

No. BT/PR41385/COT/142/19/2021
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 28.09.2021

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules, 1978, for the implementation of the project entitled: "**DRY POWDER INHALATION CONTAINING BIODEGRADABLE NANOPARTICLES OF NICLOSAMIDE TO COMBAT COVID-19 INFECTION**" for a period of 2 Year 0 Month at a total cost of Rs. **5835830** (Rupees Fifty Eight Lakhs Thirty Five Thousand Eight Hundred and Thirty Only) on the terms and conditions detailed here under:-

2 The Project :

2.1 Title : "DRY POWDER INHALATION CONTAINING BIODEGRADABLE NANOPARTICLES OF NICLOSAMIDE TO COMBAT COVID-19 INFECTION"

2.2 Details of the Investigators:

Project Coordinator

Dr. Nilesh Manoharrao Mahajan

Professor

Pharmaceutics

Dadasaheb Balpande College of Pharmacy, Besa, Nagpur

Dadasaheb Balpande College of Pharmacy,

Near Swami Samarth Mandir, Besa-Ghoghali Road, Besa, Nagpur ,

Maharashtra , Nagpur - 440037, Nagpur, Maharashtra, 440037

Principal Investigators:

Dr. Nilesh Manoharrao Mahajan

Professor

Pharmaceutics

Dadasaheb Balpande College of Pharmacy, Besa, Nagpur

Dadasaheb Balpande College of Pharmacy,

Near Swami Samarth Mandir, Besa-Ghoghali Road, Besa,

Nagpur , Maharashtra , Nagpur - 440037,

Nagpur, Maharashtra, 440037

Dr. Anil M Pethe

Associate Professor

Pharmaceutics

School of Pharmacy and Technology Management, SVKM'S

NMIMS, Hyderabad Campus

Plot No. B-4, Green Industrial Park, TSIIC, Polepally SEZ

Polepally, Hyderabad, Telangana, 509301

Dr. Nilesh Manoharrao Mahajan

Professor

Pharmaceutics

Dadasaheb Balpande College of Pharmacy, Besa,

Nagpur

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Near Swami Samarth Mandir, Besa-Ghoghali Road,

Besa, Nagpur , Maharashtra , Nagpur - 440037,

Nagpur, Maharashtra, 440037

CO-PI:



Mr. Sachin M More

Assistant Professor
Pharmacology
Dadasaheb Balpande College of
Pharmacy, Besa, Nagpur
Besa-Ghoghali Road, Near Swami
Samrath Mandir, Besa, Nagpur,
Nagpur - 440037, Maharashtra

2.3 Objectives:**Overall Objectives:**

1. Acute inhalation toxicity study of Niclosamide
2. Determination of ED50 of Niclosamide against SARS-CoV-2
3. Preparation and evaluation of biodegradable nanoparticles of niclosamide
4. Development of DPI for the nose to lung delivery
5. Pharmacokinetic and acute toxicity study of formulation in suitable animal model
6. Development of DPI device for the in-line delivery of nanoparticles to lungs

Institute wise Objectives:**Dadasaheb Balpande College of Pharmacy, Besa, Nagpur**

1. Acute inhalation toxicity study of Niclosamide
2. Determination of ED50 of Niclosamide against SARS-CoV-2
3. Preparation and evaluation of biodegradable nanoparticles of niclosamide
4. Pharmacokinetic and acute toxicity study of formulation in suitable animal model

School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus

1. Development of Dry Powder for Inhalation (DPI) for the nose to lung delivery
2. Development of DPI device for the in-line delivery of nanoparticles to lungs

2.4 Time Schedule:

The duration of the project is 2 Year 0 Month from the date of this sanction order.

2.5 Project Cost:

The total cost of the project is Rs. **5835830/-** (Rupees Fifty Eight Lakhs Thirty Five Thousand Eight Hundred and Thirty Only) as per details given below :

Institute	Year I	Year II	Total Cost(Rs.)
1. Dadasaheb Balpande College of Pharmacy, Besa, Nagpur	3354240	1054240	4408480
2. School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus	0	1427350	1427350
Total (Rs.)	3354240	2481590	5835830

Institute wise details are:

