**Government of India**
**Ministry of Chemicals and Fertilizers**
**Department of Pharmaceuticals**

# Operational Guidelines of the Scheme for Promotion of Research and Innovation in Pharma MedTech (PRIP) Sector

## 1. Background

Pursuant Government of announcement 2023-24 to launch a new Programme to promote research and innovation in pharmaceuticals to be taken up through Centres of Excellence and encourage industry to invest in research and development in specific priority areas, and in order to transform Indian Pharma MedTech sectors from cost based to innovation-based growth by strengthening the research infrastructure in the country, Government of India has launched new scheme, viz., 'Promotion of Research and Innovation in Pharma MedTech (PRIP) Sector' (herein after referred to as 'Scheme') which has been notified vide Gazette Notification No. 199 dated 17th August 2023.

## 2. Objectives of the scheme

The objective of the scheme is to encourage industry to invest in R&D in 'Priority areas' and to inculcate the culture of quality research and nurture the pool of scientists in the country by promoting industry-academia linkage, which will lead to sustained global competitive advantage and contribute to quality employment generation in the country.

## 3. Components of the scheme:

The scheme has two components, as follows:

### 3.1 Component A:

It is proposed to establish Centres of Excellences (CoEs) at the seven existing National Institutes of Pharmaceutical Education & Research (NIPERs) a t

S A S N a g a r ( M ohali), A h m e d a b a d , H y d e r a b a d , Guwahati, Kolkata, Hajipur and Raebareli at a tentative cost of Rs. 700 cr over a period of five years, with following specializations:

| | | |
|---|---|---|
| i | NIPER Mohali | Anti-Viral and Anti-Bacterial Drug Discovery and Development |
| ii | NIPER Ahmedabad | Medical Devices |
| iii | NIPER Hyderabad | Bulk Drugs |
| iv | NIPER Kolkata | Flow Chemistry and Continuous Manufacturing |
| v | NIPER Raebareli | Novel Drug Delivery System |
| vi | NIPER Guwahati | Phytopharmaceuticals |
| vii | NIPER Hajipur | Biological Therapeutics |

These CoEs will help in building specific research capacities in the identified priority areas in a focused time bound programme, for which following actions shall be taken:

a. NIPERs should actively seek out well-established industry partners (national or international) with a significant market presence and a high order of expertise in their respective research fields for Centers of Excellence (CoEs). Industrial Partner would work with NIPERs to develop CoE and help bridge gap between the Industry and Academia.

b. Research under Component A would be taken at CoE itself. The Research program and time-bound deliverables of CoEs will be fixed in consultation with the Board of Governors (BoGs) of the respective institutes.

c. The financial reporting/ approval of activities of CoE shall be subject to Government rules and subject to approval / overall supervision of BoG and, where applicable of DoP.

**Submission and Approval of the proposal for CoE**

i. NIPERs will be required furnish their proposal in consultation with BoG within a period of 30 days of issuance of these

guidelines for setting up of CoE in the format as at **Appendix I**.

ii. NIPERs would be required to furnish an undertaking that no regular manpower posts would be created out of the financial assistance provided under the scheme and expenditure on salaries of contractual workforce employed for the CoE after 5 years would be borne by them.

iii. NIPERs would be required to ensure that CoEs achieve self-sufficiency within five years of their establishment. An undertaking as at **Appendix II** would be required to be furnished by NIPERs.

iv. NIPER will delineate the precise allocation and utilization of funds and provide a detailed breakdown of the financial resource deployment. The same should outline the allocation for essential activities such as research infrastructure development, equipment procurement, on-going operational expenses, etc.

v. NIPERs need to demonstrate prudent fiscal management and effective resource utilization, aligning with the objectives of the PRIP Scheme to promote innovation and research excellence in the pharmaceutical and Med-Tech sectors.

vi. NIPER shall ensure strict adherence to the provisions of GFR for execution of the CoEs activities.

vii. The proposals will be appraised, and after incorporating its inputs and suggestions, if any, approved by the DoP.

### 3.1.1 Monitoring and Evaluation of CoE

The progress of CoE will be monitored by in the following manner:

**In-house CoE Committee** - Each NIPER will form a CoE committee under the chairmanship of their director with representatives of Industry stakeholder, research/academic institution with relevant expertise, Departmental Heads concerned, Finance Officer of the Institute as members for regular monitoring of the CoE.

**The in-house committee shall have the following responsibility-**

i. The in-house committee shall be responsible for day-to-day monitoring and administrations of the CoE.

ii. The In-house committee shall be responsible for timely execution of the deliverables of the CoE as per the approved proposal.

iii. The In-house Committee shall submit quarterly progress report of the Centre of Excellence (CoE) to the Steering Committee.

**Board of Governors (BoG), NIPER-** Shall be the BoG of the respective NIPER, constituted as per the provisions of The NIPER Act,1998 and NIPER(Amendment)Act, 2021.The BoG shall have the following functions-

**i.** The Research program and time-bound deliverables of CoEs will be fixed in consultation with the Board of Governors (BoGs) of the respective institutes.

ii. All the financial approval of activities of CoE subject to approval / overall supervision of BoG and, shall be subject to Government rules(GFR) and where applicable of DoP.

**Steering Committee (SC)** - The Steering Committee (SC) will be set up under the chairpersonship of Secretary (DoP), with Joint Secretary (NIPER/R&D, DoP), Representative from CDSCO, FA (DoP) and Director/ Deputy Secretary (NIPER/R&D, DoP) as members. The Steering Committee may co-opt technical members. The functions of the Steering Committee will as follow-

I. The progress of CoE will be reviewed by SC.

ii. The SC may revise ceilings under non-recurring and recurring heads as deemed appropriate for respective CoEs during the tenure of the Scheme restricted to the Component A ceilings.

iii.The SC will also be authorized to carry out any amendments in the deliverable and outcome of the CoE considering advice of the in-house NIPER committee, if any.

The funding allocated under this component shall not be diverted to component B.

### 3.2 Applicants under Component B: <u>Promotion of Research in Pharma MedTech sector:</u>

The financial assistance under this component would be provided to promote R&D in six priority areas, which are detailed in **Appendix-III.** The component is further divided into the following three categories:

i. **Category B-I** – Up to **Nine established Pharma-Medtech companies** will be selected under this category, who are willing to carry out research work in one or more of the six priority areas in collaboration with Government Institutes of National Repute as per **Appendix X,** conducting research in domain of Pharmaceuticals and Medical Devices. Investment made by the companies on the projects at the institute would be supported at the rate of 35% of the total cost or Rs 125cr whichever is less on a milestone basis from TRL 1 to reach TRL 9 over a period of five year on benefit sharing principle. A company may apply for funding under this category at any stage of research (TRL 1-9). However, funding will be provided for ongoing approved project *vis a vis* current TRL. Decision regarding IP rights, ownership of the assets created would be as per prior agreement between the company and individual institute itself.

ii. **Category B-II** - Up to **Thirty research projects** in any of the six priority areas which are at successfully validated level will be selected under the category. The research work at entry of the beneficiaries in this category should be at either TRL 5 or 6. The Research work would be supported at the rate of 35% of the total cost or Rs 100 cr whichever is less on a milestone basis from TRL 5 to reach TRL 9 over a period of five year on benefit sharing principle.

iii. **Category B-III** - Funding up to Rs 1Cr would be provided to research projects in any of the six priority areas to help innovators including Indian startups and MSMEs to reach TRL 4. Around **125 research projects** from innovators/ start-ups/ SMEs/ MSMEs having potential or having made sufficient headway in the research of priority areas will be selected.

4. **Definitions**

**4.1** Annual **turnover:** Annual turnover, in reference to a business or company, is a financial metric that represents the total revenue generated by the company from its primary operations over a specific period of 12

months. It is commonly calculated on an annual basis and provides an indication of the company's sales performance and the scale of its business activities. The annual turnover figure includes all income generated from the sale of goods or services, excluding any taxes, discounts, or returns. It reflects the total value of all sales made during the specified period, regardless of whether the payment has been received or not.

**4.2 Applicant:** Applicants for the Component B of the Scheme shall be any Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP), start-ups or a Company /Group of companies registered in India and making an application for seeking approval under the Scheme. The applicant should not have been declared as bankrupt or willful defaulter or reported as fraud by any bank or financial institution or non-banking financial company.

**4.3 Applicant Groups**: The applicants shall apply within the following three groups based on the respective criteria:

**4.3.1 Category B-I:** Applicants having annual revenue for pharmaceutical goods more than or equal Rs 1,000 Cr with average R&D expenditure of 3-5% in last five year and for medical devices, the annual turnover should not be less than Rs. 250 Cr and existing R&D expenditure should be minimum 1-3% of total annual revenue.

**4.3.2 Category B-II**: R&D projects in priority areas at higher TRL level (TRL-5/6 to TRL-9).

**4.3.3 Category B-III**: Research Projects in priority area at TRL 1 onwards to TRL 4. Preference will be given to startups/MSME/SME.

**4.4 Application:** Application submitted by an applicant to the Project Management Agency (PMA) as per the Application form prescribed under these guidelines containing requisite information, along with supporting documents and application fee.

**4.5 Application Acknowledgement Date:** The date on which an application is acknowledged by the PMA after carrying out initial scrutiny in this regard.

**4.6** Application **Approval Date:** The date on which approval letter under the Scheme is issued by the PMA.

**4.7** Application **Window:** Time period allowed for filing the applications. The application window shall be opened based on notice issued by the department from time to time.

**4.8 Base year:** Financial Year 2023-24.

**4.9 Clinical Trials:** shall means clinical trials as defined in Drug and Cosmetics Act and approved by the competent authority as defined in the act as amended from time to time.

**4.10 Empowered Committee (EC**): It refers to the committee constituted by DoP under the chairpersonship of CEO, NITI Aayog with Secretary level representatives from the Departments of Pharmaceuticals, Health & Family Welfare, Health Research, Biotechnology, AYUSH, Science & Technology, Scientific and Industrial Research, Scientific Secretary, O/o Principal Scientific Advisor to the Government of India (PSA) and Additional Secretary & Financial Advisor, Department of Pharmaceuticals as members.

**4.11** Financial **Year:** Financial Year begins on the 1st of April of a year and ends on 31st March of the following year.

**4.12 Force Majeure:** Extraordinary events or circumstances beyond human control such as an event described as an act of God (like a natural calamity) or events such as war, strike, public health emergency, riots, crimes (but not including negligence or wrong- doing, predictable/ seasonal rain and any other events specifically excluded).

**4.13 Funding:** It is the financial assistance provided to each selected participant based on the laid down eligibility criteria.

**4.14** Project **Appraisal and Approval Committee (PAAC):** It refers to the committee formed under the chairpersonship of Secretary (Pharmaceuticals) with representatives (not below the level of Joint Secretary) from DST, DSIR, DBT, DGHS, DHR, AYUSH and CDSCO to examine and approve the projects as well as consider and approve claims for disbursements.

