Invitation for Expression of Interest (EoI)
For

Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy

By ICMR-Hqrs
Indian Council of Medical Research
(Department of Health Research, GoI)
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Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations, companies, manufacturers for the **Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy.**

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in).

Schedule for the Proponents is as under:

EoI Document Number	
Date of Publication	
Last date of submission	

Note:

All applications must be submitted through the ICMR e-PMS portal (https://epms.icmr.org.in/userLogin).

Steps for submission:

1. Log in to the ePMS portal https://epms.icmr.org.in/userLogin
2. Complete the PI profile and institutional details.
3. Navigate to: Proposal submission → EoI → Click on Apply against the call name
4. Fill in the EoI form step-by-step and upload all relevant documents and submit.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the Competent Authority ICMR and duly notified on its website.

2. Background

Neonatal hyperbilirubinemia is among the most common conditions affecting newborns, with approximately 60% of term infants and 80% of preterm infants developing clinical jaundice within the first week of life. In its severe form (severe neonatal hyperbilirubinemia, SNH), unconjugated bilirubin can cross the blood-brain barrier and deposit in neural tissue, resulting in bilirubin encephalopathy — a spectrum of acute and chronic neurological injury including kernicterus. In India, severe jaundice accounts for 15–25% of neonatal admissions and carries a case fatality rate of 5–10%, underscoring its substantial contribution to neonatal morbidity and mortality, particularly in resource-limited settings.

Current management of SNH relies primarily on phototherapy and, in severe or refractory cases, exchange transfusion. Both interventions are resource-intensive, require dedicated hospital infrastructure and trained personnel, and remain inaccessible at many primary and secondary care facilities, especially in low- and middle-income countries where the burden of neonatal jaundice is highest. Consequently, a substantial proportion of at-risk neonates — particularly those born outside tertiary care settings — are unable to receive timely intervention, increasing their risk of progression to bilirubin encephalopathy. There remains, therefore, a pressing need for a simple, rapidly acting, and widely deployable therapeutic option that can be administered even where phototherapy devices are unavailable.

A citrate-functionalized manganese oxide nanoparticle (C-Mn3O4 NP), developed as an orally administered nanodrug, has emerged as a promising candidate to address this gap. The nanodrug acts by directly interacting with bilirubin and converting it into methyl vinyl maleimide (MVM), a known phototherapy byproduct that is safely eliminated via the enteral route. In preclinical rodent and porcine models of neonatal hyperbilirubinemia, a single oral dose produced significant reductions in total serum bilirubin and unconjugated bilirubin within 4–8 hours of administration; in rodents, neural bilirubin load was reduced by approximately 85%, with corresponding improvements in neurobehavioral, neuromotor, and cognitive outcomes. Repeated administration over 90 days in rodents, along with porcine safety studies, showed no evidence of drug-related toxicity at the intended therapeutic dose. Building on this preclinical evidence, a pilot Phase I/II study was completed in 207 neonates that demonstrated adjunctive use of the nanodrug was associated with a marked reduction in neonatal mortality (~94%), a decreased need for exchange transfusion (~92%) among neonates with severe hyperbilirubinemia, and a ~50% reduction in phototherapy duration, with no observed adverse effects [Mallick, A. K., Dutta, T., Hauli, R., Mallick, A., Adhikari, A., and Bhutani, V. K. (2026) Citrate-Functionalized Manganese Oxide Nanoparticles in Neonates ≥35 Weeks Gestation at Risk of Acute Bilirubin Encephalopathy: A Phase 1 Observational Trial. *Pediatric Research*, 2026 Jun 2. doi: 10.1038/s41390-026-05144-8]. These findings support the technology's potential as a safe, single-dose, orally administered adjunct or alternative to existing standard-of-care interventions, deployable even at primary health centres lacking phototherapy infrastructure.

The Indian Council of Medical Research (ICMR), an autonomous organization under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, is the apex body in the country for the formulation, coordination, and promotion of biomedical research. ICMR has consistently sought to address the growing demands of scientific advances in biomedical research while developing practical solutions to the country's pressing healthcare challenges. Through its constituent institute, the ICMR-National Institute for Pre-Clinical Research (ICMR-NIPCR), ICMR has collaborated with a U.S.-based researcher (the "Collaborator") to develop this nanodrug technology for pursuing clinical trials (CTRI/2023/02/049596; CTRI/2024/07/071406), corresponding to a Technology Readiness Level of TRL-5.

To support the technology's progression toward regulatory clinical evaluation, ICMR — through its Division of Development Research — is committed to accelerating the translation of this indigenous nanodrug into a manufacturable, GMP-compliant clinical product. Having successfully completed preclinical validation, the technology now requires manufacture of GMP-compliant test batches to support the clinical trials evaluation in India.

Accordingly, ICMR invites Expressions of Interest (EoI) from eligible pharmaceutical manufacturers, Contract Development and Manufacturing Organizations (CDMOs), and other qualified industry partners possessing valid CDSCO manufacturing licenses, GMP-compliant facilities, and demonstrated experience in sterile/oral formulation manufacturing — with experience in nanomedicines, nanoparticle formulations, or similar advanced drug delivery systems considered desirable — for undertaking test batch manufacturing of the C-Mn3O4 NP nanodrug. The selected manufacturing partner will be responsible for producing GMP-compliant clinical trial batches in accordance with agreed specifications.