Budget Head	Year I	Year II	Total(Rs.)
1. Dadasaheb Balpande College of Pharmacy, Besa, Nagpur			
Equipment	2000000.00		2000000.00
Manpower	654240.00	654240.00	1308480.00
Overhead	75000.00	75000.00	150000.00
Travel	50000.00	50000.00	100000.00
Consumables	500000.00	200000.00	700000.00
Contingency	75000.00	75000.00	150000.00
Total (Rs.)	3354240.00	1054240.00	4408480.00
2. School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus			
Equipment	0.00	952350.00	952350.00
Overhead	0.00	50000.00	50000.00
Travel	0.00	50000.00	50000.00
Consumables	0.00	300000.00	300000.00
Contingency	0.00	75000.00	75000.00
Total (Rs.)	0.00	1427350.00	1427350.00

2.6 Equipment:

The details of the equipment sanctioned for the implementation of the project at **Annexure-I**

2.7 Manpower:

The details of the manpower sanctioned for the implementation of the project at **Annexure-II**

2.8 Quarterly deliverables:

The details of the quarterly deliverables of the project at **Annexure-III-A**

3. Head of Account:

The **Non-Recurring** expenditure involved is debitable to:

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

The **Recurring** expenditure involved is debitable to:

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

4. Terms & Conditions:

- 4.1** The other terms and conditions governing this sanction are attached at Annexure- III.
- 4.2A** Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/installment will be made only after signing of MoA between the grantee institutions and DBT. In case of NGO's and Private Institution's, execution of MOA is mandatory before first release. A format of the MoA is enclosed in Annexure-IV
- 4.3** The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The interest earned should be remitted to the Consolidated fund of India through Bharat Kosh portal(www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.
- 5.** No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.
- 6.** The Dr. Anil M. Pethe, School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus, Hyderabad, Telangana and The Dr. Ujwala N. Mahajan, Dadasaheb Balpande College of Pharmacy, Besa, Nagpur, Nagpur, Maharashtra would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.
- 7.** PI's of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-05/2019 dated on 30 Jan 2019. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.
- 8.** As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organisation is called upon to do so.
- 9.** If the Research Project involves biological resources, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org
- 10.(I)** The PIs/Implementing Agencies shall strictly adhere to the GoI instructions issued vide OM No.F.4.1.2021-PPD dated 30.6.2021 in the matter of issue of Global tender Enquiry with special reference to instructions contained under para 4 of the said OM for procurement of equipments, spares and consumables for research purposes and shall not issue Global Tenders Enquiries before seeking the approval of the competent authority.
- (II)** After incurring the expenditure on import of such items and at the time of submission of UCs to the department next year, the PIs will also furnish the copy of the approval sought from the competent authority for issue of the GTE for such items of import. The release of next installment of grant will be subject to the fulfillment of the above condition.

Annexure -I

Details of the Equipment sanctioned for the implementation of the project entitled "**DRY POWDER INHALATION CONTAINING BIODEGRADABLE NANOPARTICLES OF NICLOSAMIDE TO COMBAT COVID-19 INFECTION**":

Dadasaheb Balpande College of Pharmacy, Besa, Nagpur			
SNo.	Name of Equipment	No.	Cost(Rs.)
1.	Zetasizer	1	2000000.00
Total			2000000.00
School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus			
SNo.	Name of Equipment	No.	Cost(Rs.)
1.	Freeze Dryer	1	952350.00
Total			952350.00

(Dr. Varshneya Singh)
Scientist 'C'

डॉ. वार्शेन्या सिंह / Dr. VARSHNEYA SINGH
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली-110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

11. This issues under the power delegated to this Department as per IFD Order No. G-17012/1/2020-IFD-DBT dated 29.12.2020 and with the concurrence of IFD vide their SAN No. 102/IFD/SAN/1296/2021-2022 dated September, 28 2021.

12. This sanction order has been noted at serial no. 132 in the Register of Grants.

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi - 110 003.