**4.15** Project **Management Agency (PMA):** is the agency appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification

of eligibility and examination of disbursement claims in accordance with these guidelines.

4.16 **Project Management Unit (PMU): -** is the unit established in the dept of Pharmaceuticals to work as secretariat for the administrations and execution of both scheme.

4.17 **Participants**: shall refers to applicants selected under the scheme.

4.18 **Net sale**: shall refers to Gross sales less the cost of return, allowances and discounts.

**4.19 R&D expenditure:** This includes expenditure on R&D and product development including clinical trial costs in India only. All non-creditable taxes and duties would be included in such expenditure**.**

**4.20 R&D cost:** This includes expenditure incurred by the participants on the project selected under the scheme, including clinical trials whether in-house or through CRO, subject to verification. and shall not include expenditure on R&D counted as investment under PLI 2.O. All non-creditable taxes and duties would be included in such expenditure**.**

**4.21 Successor-in-interest** refers to a party or entity that succeeds or takes over the rights, obligations, and interests of another party in a legal or business context. It typically occurs when there is a transfer or transition of ownership, assets, liabilities, or contractual relationships from one entity to another. The successor-in-interest essentially steps into the shoes of the original party and assumes their rights, responsibilities, and legal standing.

**4.22** Technical **Committee:** A technical committee of 5-7 members with representatives from scientific departments, CDSCO and experts from industry & academia would be set up.

**4.23 Technology Readiness Levels (TRL**): Technology Readiness Levels (TRLs) are methods for estimating the maturity of technologies during the acquisition phase of a program. TRLs are based on a scale from 1 to 9 with 9 being the most mature technology. For the purpose of the scheme, TRL as

defined by DBT-BIRAC are taken as the standards. TRL Levels are indicated at **Appendix XI.**

**4.24 Transfer of Technology (ToT):** Transfer of technology refers to the process of sharing and disseminating knowledge, expertise, skills, and intellectual property from one entity to another. It involves the transmission of technology-related information, innovations, techniques, or methodologies from a source (such as a research institution, company, or individual) to a recipient (another organization, industry, or country) for the purpose of adoption, implementation, and utilization.

**4.25 Group of Companies**: Group Company(ies) shall mean two or more enterprises which, directly or indirectly, are in a position to:

Exercise twenty-six percent or more of voting rights in other enterprise.

Or

Appoint more than fifty percent of members of Board of Directors in the other enterprise, as defined in the FDI Policy Circular of 2017.

**5. Tenure of the scheme:** The tenure of the scheme will be for a period of five years from FY 2023- 24 to FY 2027-28.

**6. Selection of the applicants:** Selection of the applicants in each group will be governed by the parameters given in **Appendix IV.**

6.1 All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria as given in **Appendix IV.**

6.2 The applicant securing highest marks shall be ranked Number 1, followed by applicant securing second highest marks and so on.

6.3 The selection of the applicants shall be in the order of their ranks.

6.4 If two or more applicants have same score, the applicant having higher marks in respect for R&D expenditure criteria will be ranked higher for B-I and, for Group B-II and BIII the projects applying for R&D in priority area (5&6) will be ranked higher. Applicants undertaking R&D in same area, the one with higher TRL level will be ranked higher.

6.5 **Number of applicants to be selected**:

**Group A**: 9 participants with maximum of 3 Foreign MNCs

**Group B**: 30 participants/projects with maximum of 10 Foreign MNCs

**Group C**: 125 participants, of which:

- Minimum of 50 startups subject to sufficient eligible applicants
- Minimum of 20 Medtech projects subject to sufficient eligible applicants.
- Any company/Group of Companies can apply in both BI & BII but would be selected in either BI or BII.
- Any company/group companies can be selected in maximum 3 projects overall.

## 7. Funding provided to grantees under the scheme:

7.1 Project cost to be approved for R&D will be calculated post application acceptance.

7.2 The funding allocated for various categories would be as follows:

**Category B I -** Rs. 1,125 crores

**Category BII -** Rs. 3,000 crores

**Category B III** - Rs. 125 crores

7.3 The funding allocation is milestone based will be released in the following instalments:

| | |
|---|---|
| 1st Instalment: Signing of Agreement | 10% |
| 2nd Instalment: Completion of 1st Milestone | 30% |
| 3rd Instalment: Completion of 2nd Milestone | 30% |
| 4th Instalment: Completion of approved project and submission of final report | 30% |
| Total | 100% |

The milestones achieved by the applicants will be reviewed periodically by PMA. Last instalment will be released after submission of project completion report.

7.4 The funding allocated for one category, if left under-utilized at the end of the year can be moved to other category applicants based on their need and performance. The modalities in this regard shall be finalized by PMA with the inputs from PMU.

7.5 For the proposals finally approved for funding support, PMA will sign agreement with grantees on behalf of DoP.

7.6 Necessary guidance notes and templates are provided to Grantees by PMA.

7.7 All grantees are required to open a separate, auditable, no-lien bank account with a scheduled commercial bank in order to receive the funds.

**Budget planning:**

| **Details** | **Category B I** | **Category B II** | **Category B III** |
|---|---|---|---|
| | | **Nonrecurring cost** | |
| Upgradation of Equipment/ infrastructure | 20% | 30% | 70% |
| | | **Recurring cost** | |
| Manpower, Consumables, Approvals, Clinical Trials, Travel, Contingencies etc., | 80% | 70% | 30% |

| | |
|---|---|
| **Waivers** | The above guidelines shall be followed unless there is a specific exemption by DoP. |

9. **Benefit sharing:**

**9.1 Category B I and B II:**

9.1.1 Beneficiaries under category B I and B II will need to share the benefits for the successful product/technology developed through DoP's support in either of the following ways:

a. Through 10 % benefit sharing on net sale proceeds per year of the product starting from first sale of the product/technology till 10 years; or

b. Through 10% benefit sharing on net sale of the product till amount starting from first sale of the product/technology till the amount is equivalent to 150% of assistance received from DoP: or

c. In the form of equity (face value of shares equivalent to 100% of the assistance provided by DoP).

9.1.2 Beneficiaries will have the option to choose one of the above at the time of signing the agreement.

9.1.3 DoP may seek payment by way of one-time transaction in the occurrence of events as under:

a. The fund recipient entity successfully commercializes the product/technology supported through PRIP scheme.

b. Licensing/Assignment/ Technology-transfer of the Project developments to any third party where the fund recipient is not undertaking direct market reach which also be treated as successful commercialization.

c. If the fund recipient intent to transfer or sell/assign the interest of developments, it shall take prior written permission from DoP before doing so. DoP reserves the right to realize the benefit sharing, in case of one-time transaction, as will be mutually while granting such permission.

d. If the fund recipient licenses the interest of project developments for periodical payments including benefit sharing, then the fund recipient can also continue to share the benefits as prescribed by DoP to be met from the periodical proceeds received from licensees/sub- licensees.

e. In cases of significant changes such as public offering of shares, raising of venture funds, change in the share holding pattern, change in the legal entity status, changes due to substantial expansion, merger and acquisition etc. DoP reserves the right to enforce the benefit sharing obligation or the Surety Bond and recover the remaining benefit sharing committed for the project through the resolution or liquidation process as a receivable in favour of DoP.

9.1.4 Payment of benefit sharing shall fall due beginning with the first sale of the product(s) and the liability to pay benefit sharing will terminate upon the first of any of the following two events to occur:

a. Payment of 10 % benefit sharing on net sale of the product for a period of 10 years.

b. Through 10% benefit sharing on net sale of the product till amount is equivalent to 150% of assistance disbursed from DoP that was not returned as unutilized funds OR in the form of equity
c. in case of Foreclosure or Termination of Project.

**9.2 Category B-III:**

9.2.1 Beneficiaries under category B III will need to share the benefits for the successful product/technology developed through DoP's support in either of the following ways:

a. Through 5% % benefit sharing on net sale proceeds per year of the product starting from first sale of the product/technology till 10 years; or

b. Through 5% benefit sharing on net sale of the product till amount starting from first sale of the product/technology till the amount is equivalent to 100% of assistance received from DoP: or
c. In the form of equity (face value of shares equivalent to 100% of the assistance provided by DoP).

9.2.2 DoP would also seek payment in case there is transfer of intermittent technology, know-how, application to third party to further carry out commercialization with/ without further development by way of one-time transaction.

9.2.3 Payment of benefit sharing shall fall due beginning with the first sale of the product(s) and the liability to pay benefit sharing will terminate upon the first of any of the following two events to occur:

a. Payment of 5% % benefit sharing on net sale of the product for a period of 10 years.

b. Through 5%% benefit sharing on net sale of the product till amount is equivalent to 100% of assistance disbursed from DoP that was not returned as unutilized funds OR in the form of equity
c. in case of Foreclosure or Termination of Project.

**10.Application:**

10.1 The applicant is required to submit the application as per the form prescribed in **Appendix V**.

10.2 The Scheme shall be open for applications during the Application Window which is for 45 days. No application shall be accepted after the end of the Application Window.

10.3 A period of 45 days is considered as application under scrutiny after the closure of application window.

10.4 Considering the time taken for selection of participants, FY 2023-24 shall be gestation period.

10.5 An applicant shall submit an undertaking in the format given in **Appendix VI**, the Details of In-house R&D as per the forgiven in **Appendix VII** and the details of No lien account as per the format given in **Appendix VIII**.

10.6 On receipt of an application in the prescribed format, PMA will conduct an examination as per the checklist. The aforesaid examination shall preferably be completed within 15 working days from the date of the receipt of the application or any subsequent submission of the revised application if the original application was returned as incomplete earlier.

Thereafter, the PMA shall issue an acknowledgement of receipt of the application. This acknowledgement shall not be construed as approval of the Scheme.

10.7 In case, on the above-mentioned examination, an application is found to be incomplete, PMA shall inform the applicant accordingly within 15 working days of receipt of the application. An applicant must complete the shortcomings within 15 days of such communication from PMA, failing which the application will be closed under intimation to the applicant.

10.8 A non-refundable application fee, as mentioned in **Appendix V** of these guidelines, would be payable for each application. The application fee would be accepted electronically only.

## 11. Online Portal:

11.1 All applications will be submitted through an online portal maintained by the PMA. In case the portal is not available, applications may be submitted in physical form to the PMA.

11.2 Upon successful submission of an application, PMA will issue a unique Application ID to the applicant for all future references pertaining to the Scheme.

11.3 Application can be made on the online portal.

## 12. Role and Responsibilities of the Project Management Agency (PMA)

12.1 The PMA shall be responsible for:

12.1.1 Development and maintenance of an online portal for receipt of the applications.

12.1.2 Receipt of applications, examination and processing of applications and issuing acknowledgements.

12.1.3 Evaluation of the received application on financials ground (Verification of annual turnover, R&D expenditure committed investment for determining eligibility for disbursement of incentive. and evaluation of the documents submitted.

