkhura S, Shukla A, et al. Modulating ionic linkages in the heterocyclic sulfated polysaccharide carrageenan for enhanced selectivity against amelanotic melanoma cells. ChemistrySelect. 20249(20):e202400185	1.9	CORRESPONDING	Research journal
1 Shukla A, Kumar S, Bhatt A, Purohit P. Conversion of iota carrageenan hydrocolloids to hydrophobic hydrocolloids by the replacement of potassium to barium ion for the entrapment of water insoluble drugs. Discov Appl Sci. 20246:244.	2	CORRESPONDING	Barium ion linked carrageenan for hydrophobicity

Experience as Investigator (completed projects)

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

All Ongoing research projects

Project Id	Title	Grant Amount	Funding Agency	Start Date	End Date	Duration

Name of PI/Co-Pi	**DOB**	**Domain Expertise**	**Number of articles in Pub Med (Past 10 years)**	**h-index**	**Fellow of Academies**	**Role in Proposal**
Prof Ganesh kumar	1978-12-13	Nanotechnology, Target drug delivery system, 6-Gingerol bioavailability enhancement	12	4	NA	PI

Short resume PI/Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
K Ganesh, D Archana, K Preeti "Galactosylated Albumin nanoparticles bearing Cimetidine for effective management of Acetaminophen induced hepatotoxicity" International Journal of Nano Dimension (Web of Science-ESCI Indexed). 2014, Vol-5, Issue-5, 431-440. DOI- 10.7508/IJND.2014.05.002,	1.5	CORRESPONDING	Nano-Targeted Drug Delivery system
Kumar Ganesh, Dhyani Archana, and Kothiyal Preeti "Galactosylated Albumin Nanoparticles of Simvastatin" Iranian J. Pharm. Res. (Pubmed SCI Indexed, 2015 spring 14(2): 407–415. URL: https://doi.org/10.22037/ijpr.2015.1704	2	CORRESPONDING	Nano- Targeted Drug Delivery system
Archana Dhyani, Ganesh Kumar" Ocular Delivery of Atenolol Loaded Microsponge In-Situ Gel: Development, Characterization and In-Vitro Evaluation" Indian Journal of Pharmaceutical Education and Research (SCIE Scopus Indexed) Jan-Mar, 2022, Vol 56, Issue 1 (Suppl),s75-s80. URL:http://dx.doi.org/10.5530/ijper.56.1s.45	0.8	first	Micro- Targeted Drug Delivery system
Ganesh Kumar, Meenakshi Bhatt. "Formulation and Optimization of Trandolapril Orodispersible Tablet by Using Quality by Design (QbD) Approach" Letter in Drug Design Discovery (Bentham Science, SCI Scopus Indexed, IF-1.15) Volume 20, Issue 9, 2023, 1194 – 1203. DOI: https://dx.doi.org/10.2174/1570180819666220429153102	2	first	Design of Experiment (DoE) Quality by Design (QbD)
Archana Dhyani, Ganesh Kumar" Fabrication, Characterization, and in vitro Evaluation of Atenolol Loaded Microsponges for Ocular Delivery" Indian Journal of Pharmaceutical Education and Research Jan-Mar, 2024 58(1s):s149-s157. doi:10.5530/ijper.58.1s.14	0.8	first	Micro- Targeted Drug Delivery system
Kumar, G., Nautiyal U., Bhatt M. and Dhyani A. (2024) "Development and Characterization of Gold Nanoparticles Conjugates to Increase Bioavailability of 6-Gingerol", Journal of Pharmaceutical Research International 36(5), pp. 12–24.	0.6	first	Research journal
Nupur Katariya, A S Farshwan, Nidhi Nainwal, Ganesh Kumar (2024) "Diagnostic and Therapeutic Role of Mesoporous Silica Nanoparticles in Combating Cancer", International Journal of Applied Pharmaceutics Vol 16, Issue 5, 2024, 31-37. DOI: https://dx.doi.org/10.22159/ijap.2024v16i5.51647	1.4	CORRESPONDING	Nanoparticle for cancer combating
Archana Dhyani, Ganesh Kumar (2025) "Development and Characterization of Atenolol Based Microsponge Gel for Ophthalmic Delivery" Indian Journal of Pharmaceutical Education and Research, Vol 59, Issue 1 (Suppl), Jan-Mar, 2025.	0.8	CORRESPONDING	Micro- Targeted Drug Delivery system

Experience as Investigator (completed projects)

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
Morphological, Biochemical, Molecular functional field trial based characterization of PGPRs for plant growth promotion and disease	PI	TEQIP-III Scheme of Uttarakhand Technical University	200000.00	Isolation, morphological, biochemical and functional characterization of Rhizobial residents in Vigna Radiata from north east plane zone of Bihar" Research Journal of Chemistry and Environment (Scopus Indexed, IF-0.25), Nov 2020, Vol 24 (11), 60-65. DOI: 10.13140/RG.2.2.16295.93605

All Ongoing research projects

Project Id	Title	Grant Amount	Funding Agency	Start Date	End Date	Duration

Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

Declaration

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.

In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

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