Copy to:

- 1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
- 2 Dr. Nilesh M. Mahajan (Project Co-ordinator), Besa-Ghoghali Road, Near Swami Samarth Mandir, Besa, Nagpur - 440037
- 3 The Dr. Anil M. Pethe, School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus, Plot No. B-4, Green Industrial Park, TSIIC, Polepally SEZ, Polepally, Hyderabad - 509301, Telangana
- 4 The Dr. Ujwala N. Mahajan, Dadasaheb Balpande College of Pharmacy, Besa, Nagpur, Near Swami Samarth Mandir, Besa-Ghoghali Road, Besa, Nagpur, Nagpur - 440037, Maharashtra
- 5 Dr. Anil M Pethe, Associate Professor, Pharmaceutics, School of Pharmacy and Technology Management, SVKM'S NMIMS, Hyderabad Campus, Plot No. B-4, Green Industrial Park, TSIIC, Polepally SEZ Polepally, Hyderabad - 509301, Telangana
- 6 Dr. Nilesh Manoharrao Mahajan, Professor, Pharmaceutics, Dadasaheb Balpande College of Pharmacy, Besa, Nagpur, Dadasaheb Balpande College of Pharmacy, Near Swami Samarth Mandir, Besa-Ghoghali Road, Besa, Nagpur, Maharashtra, Nagpur - 440037, Nagpur - 440037, Maharashtra
- 7 Mr. Sachin M More, Assistant Professor, Pharmacology, Dadasaheb Balpande College of Pharmacy, Besa, Nagpur, Besa-Ghoghali Road, Near Swami Samrath Mandir, Besa, Nagpur, Nagpur - 440037, Maharashtra
- 8 Cash Section, DBT (2 copies).
- 9 Sanction Folder.
- 10 File Copy.


डॉ. वार्शनेय सिंह / Dr. Varshneya Singh
वैज्ञानिक 'सी' / Scientist 'C'
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विज्ञान और प्रौद्योगिकी मंत्रालय
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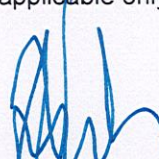
Annexure -II

Details of the manpower sanctioned for the implementation of the project entitled "**DRY POWDER INHALATION CONTAINING BIODEGRADABLE NANOPARTICLES OF NICLOSAMIDE TO COMBAT COVID-19 INFECTION**":

Head	No. of Position	Year I	Year II	Total (Rs.)
1. Dadasaheb Balpande College of Pharmacy, Besa, Nagpur				
Research Associate RA-I (Rs.47000/- + 16% HRA)	1	654240	654240	1308480
Total(Rs.)		654240	654240	1308480

Emoluments detail of research personal(s) mentioned in table(s) of Annexure-II shall be applicable only if candidate(s) met educational qualification and eligibility criteria as per DST

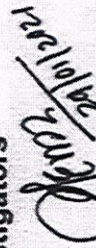
OM No. SR/S9/Z-05/2019 dated 10.07.2020.


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QUARTERLY/SIX MONTHLY/YEARLY DELIVERABLES

Objective No.	Objective / Activity	Start Month	End Month	Quarterly Deliverables	Six Monthly Deliverables	Yearly Deliverables
1	Acute inhalation toxicity study of Niclosamide	1 st	3 rd	LD50 value of Niclosamide (1 st Quarter)	---	---
2	Determination of ED50 of Niclosamide against SARS-CoV-2	4 th	6 th	---	In-vivo effective dose of Niclosamide for SARS-CoV-2 virus (II nd Quarter)	---
3	Preparation and evaluation of biodegradable nanoparticles of Niclosamide	7 th	9 th	Biodegradable nanoparticles with optimized size (III rd Quarter)	---	---
		10 th	12 th	---	---	PEGylated nanoparticles with optimum drug loadin (IV th Quarter)
4	Development of dry powder for inhalation (DPI) for the nose to lung delivery	13 th	15 th	DPI containing Niclosamide nanoparticles with optimum particle size and efficiency (V th Quarter)	---	---
5	Pharmacokinetic and acute toxicity study of formulation in suitable animal model	16 th	18 th	---	Determination of drug concentration in nasal cavity and lungs of animals (VI th Quarter)	---
6	Development of DPI device for the in-line delivery of DPI to lungs	19 th	21 st	In-line device developed and tested for delivery of DPI to lungs (VII th Quarter)	---	---
7	Compilation of results and project writing	22 nd	24 th	---	---	Project report submitted (VIII th Quarter)

Principal Investigators



Dr. Nitesh Mahajan
Professor, DBCOP
Nagpur 29/01/2021
PROFESSOR

Dr. Anil Pethe
Associate Dean
School of Pharmacy and
Technology Management
NMIMS, Hyderabad
Hyderabad



Co-Investigator



Mr. Sachin More,
Asst. Professor
DBCOP, Nagpur

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