12.1.4 Weekly submission to PMU about the status of applications received and processed under the Scheme.

12.1.5 Placing the appraisal reports of shortlisted participants before the DoP through PMU for its concurrence.

12.1.6 Submission of shortlisted applicants after concurrence of DoP to Technical Committee for technical evaluation.

12.1.7 Completion of documentary formalities and issuance of approval letter to all selected participants.

12.1.8 The PMA will have the right to carry out physical inspection of an applicant's offices through site visit with approval of DoP.

12.1.9 Verification of the reconciliation of disbursement claims with prescribed documents.

12.1.10 Compilation of data regarding progress and performance of the Scheme through Quarterly Review and other information/ documents.

12.1.11 Maintenance of records in a systematic manner, both digital and physical, to be handed over to DoP as may be mutually decided.

## 13. Project Management Unit (PMU)

13.1The PMU shall be responsible for providing secretarial services for administrations of component A &B of the scheme. The PMU shall carry out the following responsibilities:

13.1.1 Providing secretarial and other support to the Steering Committee for carrying out its responsibilities in administrations and management of Component A.

13.1.2Providing secretarial and other support to the PAAC and EC for carrying out its responsibilities in management of Component B.

13.1.3 Preparation of agenda papers for meetings and providing secretarial assistance to DoP for the same.

13.1.4 The PMU may convene stakeholders' consultations as and when deemed necessary during the tenure of the Scheme.

13.1.5 The PMU will co-ordinate with concerned departments, respective NIPERs and with TC and PMA for implementation of the scheme.

## 14. Technical Committee (TC)

14.1 The Technical Committee (TC) as defined in para 1 above, will be responsible for technical evaluation of the project, shortlisted by PMA, for appraisal and approval by PAAC.

14.2 The TC will examine and appraise the projects in respect of technical eligibility TRL level, alignment with priority area, strategic importance, alignment with National Health Priorities etc. and rank the projects for the approval of PAAC.

14.3 The Technical Committee will define the milestones in for the selected project for continuous evaluation .

14.4 Examination of claims and assess the milestone achievement for disbursement of incentive and making appropriate recommendations to the PAAC through PMU.

14.5 On a reference made by PMU, the TC will examine any technical query with respect to additional requirements, extension in duration of project, etc. and submit the report to PMU before the same is considered by PAAC.

## 15. Project Appraisal and Approval Committee (PAAC)

15.1 The Project Appraisal and Approval committee (PAAC), as defined in para 1 above, will perform following functions:

15.2 PAAC will examine and approve the projects, consider and approve claims for disbursements and take appropriate steps to contain the expenditure within the prescribed outlay.

15.3 The PAAC shall meet as often as necessary to ensure timely consideration of applications and disbursement claims and conduct periodic review of the Scheme. The PAAC will consider applications, as recommended by the PMA and TC, for approval under the Scheme.

15.4 The PAAC may seek such additional information as considered necessary for approval. The PAAC, while considering applications for approval, shall ensure that the total amount of f payable does not exceed the financial outlay of the Scheme.

15.5 The PAAC will conduct a periodic review of selected applicants with respect to their employment generation and development under the Scheme.

15.6 The PAAC will consider claims for disbursement, as examined and recommended by the PMA, for disbursement of funding.

15.7 The PAAC may seek input from the Technical Committee on technical issues related to the Scheme, as may be deemed necessary.
15.8 The PAAC may request additional information, details and documents from the applicant as deemed necessary.

## 16. Empowered Committee (EC)

16.1 The Empowered Committee (EC) as defined in para 1 above will perform following functions:

16.2 The EC shall monitor and conduct periodic review of the Scheme and define Nationals Health priorities preference for the scheme.
16.3 The EC will also be authorized to carry out any amendments in the scheme and the guidelines thereof.
16.4 The EC may revise incentive rates and ceiling, if required, be done, shall not result in exceeding the total financial o of the scheme.
16.5 In case of a Force Majeure event, the EC may amend, modify or withdraw any Clause under the Scheme.

## 17. Approval and disbursement of funding under the Scheme

17.1 Application under the Scheme can be made by any company registered in India.
17.2 An application, complete in all aspects, will have to be submitted before the due date. Acknowledgement will be issued after initial scrutiny of the application.
17.3 The eligible applicants will be appraised on an ongoing basis and considered for approval, based on predefined selection criteria.
17.4 The funding shall be released to the selected participants under the scheme who meet the required threshold criteria.
17.5 Timely disbursals of funding by the PMA will be monitored by DoP and reviewed by the PAAC subject to budgetary allocations by the Department of Expenditure.
17.6 The funding will be provided on investment in research as defined in scheme guidelines in respect of maximum period of 5 years for component B from the date of approval.
17.7 The progress in approval of applications and disbursal of funding shall be monitored on an ongoing basis against the monitoring framework to be specified in the guidelines.

17.8 The PMA shall recommend two (02) waitlisted applicants, if available, along with selected applicants, for each target segment.

17.9 All the applications will be finalized within 90 days from the date of closure of the application window.

17.10 After receiving approval from the PAAC, the PMA will issue a letter to the selected applicant within 5 working days, communicating approval under the Scheme. The approval letter shall clearly mention the following:

i Name of the applicant

ii Target area of research

iii Funding allocated.

iv Baseline (if any)

v Scheduled date of commencement of the work

17.11 The selected applicant shall submit, within two weeks of date of issuance of approval letter by the PMA, a bank guarantee of prescribed amount along with undertaking as per **Appendix VIII**, in favour of PMA.

17.12 The aforesaid approval letter shall not be construed as a guarantee for disbursement of incentive as the same will be dependent upon verification of eligibility after submission of disbursal claim and other criteria defined in these guidelines.

17.13 If the selected applicant is found to be ineligible at any stage, or if it has not compiled with notifications, orders, guidelines etc., of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason, the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.

17.14 For claiming incentive under the Scheme, applicants will be required to submit claims for disbursement of incentive to the PMA. Applicants must ensure that the claims are complete in all respects and are accompanied by all the documents required as per prescribed format and made available on the online portal.

17.15 An applicant may submit a claim for disbursement of incentive on annual basis. Claims for any period shall be made only once, unless

withdrawn, and no subsequent part claims shall be allowed for the said period.

17.16 Claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, same shall be released after submission of final audited accounts of the Company for the project.

17.17 The PMA shall examine and verify eligibility and assess incentive payable to an applicant based on the method laid down in these guidelines and the approval letter issued to the applicant.

17.18 The PMA will have the right to verify any document(s) in relation to the claim for incentives including but not limited to Statutory Auditor or Independent Chartered Accountant certificates, whichever is applicable, and returns furnished to various Ministries / Departments / Agencies. The PMA shall also have the right to examine the end realization and settlement/ payments corresponding to sales and investment respectively by way of Statutory Auditor or Independent Chartered Accountant certificates, bank statements etc. to the extent deemed necessary.

17.19 In case of any doubt with respect to determining eligibility and incentive amount due, or any other matter in discharge of its duties and responsibilities, the PMA may refer such matter to PAAC for clarification and the decision of PAAC shall be final in this regard.

17.20 The PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to PAAC.

17.21 PAAC will consider claims for disbursement of incentive, as examined and recommended by the PMA.

17.22 PMA will maintain a separate Bank Account for receipt of application fees from applicants and funds from DoP related to the incentives and make disbursements of incentive amount to the applicants upon approval of the claim by DoP. All interest earned on this account shall accrue to the Consolidated Fund of India.

17.23 PMA shall disburse the incentive through direct transfer (via PFMS) after approval of the claim and completion of all pre-disbursal formalities by the applicant.

17.24 If the PMA or DoP is satisfied that eligibility under the Scheme and / or disbursement of incentives have been obtained by misrepresentation of facts or falsification of information, DoP may ask the applicant to refund the incentives along with interest calculated at 3 years SBI MCLR prevailing on date of disbursement, compounded annually, after giving an opportunity to the applicant of being heard. In this regard, the applicants shall submit an undertaking in the format prescribed at **Appendix V**.

17.25 DoP shall make budgetary provisions for disbursal of incentives under the Scheme. The PMA will submit budgetary requirements to DoP as a consolidated amount on quarterly basis.

17.26 PMA shall furnish, an applicant and product wise statement of all claims received, processed and approved and all incentives, disbursed and pending, to DoP on quarterly basis.

17.27 Yearly review will be undertaken by the EC and half yearly review with respect to progress and performance of the Scheme will be done by PAAC.

17.28 All approved applicants shall be required to furnish self-certified Quarterly Review Report within 30 days from the end of each quarter which will be reviewed by DoP.

## 18. Residual

18.1 In case the project is declared unsuccessful/commercially viable, the remaining assistance would not be released and any un- utilized amount as on date would be refunded to DoE within 30 days of the declaration.

18.2 To obviate any malpractices in the financial matters where disbursements are made to companies by the Government, it has been decided to provide a deterrent against corrupt practices for promotion of transparency and equity. Therefore, keeping in view the sensitives involved in the process and taking cue from the instructions of the Central Vigilance Commission regarding adoption of an Integrity Pact in the matter of procurement, it has been decided to obtain

undertaking(s) from applicants under the Scheme as per format at **Appendix X.**

18.3 An applicant shall intimate the PMA of any change in the shareholding pattern during the tenure of Scheme, after up-dation with the Registrar of Companies (RoC).

18.4 Any change in the shareholding pattern of an applicant leading to a successor-in interest during the tenure of the Scheme, shall be intimated by PMA for approval of the DoP to consider for disbursal of incentives.

18.5 In the event of a change to the successor-in-interest, any investments previously undertaken by the initial applicant-whose approval was sanctioned under the scheme-will be acknowledged when establishing eligibility.

Furthermore, If a company previously identified as part of the applicants group, whose investment were included in the computation of minimum cumulative investment under the scheme, cease to be affiliated with the applicant ,the investment contributed by such disaffiliated group companies will no longer be counted in the calculation of minimum cumulative investment for future investment claims .To make up for this deficit in the investment applicant or the remaining group companies will need to compensate before making any subsequent incentive claims.

18.6 All transactions by the selected applicant with Related Parties will be subject to the provisions of relevant statutes and Accounting Standards – 18 and corresponding Ind-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and/ or eligible committed investment.

18.7 An applicant should inform PMA and DoP of any additional IP's being generated from the project which may fall under the Benefit Sharing Clause of respective Category of Component B.

*****

**Appendix I**

# FORM FOR ESTABLISHING CENTRE OF EXCELLENCE AT NIPERs

## Table 1: Basic Details

| S. No. | Outline | Details |
|---|---|---|
| 1. | **Name of the Institute and area of specialization** | |
| 2. | **Proposed Outlay*** The NIPERs will clearly define both recurring & non-recurring costs of the respective CoEs in consultation with their BoG. | |
| 3. | **Duration** | 2023-24 to 2026-27 |
| 4. | **Objectives of the COEs** | |
| 5. | **Manpower Requirement*** No regular manpower will be created from the financial assistance provided under the scheme. | |
| 6. | **Target Beneficiary of COEs** | |
| 7. | **Outline the significant initiative** that NIPER plans to undertake within the specialized domain of its Centers of Excellence (CoEs). | |
| 8. | **Measurable outputs/outcomes*** | |

| | | |
|---|---|---|
| | NIPER will clearly define their measurable outputs/ outcomes that they aim to accomplish through COEs.<br><br>*The deliverables of CoEs will be fixed by the Department of Pharmaceuticals in consultations with Board of Governors (BoGs) of the respective institutes.<br>The CoEs will be reviewed based on set deliverables. | |
| 9. | Planned Industry-Institution collaboration | |
| 10. | Approval and Clearance | |

1. **General**

1.1 Specialized Area of the COEs:

1.2 Total estimated financial outlay:

2. **Proposed Outlay**

**Details of proposed financial outlays.**

Please provide component-wise cost estimates for usage of proposed outlay for different requirements:

**Table 2: Financial outlay on different requirements**

| S. No. | Segment | Subject | Justification | Amount (in crore) |
|---|---|---|---|---|
| **1.** | **Recurring** | | | |
| **2.** | | | | |
| **3** | **Non-Recurring** | | | |
| **4** | | | | |
| | **Total** | | | |

3. **Duration**

Please provide year-wise cost estimates for usage of proposed outlay in the table below.

**Table 3: Details of the Financial (year-wise)**

| **Segmen t** | | **Subject** | **Proposed Outlay (year wise) (in crores)** | | | | |
|---|---|---|---|---|---|---|---|
| | | | **2023-24** (Preparatory year) | **2024-25** | **2025-26** | **2026-27** | **2027-28** |
| **Recurring ng** | 1 | **Subject Justification:** | | | | | |
| | 2 | **Subject Justification:** | | | | | |
| **Non-Recurring** | 3 | **Subject Justification:** | | | | | |
| | 4. | **Subject Justification:** | | | | | |
| **Total** | | | | | | | |
| **Grand Total** | | | | | | | |

4. **Objectives of COEs**

Enumerate the primary objectives that NIPER is striving to achieve within its designated Center of Excellence (CoEs) and elucidate how these objectives align with the overarching goals of the PRIP Scheme and the mandate of Department of Pharmaceuticals.

5. **Manpower Requirement**

No regular manpower will be created from the financial assistance provided under the scheme. Information regarding the workforce engaged to be communicated to the Project Monitoring Agency (PMA) through quarterly reports.

**Table 4: Manpower Requirement**

| Sno. | Temporary Manpower Requirement (in no. of personnel) | Details of outsourcing of services | Associated Cost and funding Source | Remarks |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

6. **Target Beneficiaries**

A. Please specify the target beneficiaries in terms of location, area and segment of population, industries, companies, institutions, etc.

B. Please give the details of estimated coverage of target population and basis for selection of the target beneficiaries.

7. **Significant Initiative**

Outline the significant initiative that NIPER plans to undertake within the specialized domain of its Center of Excellence (CoEs).

**Table 5: Key Initiative Undertaking**

| Sno. | Key Initiative undertaken | Impact |
|---|---|---|
| **1.** | | |
| **2.** | | |
| **3.** | | |
| **4** | | |
| **5** | | |
| **6** | | |

## 8. Outcomes and Deliverables

Indicate year-wise targets for outputs and outcomes of NIPER along with the activities to be undertaken and inputs to be used in the form of measurable indicators in the table below. Data sources for each indicator must be clearly mentioned along with key assumptions and risks involved (if any) along with their severity as perceived by the proposer. Baseline data (Year and Value) should also be benchmarked and mentioned for all indicators.

**Table 6: Measurable Indicators for Outcome/Output**

| Sno | Output/Deliverables | Activities undertaken | Measurable Indicators | Impact |
|---|---|---|---|---|
| **1** | | | | |
| **2** | | | | |
| **3** | | | | |
| **4** | | | | |

| | | | | |
|---|---|---|---|---|
| **5** | | | | |

9. **Year-wise targets for outputs and outcomes**

**Table 7: Yearly Output**

| **Highlights** | **Year I** | **Year II** | **Year III** | **Year IV** | **Year V** |
|---|---|---|---|---|---|
| **Physical /Infrastructure development** | | | | | |
| **Patents** | | | | | |
| **Publications** | | | | | |
| **Students trained** | | | | | |
| **Industry sponsored. projects** | | | | | |
| **Any other component, if any** | | | | | |

10.**Planned Industry-Institution collaboration.**

NIPERs are required to foster robust industry-academic linkages, necessitating the meticulous consideration of specified eligibility criteria when forging collaborations with industrial partners.

**Table 8: Planned Industrial Collaboration**

| **Sno.** | **Year** | **Planned Industrial Collaboration** | **Justification** | **Expected Output** |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |

11. **The tentative list of eligibility criteria to be considered by NIPERs for Academic-Industry partnership:**

**Table 9: Eligibility criteria for Industry**

| S. No | Eligibility Criteria for Industry |
|---|---|
| **1.** | Reputed Pharmaceuticals/Med-Tech Industry with existing R&D expenditure should be a minimum of 2% of total. annual revenue. |
| **2.** | **Company's experience**<br>Pharma Med-Tech company should have a minimum experience of 10 years in the respective fields. |
| **3.** | **Existing Academic Collaboration of the Industry**<br>Previous patents filed, research publications. Support available for Technology transfer, regulatory processes. Previous track record of collaboration with academic/ research institutes. |
| **4.** | Existing patent record of the industry (inclusive of national & international) |
| **5.** | Infrastructure Facilities-<br>The company should have adequate research and development infrastructure. |
| **6.** | Miscellaneous |

12. **Approvals and Clearances**

Requirement of mandatory approvals and clearances, if any from various local, state and national bodies and their availability may be indicated in a tabular form (Land acquisition, environment, forestry,

wildlife etc.)

**Table 10: Approval/ clearances**

| S. No. | Approval/Clearances | Agency concerned | Availability (Y/N) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

**Appendix II**

**Undertaking to be furnished by NIPERs.**

We, [Institute Name], hereby undertake to comply with the following conditions for availing the funding under the Scheme for establishment of the Center of Excellence (COE) in [Specify the Field] for a duration of up to 5 years:

1. We, ……., hereby acknowledge that the funding that would / may be provided to us under the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no. 199 dated 17th August, 2023 in Part-I, Section 1 of the Gazette of India (Extraordinary), will be provided to us based on, and after relying upon, the information provided by us to avail

they said incentives. We understand and acknowledge that the financial support provided under this scheme is contingent upon our strict adherence to the guidelines and regulations established by the scheme's governing authorities.

2. We hereby confirm that the information provided by us for availing the said funding is true, correct, and complete in all respects and the material fact/ information that may have an adverse impact on the information provided by us for availing the said funding has been concealed. We acknowledge and confirm that the foregoing averment is on an on-going basis and further undertake to immediately appraise the Department of Pharmaceuticals about any change in the status of information provided by us to avail the said funding.
3. We commit to providing regular progress reports and updates to the

concerned authorities, as per their requirements, to demonstrate the effective utilization of the financial assistance and the successful establishment and operation of the CoE.

4. We further commit to ensuring that the Center of Excellence (CoE) becomes self-sufficient within five years from the date of its establishment, and we will not rely on DoP for funding the salaries of individuals employed within the CoE after the period of 5 years.
5. In the event of any proposed changes, deviations, or adjustments to the plan and budget approved under this scheme, we shall promptly inform the competent authority and seek their prior approval before implementing such changes.

We hereby agree to uphold and comply with the aforementioned conditions and acknowledge that this undertaking is being submitted to the competent authority to formalize our commitment.

**Authorized**
**Signatory: [Name]**
**[Designation]**
**[Institute**
**Name] [Date]**

**Appendix III**

## PRIORITY AREAS UNDER THE SCHEME

The scheme shall cover Pharma and MedTech research under six (06) priority areas as mentioned below:

I. **Area/ Product 1**

i. New Chemical Entity (NCE)

ii. New Biological Entity (NBE)

iii. Phyto-pharmaceuticals (Natural Product)

**Area/ Product 2**

i. **Complex generics: Products with**

a. A complex active ingredient(s) (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients)

b. A complex formulation (e.g., liposomes, colloids)

c. A complex formulation technology and manufacturing processes permeation enhancers, continuous flow manufacturing

d. A novel route of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and optic dosage forms that are formulated as suspensions, emulsions or gels)

e. A complex/novel dosage form (e.g., modified release formulations, transdermal, metered dose inhalers, extended release injectable)

f. Innovative drug-device combination products (e.g., medicated catheters, auto injectors, metered dose inhalers

ii. **Biosimilars**

**Area/ Product 3 - Precision medicine (Targeted innovative therapeutics)**

i. Any approach that uses information about a person's own genes or proteins to prevent, diagnose, or treat a disease.

ii. Stem cell therapy, gene therapy

iii. Biomarkers

**Area/ Product 4 – Medical Devices**

i. AI/ML based medical devices with software development, Software as Medical Device (SaMD) and software in Medical Device (SiMD)

ii. Medical diagnostics and screening devices with genetic technology.

iii. Robotic medical devices for surgical procedures

iv. Medical devices with telemedicine facilities

**Area/Product 5- Orphan Drugs**

Medicinal products intended for diagnosis, prevention or treatment of life threatening or very serious diseases or disorders that are rare- about 450 rare diseases recorded in India (in tertiary care hospitals)

VI. **Area/ Product 6 - Drug development for AMR**

Prioritisation will be done within and among the categories based on future.

**Appendix -IV**

A. **Selection parameters**

1. **Category B I:**

- Annual turnover of the company should be not less than Rs. 1000 cr. and the existing R&D expenditure in Pharma should be minimum 3-5% of total annual revenue. As regard medical devices, the annual turnover should not be less than Rs. 250 cr. and existing R&D expenditure should be minimum 1-3% of total annual revenue.
- Committed R&D expenditure in priority areas in next 5 years.
- Joint Research publications with academia in peer-reviewed journals indexed in databases: Medline, Pubmed Central, Science Citation index, Science Citation Index Expanded, Embase, Scopus, Directory of Open Access Journals (DoAJ) etc.,
- Products launched in the market through collaboration with academia.
- Existing patent record of the industry (inclusive of national and international patents).
- Patents filed under Indian Patent Act (process patent and product patents)
- Any company may apply for funding under this category at any stage of research (TRL 1-9) however funding will be provided for ongoing approved project viz-a-viz current TRL.
- One company can perform research in multiple subareas under one priority area however undertaking by the applicant that the project with same objectives and deliverables has not received funding from any other agency.
- The proposed objectives and deliverables should not have received funding support from any other agency.
- The institute should have basic research facilities that are available for conducting research by the company.
- There must be a MoU or letter of acceptance between the applicant and the institute before applying for the benefit through the scheme, defining the usage of the infrastructure and ownership of the product developed by the company must be clearly defined.

- At least 10% of the human resources for the projects must be from the students/faculties of the institutes which will be trained by the company.
- The funding will include expenditure incurred on manpower specifically hired for the projects, raw products, equipment, consumables, cost of clinical trials regulatory process, contingencies etc.

2. **Category B II:**

The beneficiaries will be selected in this category subject to meeting the following essential criteria:

- Submission of pre-clinical trial results
- Approval for Phase 1 trials.
- Study design for Phase 2 clinical trials.
- Viability of the research being conducted.
- Sustainability, scale-up and marketing strategy.

3. **Category B III:**

Indicative criteria for selection of beneficiaries under this category are as follows:

- Start-ups and SME MSME will be given preference.
- SMEs, MSMEs and Start-up should be registered with DPIIT.
- Applicants with academia collaboration will be given preferences.
- Availability of research talent and of research infrastructure.
- Unmet need being solved, disease being targeted.
- Process patent and application process.

- Possibility of generating IP, Clear potential for becoming commercially viable product.

Financial support can be provided only once to any potential, opportunities and national importance.

B. **Eligibility criteria weightages**

**Category B-I:**

| S. No. | Eligibility Criteria | Weightage |
|---|---|---|
| 1. | Annual turnover of the company should not be less than<br>• 1000 Cr for Pharma and the existing R&D expenditure in Pharma should be a minimum of 2%-5% of total annual revenue.<br>• 250 Cr for Med-Tech and the existing R&D expenditure in Med-Tech should be at least 1-3% of total annual revenue | 10 |
| 2. | Academic Collaboration<br>• Status of NIRF Ranking based on Pharmacology and Medical Devices<br>• Availability of Research areas and Research Infrastructure<br>• Previous patent filed, research publications.<br>• Support available for Technology transfer, regulatory processes.<br>• Previous track record of collaboration with industry | 15 |
| 3. | Committed R&D expenditure in priority areas in next 5 years. | 5 |

| | | |
|---|---|---|
| | Higher the committed R&D expenditure in priority areas by the company, more points in the weightage | |
| 4. | Joint Research publications with academia in peer-reviewed journals indexed in databases: Medline, Pubmed Central, Science Citation index, Science Citation Index Expanded, Embase, Scopus, Directory of Open Access Journals (DoAJ) etc. | 5 |
| 5. | Sustainability, scale-up, and commercial viability of the proposed products (2 points each)<br>• Novelty with respect to competitors in market<br>• Proof of concept<br>• Forecast of returns in research/ Potential for high economic benefit<br>• Potential of proposed product/technology for disrupting the markets and target market for addressing niche segment<br>• Environmental Impact<br>• Go-to-market strategy.<br>• Potential business partners | 14 |
| 6. | Existing patent record of the industry (inclusive of national and international patents) | 5 |
| 7. | Patents filed under Indian Patent Act (process patent and product patents) | 5 |
| 8. | TRL Rating (TRL 1 to 9) (More the TRL Level more the weightage)<br>▪ TRL 1 to 2: 1 Points<br>▪ TRL 2 to 3: 2 Points<br>▪ TRL 3 to 4: 3 Points<br>▪ TRL >4: 6 Points<br>Any company may apply for funding under this category at any stage of research (TRL 1-9) | 6 |

| | | |
|---|---|---|
| | however funding will be provided for ongoing approved project viz-a-viz current TRL. | |
| 9. | Human resource employed-<br><br>At least 10% of the human resources for the projects must be from the students/faculties of the institutes who will be trained by the company.<br><br>The human resource workforce selected/employed may be from diverse backgrounds and points can be awarded accordingly. | 5 |
| 10. | Viability of the research on the basis of; (4 points each)<br>• Public Health Priorities/Areas of national importance in healthcare<br>• In line with objectives of the National Health Policy and<br>• Innovation and new technology<br>• Societal Impact - Solve unmet needs.<br>• One Health principles | 20 |
| 11. | Value addition in the Research ecosystem present at the selected institute in the form of:<br>• Equipment support<br>• Training support<br>• Capacity Building in any other research areas<br>• Hand-holding support<br>• Any other support | 10 |
| | **TOTAL** | **100** |

**Category B-II.**

| S. No. | Eligibility Criteria | Weightage |
|---|---|---|
| 1. | Submission of pre-clinical trial results | 10 |
| 2. | Approval for Phase 1 trials | 10 |
| 3. | Study design for Phase 2 clinical trials | 10 |
| 4. | Projects in priority areas (5,6) | 5 |
| 5. | Priority of the research on the basis of.<br>• Public Health Priorities/Areas of national importance in healthcare<br>• In line with the objectives of the National Health Policy<br>• Innovation and new technology<br>• Societal Impact<br>• Solve unmet needs | 10 |
| 6. | Infrastructure Facility- The company should have adequate research and development infrastructure | 15 |
| 7. | Sustainability, scale-up, and commercial viability of the proposed products (3 points each)<br>• Novelty with respect to competitors in market<br>• Forecast of returns in research/ Potential for high economic benefit<br>• Market Adoption and Customer Acceptance<br>• Environmental Impact<br>• Go-to-market strategy.<br>• Does the technology offer import substitution | 18 |
| 8. | TRL Rating (TRL 5 to 9) (More the TRL Level more the weightage)<br>• TRL 5 TO 6: 4 Points<br>• TRL 6 TO 7: 7 Points<br>• TRL 7 TO 9: 10 Points | 10 |

| | | |
|---|---|---|
| 9. | Previous Patents and track record of approval (No. Of National and International Patents) | 12 |
| | **TOTAL** | **100** |

**Category B-III**

| **S. No.** | **Eligibility Criteria** | **Weightage** |
|---|---|---|
| 1. | SMEs, MSMEs, and start-ups registered with DPIIT | 5 |
| 2. | SMEs, MSMEs, and Start-up with industry-academia collaboration.<br>• Previous collaboration (National / International)<br>• Industrial collaboration<br>• Academic collaboration<br>• Developing new products/ Technology through in Make in India, Startup India, and others | 20 |
| 3. | Availability of research talent and infrastructure | 20 |
| 4. | Unmet needs are being solved, disease being targeted, and national health concerns | 15 |
| 5. | Track records of patent/ citation/ research papers | 10 |
| 6. | Possibility of generating new IP | 10 |
| 7. | Potential for Employment Generation | 10 |
| 8. | Does the technology offer import substitution/ and offer export potential | 10 |
| | **TOTAL** | **100** |

**Appendix V**

**Application form: Promotion of Research & Innovation in Pharma MedTech Sector (PRIP) Scheme**

1. **Instructions:**

- The application shall be duly signed by the authorized signatory of the company.
- Applicants are advised to follow the format provided in the template for submitting their applications. Applicants are requested to provide information and enclose all supporting documents as detailed.
- All applications will be submitted through an online portal to the PMA. A non-refundable application fee as mentioned below would be payable for each application. The application fee would be accepted electronically only.
- Applicants may go through the guidelines carefully before filling in the details in the application.
- If any document which is required to be submitted along with the application is available on a government website, the website link where this document can be viewed may be provided. The responsibility of the correctness/ veracity of contents rest with the applicant(s).
- Documents to be furnished: Certificate from Statutory Auditor, Certificate from company Secretary/ Board of Directors.
- Key Personnel Details: Contact Details of three senior employees of applicant. Details would include Name, Designation, Address, Phone number and email ID.

2. **Application Fee Under the Scheme:**

| S. No | Applicant Categories | Application Fees |
|---|---|---|
| 1 | Category B I | Rs 1,00,000 |
| 2 | Category B II | Rs 1,00,000 |
| 3 | MSMEs in Category B II | Rs. 30,000 |

| | | |
|---|---|---|
| 4 | Category B III | NA |

Application Fee will be paid electronically through NEFT / RTGS to the bank account identified under PFMS as per detail given on the portal.

3. **APPLICATION FORMAT**

| **Part A: General Information** | | | | | | |
|---|---|---|---|---|---|---|
| **1.** | **Name of the Applicant** | | | | | |
| **2.** | **Title of the Project** | | | | | |
| **3.** | **Company details** | | | | | |
| | Name | Address | Ownership | Annual Turnover | Balance sheet for previous 3yrs | |
| **4.** | **Academic Institution details** *(only for Category B I)* | | | | | |
| | Name | Address | State or Central govt. | | | |
| **5.** | **Category of Applicant** | | | | | |
| | Category I | Category II | Category III | | | |
| **6.** | **Major R&D Achievements of the company** | | | | | |
| **7.** | **Area/ Sub Area of the proposal** | | | | | |
| **8.** | **TRL level** | | | | | |
| **9.** | **Total cost** | | | | | |
| | DoP | | | | | |
| | Company | | | | | |
| **10.** | **Name of the project coordinator** | | | | | |
| | Company | | | | | |
| | Institute | | | | | |
| **11.** | **Executive Summary** | | | | | |
| **12.** | **Outcome/ Deliverables in form of products** | | | | | |
| **13.** | **Benefits to Academic institute** *(only for Category B I)* | | | | | |
| | | | | | | |

| Part B: Technical Details of the proposal | |
|---|---|
| **14.** | **Introduction** |
| **15.** | **Rationale** |
| **16.** | **Objectives** |
| **17.** | **Current status of R&D on the topic/ prior art** |
| **18.** | **Current status of R&D on the topic by the applicant company** |
| **19.** | **IPR status** |
| **20.** | **Methodology** |
| **21.** | **Plan of work** |
| **22.** | **Performance Indicators/ Milestones (Half yearly)** |
| **23.** | **Plan of Partnership and Institution Building** |
| **24.** | **Expected Outcome/ Deliverables** |

| Part C: Budget Plan | | | | | | | |
|---|---|---|---|---|---|---|---|
| **25.** | **DoP contribution** | | | | | | |
| | **Item** | **1st** | **2nd** | **3rd** | **4th** | **5th** | **Total** |
| | Non - Recurring | | | | | | |
| | Recurring | | | | | | |

| **26.** | **Company contribution** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Item** | **1st** | **2nd** | **3rd** | **4th** | **5th** | **Total** |
| | Non - Recurring | | | | | | |
| | Recurring | | | | | | |

| Part D: Payment of Application Fee *(excluding Category B III)* | | | | |
|---|---|---|---|---|
| **27.** | **Details of the Application Fee** | | | |
| | Amount Due | | | |
| | Amount Paid | | Date of Payment | |

| | | | | |
|---|---|---|---|---|
| | Bank account No. (From which payment is made) | | Bank Name | |
| | IFSC Code | | Unique reference number | |

Note - Details of documents and certificates required to be uploaded by the Applicant along with the Application Form shall be provided on the Scheme Portal.

**Appendix VI**

## FORMAT OF UNDERTAKING

## (Undertaking of the Applicant on letterhead)

1. We, .....,

   hereby, acknowledge that the incentives that would / may be provided to us under the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no. 199 dated 17th August, 2023 in Part-I, Section 1 of the Gazette of India (Extraordinary), will be provided to us based on, and after relying upon, the information provided by us to avail the said incentives.

2. We hereby confirm that the information provided by us for availing the said funding is true, correct and complete in all respects and that no material fact/ information that may have an adverse impact on the information provided by us for availing the said funding has been concealed. We acknowledge and confirm that the foregoing averment is on an on-going basis and further undertake to immediately appraise the Department of Pharmaceuticals about any change in the status of the information provided by us to avail the said funding.

3. We further undertake that in the event of (i) any of the information provided by us to avail the said funding being found false, incorrect or incomplete, or (ii) in the event of the undertakings and

   confirmations stated at para 2 above being found false, incorrect, incomplete or breached; we will (a) refund the entire amount of funding availed by us along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually, for the period between excess payment and date of refund.

4. We acknowledge that the remedies provided in para 3 (a) above are not the exclusive remedies available with the Department of Pharmaceuticals and are without prejudice to any legal remedies available with

Department of Pharmaceuticals for events mentioned in Para 3 (i) and (ii) above.

**Appendix VII**

## DETAILS OF IN-HOUSE R&D

**(Undertaking from the Applicants under Category B II & B III on letterhead)**

| | |
|---|---|
| 1. | Location of the R & D unit |
| 2. | Main objectives of the R&D Program |
| 3. | Whether R&D establishment is housed in a separate building inside/outside the<br><br>factory premises? |
| 4. | List of major R&D equipment procured as on date (Details in separate sheet) |
| 5. | Do you have a full-time R&D Director/Head? if so,<br><br>a. Name & Designation<br><br>b. Qualification<br><br>c. Experience<br><br>d. Date of appointment to the post<br><br>e. Contact Nos (Telephone, Mobile, Fax and Email) |
| 6. | Details of R&D achievements made during the past 3 years (in separate sheet) |
| 7. | Give particulars of R&D projects in progress. |
| 8. | Details of grants-in-aid/ fund/ loan/ equity received from R & D programmes/<br>commercialization of technologies from any central/ State Govt. Department(s) during the last three years |

**Appendix VIII**

## DETAILS OF NO LIEN ACCOUNT

**(To be furnished on bank's printed letter head)**

**Ref No.:**
**Dated:**
**……**

**Subject: No Lien account opened in favour of M/s ---------- for project titled "-------**

**----------" under PRIP scheme.**

**Sir/ Madam,**

At the request of **M/s----------** **,** we have to advise you that we have opened a separate no lien account bearing No..... in our books for the purpose of crediting the financial assistance aggregating to **Rs. ---------- (Rupees ---------- --- only)** sanctioned by you which may be availed of by the company under PRIP scheme for project entitled "----------"

and the project cost component put in by the Company amounts to **Rs. ---------- (Rupees---------- only).**

We confirm that the said total sum of **Rs. ---------- (Rupees ---------- lakhs only)**, as and when received by us either in part or in full, will be credited by us to the said no lien account and that we will not exercise or claim any right of set off or lien on any balance lying to the credit of the said account.

It is confirmed that we had not taken any other undertaking from the account holder contrary to the certificate issued hereto.

We further confirm that we shall furnish to the Department of Pharmaceuticals, as and when required by it, a certified true copy of the

No Lien Account.

**Yours faithfully,**

**Chief Manager**

**(Name & Seal of the Bank)**

**Appendix IX**

## Consent for audit of R&D site/offices/ facility

(To be signed by full time Director / CEO / MD of the company / firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

1. Whereas the applicant namely *(name of the Company with address)* has submitted an application under Promotion of Research and Innovation in Pharma-MedTech sector in India (PRIP) Scheme for Pharmaceuticals, notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.199 dated 17th August, 2023 in Part-I, Section of the Gazette of India (Extraordinary), to Department of Pharmaceuticals (DoP), Government of India seeking incentives for

   the application pertaining to
   R&D..... (priority area) at
   (location(s)).
2. Now, therefore, the applicant or its agencies or its consultants engaged with the R&D project in priority area shall allow the PMA or any other authorized agency as designated by DoP/ PAAC for verification of facility/ offices and information/ documents submitted for the approval of application and disbursement of incentives under PRIP Scheme.

**Date**

**Signature**

**(Name & designation with address)**

**Director / CEO / MD**

**Appendix X**

## Proforma for Integrity compliance

(To be signed by full time Director/ CEO/ MD of the company/ firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

**FORMAT-A**

1. Whereas the applicant namely *(name of company with address)* has submitted an application under PRIP Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no. 199 dated 17th August 2023 in Part-I, Section of the Gazette of India (Extraordinary) to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application

pertaining to R&D …… (priority area) at..... (location(s)).

**2.** Now, therefore, the applicant including its officers / representatives commits and undertakes that he / she will take all measures necessary to prevent corruption. He / She commits to observe the following principles during his / her association / engagement with DoP or its agencies or its consultants engaged with the process of appraisal and verification of application for the approval of application and disbursement of incentives under PRIP.

**2.1** The PRIP applicant will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and verification agency appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or

other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PRIP.

**2.2** The PRIP applicant will not commit any offence under the relevant IPC / PC Act; Further, the applicant will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the DoP.

**2.3** The PRIP applicant shall disclose the name and address of the duly authorized Agents/ Representatives who will be dealing with DoP or its agencies and the remuneration of these agents or representatives shall not include any hidden amount or component to get the work done in undue manner or causing inducement of whatsoever nature whether in cash or kind to influence the normal process or practice of work.

**2.4** The PRIP applicant will disclose any and all payments he / she has made, is committed to or intends to make to agents, brokers or any other intermediaries, other than regular employees or officials of the applicant, in connection with the grant of approval or / and disbursement of incentives.

**2.5** The applicant will not offer any illicit gratification to obtain unfair advantage.

**2.6** The applicant will not collude with other parties to impair transparency and fairness.

**2.7** The applicant will not give any advantage to anyone in exchange for unprofessional behaviour.

**3.** The applicant declares that no pervious transgressions occurred in the last 3 years with any other Company in any country conforming to the anti-corruption approach or with any other Public Sector Enterprises / Central or State Government or its any instrumentality in India.

**4.** The applicant agrees that if it is found that the applicant has made any incorrect statement on this subject, the application will be closed or rejected and DoP reserve the right to initiate legal action of whatsoever nature. In case if DoP has disbursed the incentives under PRIP, the amount disbursed to applicant be recoverable along with interest

calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually besides blacklisting of the applicant and initiation of legal action of whatsoever nature at the discretion of DoP.

The contents of the above undertaking have been gone through and after understanding the same is being executed / given on……day of.....

(month / year)

**Signature (Name & designation with address)**

**Director / CEO / MD**

## FORMAT– B

1. Whereas the applicant namely *(name of company with address)* has submitted an application under PRIP Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no. 199 dated 17th August, 2023 in Part-I, Section of the Gazette of India (Extraordinary) to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application pertaining to R&D …… (priority area) at…… (location(s)).
2. And whereas, the applicant has submitted an undertaking for.

   observance and commitment for Integrity vide Undertaking dated….
   …given under the signatures/ authority of applicants…. (name and designation) to DoP in respect of aforesaid application.
3. And whereas, the applicant including its officers/ representatives gives commitment and undertake that he / she will take all measures necessary to prevent corruption and that he/ she will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and verification agency appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or

other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PRIP.

4. And whereas, the application submitted by the applicant has been given the approval by DoP vide its communication no…… dated……....

5. And whereas, the applicant has submitted a claim for disbursement of incentive dated to the PMA for claiming incentives of

   INR…….

6. And whereas, the PMA has considered the claim for disbursement of

   incentive and is in the process of disbursement / release of incentives on the claim dated…….

7. Now, therefore, we hereby confirm the compliance thereof with the Integrity Undertaking submitted to DoP duly certifying that there is no breach to the same and requests that eligible incentives under PRIP be released to applicant and the number of incentives be credited in the bank account of applicant.

8. The contents of the above Undertaking have been gone through and after duly understanding the same, is being executed / given on…… day of…… (month / year).

**Signature**
**(Name & designation with address)**

**Director / CEO / MD**

**APPENDIX XI**

**APPENDIX XI**

## TRL LEVEL

### TRL for Drugs

| Column1 | Column2 | Column3 |
|---|---|---|
| Stage | Technology Readiness Level | Definition |
| Ideation | TRL-1 | Need identified, Basic principles observed and reported (Scientific research begins to be translated into applied research and development) |
| Proof of Principle | TRL-2 | Research ideas developed, hypothesis formulated and protocols developed (Idea proven on initial level by In-vitro studies i.e., biochemical studies etc) |
| Proof of Concept demonstrated | TRL-3 | Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies (Studies |

| | | |
|---|---|---|
| | | proven by In-vitro<br>model studies i.e., relevant Cell based models, ex-vivo,<br>organoid cell model and In-vivo efficacy in minimum number<br>of animals). |
| Proof of concept established | TRL-4 | Efficacy, & safety of candidate drug formulation is<br>demonstrated in a defined animal model (Results of<br>formulation studies, pharmacokinetic studies & ADME, PD ,<br>safety of candidate formulations preliminary level and<br>efficacy in in-vivo disease model) |
| Early-stage validation | TRL-5 | Pre-clinical studies, including GLP efficacy, acute and<br>chronic toxicity in animal model producing sufficient data for<br>DCGI application for clinical trials. DCGI approval for Phase-1 trial |
| null | TRL-6 | Material produced in GLP facility for clinical trials. Phase-1<br>Clinical trials done, and results submitted to DCGI.<br>Investigative new drug application reviewed by DCGI for<br>approving Phase-II Clinical trials |
| Late-stage Validation | TRL-7 | Phase-II Clinical trials completed, and data reviewed by DCGI<br>and Phase-III Clinical trial plan approved |
| Pre-commercialization | TRL-8 | Phase-III Clinical trials completed successfully. DCGI<br>approves the New Drug Application and provides commercial |

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|---|---|---|
| | | manufacturing license for market introduction |
| Commercialization and post market studies | TRL-9 | Commercial launch of the new drug, Post marketing studies and surveillance |

**TRL for Biosimilars**

| **Stage** | **Technology Readiness Level** | **Definition** |
|---|---|---|
| Ideation | TRL-1 | Review of Scientific Knowledge Base Scientific findings are reviewed, including patent status and assessed as a foundation for conceptualizing new technologies |
| Proof of Principle | TRL-2 | Development of Hypotheses and Experimental Designs Scientific studies to identify the innovator molecule. Development of Biosimilar along with assays to test activities of candidate molecules in vitro. High expression Clone available |
| Proof of Concept demonstrated | TRL-3 | Identification and Characterization of Preliminary Product Expression of biosimilar product, studies for efficacy and toxicities in vitro. Comparative evaluation of product for Bio similarity with innovator molecule a. Physiochemical b. Biological - in-vitro and in-vivo |

| | | |
|---|---|---|
| | | Cell line characterization of Master Cell bank and<br>Working Cell Bank & process development<br>Bio similarity demonstrated, in vitro efficacy and<br>preliminary efficacy demonstrated in vivo in appropriate<br>small animal model |
| Proof of concept established | TRL-4 | Process development, optimization, demonstration of<br>bio similarity and generation of consistency data<br>Optimization of process development for performing<br>preclinical studies. Generation of three consistent batches.<br>Formulation development,<br>Appropriate formulation finalized for the route of<br>administration. Draft Product Profile.<br>Process optimized<br>and regulatory approvals for preclinical candidate<br>compound from the relevant body (RCGM/GEAC). |
| Early-stage validation | TRL-5 | Advanced Characterization of Product and Initiation<br>of Manufacturing |
| | | Conduct pre-clinical studies (in vivo toxicity and efficacy<br>in relevant in vivo models; PK/PD studies, ADME<br>characteristics and/or immune responses) as necessary for<br>regulatory filing. Identify manufacturing partners.<br>Submission of pre-clinical data to RCGM |

| | | |
|---|---|---|
| null | TRL-6 | Regulated Production, Regulatory Submission<br>Manufacture GMP-compliant pilot lots. Begin stability testing on biosimilar. Develop assays/analytical methods for product characterization and release (potency, purity, sterility and identity). |
| Late-stage Validation | TRL-7 | Scale-up, Completion of GMP Process Validation and Consistency Lot Manufacturing and Regulatory<br>Approvals<br>Develop a scalable and reproducible manufacturing<br>process amenable to GMP. Determine dosing and<br>treatment population for Phase 3 study. Complete stability studies of the GMP drug product in a formulation, dosage form, and container consistent with Target Product<br>Profile. Finalize GMP manufacturing process. Identify clinical sites and begin contract negotiations. DCGI<br>Approval for the Phase 3 Clinical study |
| Pre-commercialization | TRL-8 | Clinical Trials Phase 3 and Approval or Licensure<br>Complete clinical efficacy trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit Biologics Licensing Application BLA. |

| | | |
|---|---|---|
| Commercialization and post market studies | TRL-9 | Full commercial application. The technology has been fully developed and can be distributed/marketed. Post-marketing surveillance. |

## TRL for Medical Devices

| **Stage** | **Technology Readiness Level** | **Definition (Medical Devices including diagnostic devices)** | **Definition (In vitro Diagnostic Kits& reagents)** | **Definition (Biomedical implants)** |
|---|---|---|---|---|
| Ideation | TRL-1 | Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development) | Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development) | Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development) |
| Proof of Principle | TRL-2 | Market surveillance data and competitor analysis available to support the idea. Basic device design | Hypothesis formulated and protocols developed. Market surveillance data | Market surveillance data and competitor analysis available |

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|---|---|---|---|---|
| | | ready and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured. Development of individual components initiated. | and competitor analysis available to support idea. Individual core components of kit/reagents (Antibodies/ Antigens/Aptamers/Nano particles) finalized, developed/procured for testing | to support the idea. Basic implant design ready, candidate materials shortlisted and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured |
| Proof of Concept demonstrated | TRL-3 | Individual modules/Components/PCBs/Software s/Systems developed and tested separately for its functionality on a breadboard/laboratory level. Material safety, electrical safety & biocompatibility of the systems demonstrated | Individual core components optimized at lab scale. Demonstrated the limit of detection/Sensitivity with metabolite serial dilution or ELISA or spiked biological sample studies. | Material research completed and material properties of the finalized material/composites compared against benchmarks. Relevant ASTM standard tests (strength, ductility, corrosion, surface properties, antimicrobial |

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| | | | | activity, usability, shelf life etc.) on the material performed successfully. Material sterilization method finalized. Biocompatibility (ISO 10993) proven in in vitro cytotoxicity assays. |
| Proof of concept established | TRL-4 | Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment or animal model (with Institutional Animal Ethics Committee approvals) | Optimized core components integrated into the kit or platform (Microfluidics/ filter paper/ LFA etc.) along with the reagents to come up with a functional prototype of the kit. Integrated system tested in house with metabolite | Material safety and or imaging compatibility proven in in vivo small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization |

| | | | | |
|---|---|---|---|---|
| | | | | and packaging established. |
| | | | serial dilution or ELISA or spiked biological sample studies. | |
| Early stage validation | TRL-5 | Relevant IEC & ISO tests (Electromagnetic interference, Electromagnetic compatibility, Electrical safety, Biocompatibility, software test, radiation safety test drop test, packaging test, transportation test, physico –chemical and mechanical testing etc.) of the device performed, and safety proven. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO | Integrated system tested in-house extensively with clinical samples (Blood, Urine, Sputum etc.) before taking it for clinical validation. Analytical validation of the kit completed. Shelf life, stability data of the kit reagents available. Quality management certification (ISO13485) in place Clinical study plan approved by Institutional Ethical | In vivo pre-clinical studies performed (with Institutional Animal Ethics Committee approvals) using functional prototype implant device on the relevant small or big animal (disease) models to establish its safety (tissue reactivity/ allergy/degradability, Histopathology) and efficacy (. Quality management certification (ISO13485) in place. Design |

| | | | | |
|---|---|---|---|---|
| | | | Committee and/or CDSCO | iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO |
| | TRL-6 | Fully functional clinical grade device ready with regulatory dossier for use on human subjects/patients. Quality assurance certification (like CE) applied. Pilot clinical study/trials on limited number of subjects/patients to prove safety and substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval | Clinical study performed on statistically significant number of samples at one or two centres to define the specificity and sensitivity of the Assay/kit. Quality assurance certification for the product applied/obtained | Clinical level implant device fabricated using clinical grade material in GMP facility with safety dossier for use on human subjects/patients.. Quality assurance certification (like CE) applied. Pilot clinical trials performed on statistically significant number of patients against |

| | | | | |
|---|---|---|---|---|
| | | | | the predicate implant device to prove safety, substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval. |
| Late stage Validation | TRL-7 | Manufacturing lines established.<br>Design for manufacture (DFM)<br>finalised and devices manufactured.<br>Documentation on design history file<br>(DHF) ready.<br>Pivotal clinical study/trials completed<br>and clinical performance data<br>submitted to CDSCO for manufacturing license | Multi-Centric Trials completed at NABL accredited centres and performance evaluation report submitted to CDSCOfor Commercial license.<br>Performance evaluation report of notified products (IVD for HIV, HCV, HBV and Blood grouping sera) obtained from NIB, Noida. | Manufacturing lines established.<br>Design for manufacture (DFM) finalised and devices manufactured.<br>Documentation on design history file (DHF) ready.<br>Pivotal clinical study/trials completed and clinical performance data submitted to CDSCO for manufacturing license |
| Pre-commerc | TRL-8 | Manufacturing license obtained from | Manufacturing license | Manufacturing license |

| | | | | |
|---|---|---|---|---|
| iali zation | | CDSCO and commercial batch manufacturing initiated | obtained and commercial scale manufacturing set up/Packing/labelli ng etc. Commercial batch manufacturing initiated | obtained from CDSCO and commercial batch manufacturing initiated |
| Commer cial ization and post market studies | TRL-9 | Commercial launch of the new device, Post marketing studies and surveillance | Commercial launch of in vitro diagnostic kit or reagents and Post marketing studies and surveillance | Commercial launch of the implant, Post marketing studies and surveillance |

### *4. TRL for Regenerative Medicine*

| **Stage** | **Technology Readiness Level** | **Definition** |
|---|---|---|
| Ideation | TRL-1 | Scientific findings are reviewed and assessed as a foundation for conceptualizing new technologies. |
| Proof of Principle | TRL-2 | Development of Hypotheses and Experimental Protocol Designs - Hypothesis (es) generated, research plans and/or protocols are developed. |

| | | |
|---|---|---|
| Proofof Concept demonstrated | TRL-3 | Target/Candidate Identification and their Characterization<br><br>Mandatory registration of Institutional Committee for Stem Cell Research (ICSCR) and Institutional Ethics Committee (IEC), with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and CDSCO respectively<br><br>Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components.<br><br>-Sample collection after informed consent from the voluntary donor and begin characterization of candidate(s).<br>-Preliminary efficacy demonstrated in vitro and in vivo.<br><br>• Identify target and/or candidate.<br>• Demonstrate in vitro activity of candidate(s)<br>• Generate preliminary in vivo as proof-of-concept efficacy data (non-GLP). |

| | | |
|---|---|---|
| Proofof concept established | TRL-4 | Candidate Optimization and Non-GLP In Vivo Demonstration of Activity and Efficacy<br><br>Animal Models: Initiate development of appropriate and relevant animal model(s) for the desired indications and perform non-GLP in vivo toxicity and efficacy.<br><br>Assays: Initiate development of appropriate and relevant assays and associated reagents for the desired indications.<br><br>Manufacturing: Manufacture laboratory-scale (i.e., non-GMP) quantities of bulk product and proposed formulated product.<br><br>• Demonstrate non-GLP in vivo activity and potential for efficacy consistent with the product's intended use (i.e., dose, schedule, duration, route of administration, and route). |

**APPENDIX X**

**INSTITUTE OF NATIONAL REPUTE AFFILIATED TO PHARMACEUTICALS AND MEDICAL DEVICES**

Note: this list is indicative only and non-exhaustive*

| | |
|---|---|
| **Department of Pharmaceuticals Institute** | |
| 1 | National Institute of Pharmaceutical Education and Research, Mohali (http://www.niper.gov.in) |
| 2 | National Institute of Pharmaceutical Education and Research, Hajipur (https://www.niperhajipur.ac.in) |
| 3 | National Institute of Pharmaceutical Education and Research, Kolkata (http://www.niperkolkata.edu.in) |
| 4 | National Institute of Pharmaceutical Education and Research, Hyderabad (http://www.niperhyd.ac.in) |
| 5 | National Institute of Pharmaceutical Education and Research, Guwahati (https://niperguwahati.ac.in) |
| 6 | National Institute of Pharmaceutical Education and Research, Ahmedabad (https://www.niperahm.ac.in) |
| 7 | National Institute of Pharmaceutical Education and Research, Raebareli (http://niperraebareli.edu.in) |
| | |
| **CSIR INSTITUTES** | |
| 1 | Centre for Cellular and Molecular Biology (www.ccmb.res.in) |
| 2 | Central Drug Research Institute (www.cdriindia.org) |
| 3 | Institute of Genomics and Integrative Biology (www.igib.res.in) |
| 4 | CSIR-Institute of Himalayan Bioresource Technology (https://www.ihbt.res.in/en/) |
| 5 | CSIR-Indian Institute of Chemical Biology (http://www.iicb.res.in) |
| 6. | Indian Institute of Chemical Technology (www.iictindia.org) |
| 7. | Indian Institute of Integrative Medicine (www.iiim.res.in) |

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| 8. | Indian Institute of Toxicology Research (www.iitrindia.org) |
| 9. | CSIR-Institute of Microbial Technology (https://www.imtech.res.in/) |
| 10. | National Chemical Laboratory (www.ncl.india.org) |
| **DBT INSTITUTES** | |
| 1. | National Institute of Immunology (http://www.nii.res.in/) |
| 2. | National Centre for Cell Science (https://www.nccs.res.in/) |
| 3. | National Brain Research Centre (http://www.nbrc.ac.in/newweb/) |
| 4. | Institute of Life Sciences (https://www.ils.res.in/) |
| 5. | Rajiv Gandhi Centre for Biotechnology (https://www.rgcb.res.in/) |
| 6. | Institute for Stem Cell Science and Regenerative Medicine (https://www.instem.res.in/) |
| 7. | Translational Health Science and Technology Institute (https://thsti.res.in/newthsti/) |
| 8. | National Institute of Biomedical Genomics (https://www.nibmg.ac.in/) |
| 9. | Regional Center for Biotechnology (https://www.rcb.res.in) |
| 10. | Center for DNA Fingerprinting and Diagnostics [CDFD] |
| 11. | National Institute of Plant Genome Research |
| 12. | National Institute of Animal Biotechnology (NIAB) |

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|---|---|
| 13 | International Center for Genetic Engineering and Biotechnology (ICGEB) |
| 14 | National Centre for Cell Science (NCCS), Pune |
| 15 | National Institute of Biomedical Genomics (NIBMG), Kalyani |
| **Department of Higher Education** | |
| 1. | Indian Institute of Technology (IIT), Hyderabad (https://www.iith.ac.in) |
| 2 | Indian Institute of Technology (IIT), Mumbai (https://www.iitb.ac.in) |
| 3. | Indian Institute of Technology (IIT), Patna (https://www.iitp.ac.in) |
| 4. | Indian Institute of Technology (IIT), Delhi (https://www.iitd.ac.in) |
| 5. | Indian Institute of Technology (IIT), Ropar (https://www.iitrpr.ac.in) |
| 6. | Indian Institute of Technology (IIT), Mandi (https://www.iitmandi.ac.in) |
| 7. | Indian Institute of Technology (IIT), Roorkee (https://www.iitr.ac.in) |
| 8. | Indian Institute of Technology (Banaras Hindu University), Varanasi (https:// www.iitbhu.ac.in) |
| 9. | Indian Institute of Technology (lIT), Jammu (https://www.iitjammu.ac.in) |
| 10. | Indian Institute of Technology (IIT), Palakkad (https://www.iitpkd.ac.in) |
| 11. | Indian Institute of Technology (IIT), Tirupati (https://www.iitp.ac.in) |
| 12 | Indian Institute of Technology (IIT), Goa (https://www.iitgoa.ac.in) |
| 13. | Indian Institute of Technology (IIT), Bhilai (https://www.iitbhilai.ac.in) |
| 14. | Indian Institute of Technology (IIT) Dharwad (https://www.iitdh.ac.in) |

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| 15. | Indian Institute of Technology Gandhinagar (https://iitgn.ac.in) |
| 16 | Indian Institute of Technology Kharagpur, West Bengal (https://www.iitkgp.ac.in/) |
| 17 | Indian Institute of Technology Madras, Chennai , Tamil Nadu (https://www.iitm.ac.in/) |
| 18 | Indian Institute of Technology Guwahati, Assam (https://www.iitg.ac.in/) |
| 19 | Indian Institute of Technology Jodhpur, Rajasthan (https://www.iitj.ac.in/) |
| 20 | Indian Institute of Technology Kanpur, Uttar Pradesh (https://www.iitk.ac.in/) |
| 21 | Indian Institute of Technology Indore, Madhya Pradesh (https://www.iiti.ac.in/) |
| 22 | Indian Institute of Science Education and Research (IISER), Pune (https://www.iiserpune.ac.in) |
| 23 | Indian Institute of Science Education and Research (IISER), Kolkata (https://www.iiserkol.ac.in) |
| 24 | Indian Institute of Science Education and Research (IISER), Mohali (https://vvww.iisermohali.ac.in) |
| 25 | Indian Institute of Science Education and Research (IISER), Bhopal (https://www.iiserb.ac.in) |
| 26 | Indian Institute of Science Education and Research (IISER), Thiruvanathapuram (https://www.iisertvm.ac.in) |
| 27 | Indian Institute of Science Education and Research (IISER), Tirupati (https:// www.iisertirupati.ac.in) |
| 28 | Indian Institute of Science Education and Research (1ISER), Berhampur (https://www.iiserbpr.ac.in) |
| 29 | All India Institute of Medical Sciences, Rishikesh |
| 30 | All India Institute of Medical Sciences, Bhopal, Madhya Pradesh |

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|---|---|
| 31 | All India Institute of Medical Sciences, Bathinda, Punjab |
| 32 | All India Institute of Medical Sciences, Bhubaneswar, Odisha |
| 33 | All India Institute of Medical Sciences, Bibinagar, Telangana |
| 34 | All India Institute of Medical Sciences, Deoghar, Jharkhand |
| 35 | All India Institute of Medical Sciences, Gorakhpur, Uttar Pradesh |
| 36 | All India Institute of Medical Sciences, Jodhpur, Rajasthan |
| 37 | All India Institute of Medical Sciences, Mangalagiri, Andhra Pradesh |
| 38 | All India Institute of Medical Sciences, Nagpur, Maharashtra |
| 39 | All India Institute of Medical Sciences, Kalyani, West Bengal |
| 40 | All India Institute of Medical Sciences, New Delhi, Delhi |
| 41 | All India Institute of Medical Sciences, Patna, Bihar |
| 42 | All India Institute of Medical Sciences, Raebareli, Uttar Pradesh |
| 43 | All India Institute of Medical Sciences, Raipur, Chhattisgarh |
| 44 | Postgraduate Institute of Medical Education and Research, Chandigarh |
| 45 | Dr. B. R. Ambedkar National Institute of Technology, Jalandhar, Punjab |
| 46 | Maulana Azad National Institute of Technology, Bhopal Madhya Pradesh |
| 47 | National Institute of Technology, Calicut Kozhikode Kerala |
| 48 | Motilal Nehru National Institute of Technology, Allahabad |
| 49 | National Institute of Technology, Durgapur, West Bengal |
| 50 | National Institute of Technology, Hamirpur, Himachal Pradesh |
| 51 | Malaviya National Institute of Technology, Jaipur, Rajasthan |
| 52 | National Institute of Technology, Yupia, Arunachal Pradesh |
| 53 | National Institute of Technology, Andhra Pradesh |

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| 54 | National Institute of Technology, Sikkim Ravangla |
| 55 | National Institute of Technology, Nagaland, Dimapur |
| 56 | National Institute of Technology, Mizoram |
| 57 | National Institute of Technology, Manipur, Imphal |
| 58 | National Institute of Technology, Delhi |
| 59 | National Institute of Technology, Meghalaya, Shillong |
| 60 | National Institute of Technology, Goa |
| 61 | National Institute of Technology, Puducherry, Puducherry |
| 62 | National Institute of Technology, Warangal Warangal Telangana |
| 63 | National Institute of Technology, Agartala, Tripura |
| 64 | National Institute of Technology, Raipur, Chhattisgarh |
| 65 | Sardar Vallabhbhai National Institute of Technology, Surat, Gujarat |
| 66 | National Institute of Technology, Karnataka Surathkal Karnataka |
| 67 | National Institute of Technology, Tiruchirappalli Tamil Nadu |
| 68 | National Institute of Technology, Rourkela, Odisha |
| 69 | National Institute of Technology, Silchar, Assam |
| 70 | National Institute of Technology, Srinagar, Jammu and Kashmir |
| 71 | National Institute of Technology, Uttarakhand |
| 72 | National Institute of Technology, Jamshedpur, Jharkhand |
| 73 | National Institute of Technology, Kurukshetra, Haryana |
| 74 | Visvesvaraya National Institute of Technology, Nagpur, Maharashtra |
| 75 | National Institute of Technology, Patna Patna Bihar |
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| **DHR/ICMR Research Instituions** | |
| 1. | National JALMA Institute for Leprosy & Other Mycobacterial Diseases (https://www.jalma-icmr.org.in/) |
| 2. | National Institute of Cancer Prevention and Research (https://nicpr.icmr.org.in/) |
| 3. | National Institute of Occupational Health (http://nioh.org/) |
| 4. | National Centre for Disease Informatics and Research (https://ncdirindia.org/) |
| 5. | Bhopal Memorial Hospital & Research Centre (http://bmhrc.ac.in/) |
| 6. | National Institute for Research in Environmental Health (https://nireh.icmr.org.in/) |
| 7. | National Institute for Research in Tuberculosis (http://www.nirt.res.in/) |
| 8. | National Institute of Malaria Research (https://nimr.org.in/) |
| 9. | National Institute of Pathology (http://instpath.gov.in/) |
| 10. | National Institute of Medical Statistics (http://icmr-nims.nic.in/) |
| 11. | National Institute of Nutrition (https://www.nin.res.in/index.html) |
| 12. | National Institute of Cholera and Enteric Diseases (http://www.niced.org.in/) |
| 13. | National Institute for Research in Reproductive Health (http://nirrh.res.in/) |
| 14. | National Institute of Immunohematology (https://www.niih.org.in/) |
| 15. | National Institute of Virology (https://www.niv.co.in/) |
| 16. | National AIDS Research Institute (https://nari-icmr.res.in/) |
| 17. | Rajendra Memorial Research Institute of Medical Sciences (http://www.rmrims.org.in/) |
| **DRDO INSTITUTES** | |

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| 1. | Defence Bioengineering & Electro-medical Laboratory (https://www.drdo.gov.in/labs-and-establishments/defence-bio-engineering-electro-medical-laboratory-debel) |
| 2. | Defence Institute of Bio-Energy Research (https://www.drdo.gov.in/labs-and- establishments/defence-institute-bio-energy-research-diber) |
| 3. | Defence Institute of High-Altitude Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-high-altitude-research-dihar) |
| 4. | Defence Institute of Physiology & Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/defence-institute-physiology-allied-sciences-dipas) |
| 5. | Defence Institute of Psychological Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-psychological-research-dipr) |
| 6. | Institute of Nuclear Medicine and Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/institute-nuclear- medicine-allied-sciences-inmas) |
| | **AYUSH INSTITUTES** |
| 1. | Central Council for Research in Ayurvedic Sciences (http://www.ccras.nic.in/) |
| 2. | Central Council for Research in Homoeopathy (https://www.ccrhindia.nic.in/) |
| 3. | Central Council for Research in Unani Medicine (https://ccrum.res.in/) |
| 4. | Central Council for Research in Siddha (http://siddhacouncil.com/home/) |
| 5. | Central Council for Research in Yoga and Naturopath (http://www.ccryn.gov.in/) |
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