3. Objective

The formulation is intended for oral administration as a single therapeutic dose. The presentation/container requirements are as follows:

- **Oral suspension** of C-Mn_3O_4 NP, formulated and manufactured in accordance with applicable microbial-limit and bioburden specifications for oral pharmaceutical preparations
- **Unit-dose or multi-dose container formats** (e.g., 1 mL or other suitable presentations), to be finalized based on the dosing regimen — smaller formats are preferred to minimize contamination risk, reduce bottle-tip contact, and support subject traceability and dose accountability during clinical trial dispensing
- **Matching formulation excipients** as required for the oral suspension (illustrative excipients under consideration include glycerol as a viscosity modifier/humectant, potassium sorbate as a preservative, and sucralose as a sweetener), finalized by the selected manufacturer as part of formulation development

4. Scope of Work

i. ICMR is willing to engage with eligible organizations, companies, and manufacturers for the **'Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy'.**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the multiple strengths of '**C-Mn_3O_4 NP Nanodrug Formulations for Neonatal Hyperbilirubinemia'** or undertake further R&D and commercialize the end product(s).

iii. The Company has to assure that the product will be taken up till market approval if the results are positive.

iv. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a "Exclusive/Non-Exclusive" basis with single/multiple companies to enable wider outreach of the requisite strengths of **C-Mn_3O_4 NP Nanodrug Formulations for Neonatal Hyperbilirubinemia** (Product) for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

Role of ICMR:

i. **ICMR** will provide expert guidance & technical support in **R&D for development of C-Mn_3O_4 NP Nanodrug Formulations for Neonatal Hyperbilirubinemia**, in all phases. Such technical oversight by **Scientist of ICMR** would accelerate the development of the Product and its commercialization.

ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.

iii. ICMR would provide support and facilitation to conduct the R&D/clinical study of new product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.

iv. ICMR shall have no financial implications unless otherwise specified.

Role of Company

i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for technology/product development/ validation/ scale-up either directly or otherwise.

ii. The Company shall have provisions to undertake the scale-up as required for the **Development of C-Mn_3O_4 NP Nanodrug Formulations for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy,** in a set milestone.

iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

iv. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for technology/product development to its commercialization.

vi. The company is expected to be the sponsor and fulfill all regulatory functions.

5. Intellectual Property Rights

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

ICMR legally possess the rights and authority to retain full or part of the 'Product' by itself or to assign at its discretion full or part of the Product including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the product through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

6. Process involved in Partnership/Collaboration/Product Transfer

Interested companies/manufacturers are invited to collaborate with ICMR for development & commercialization of the Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/product transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @ 1% or 2% on Net sales, as applicable, according to the ICMR Guidelines for Technology/Product Development Collaboration.

7. Publication

i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).

ii. Support of ICMR must be duly acknowledged in all publications by the Company and vice versa.

iii. ICMR Scientists can be given due advantage of authorships in the publications arising out of Licensing/co-development.

8. Data Rights

i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding for the clinical trial.

ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.

iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 and other applicable data protection laws and regulations while dealing with such data

9. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)

ii. Authorization Letter (Format – 2)

iii. Undertaking with regard to Blacklisting (Format-3)

iv. Undertaking with regard to Non-Conviction (Format – 4)

v. EoI document with each page duly stamped and signed by the Authorized signatory.

vi. Undertaking with regard to Functional Manufacturing Facility and Quality Control Laboratory (Format – 5)

vii. Undertaking regarding Manufacturing Capacity (Format-6)

viii. Supporting documents, as mentioned in Format-1

ix. MSME Certificate (if applicable)

x. Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product (As per format – 7)

xi. Supported evidence in form of research paper/articles published in peer reviewed journals, or detailed report containing Data pertaining to drug/product formulation developed

xii. Concept Proposal (Format-8)

xiii. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

10. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EoI.

ii. Not in the prescribed format.

iii. Not properly stamped and signed.

iv. Received after the expiry of due date and time.

v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).

vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

vii. Applications not fulfilling the terms of the document will be summarily rejected.

viii. Any other non-compliance.

11. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted.

12. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria**	**Supporting copy of documents required** (All documents must be self- attested by the authorized person of the proponent)
General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India.	Registration of firm/ organization/ Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable

2	The proponent must be registered in India with taxation and other Administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
4	The proponent should have not been Blacklisted by any of the government funding agency/department.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –3)
5	The proponent and its promoters should have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –4)
Specific Criteria (Based on the nature of the Proposal)		
6	The proponent should have Functional Manufacturing Facility and Quality Control Laboratory to carryout R&D for the technology/product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
7	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
8	Proponents should have developed or have established proof of concept for development of product formulation and have done preclinical studies for safety.	Supported evidence in form of research paper/articles published in peer reviewed journals, or should submit detailed report containing Data of preclinical studies
10	The applicant should have adequate GMP-compliant manufacturing capacity to develop, manufacture, package, test, and supply the investigational **C-Mn_3O_4 NP Nanodrug Formulations** in quantities sufficient to support the proposed multicenter clinical trials, including all enrolled participants throughout the study duration, with provision for replacement supplies and contingency requirements.	Undertaking (As per format – 6)
11	• Experience in manufacturing oral solid and/or liquid dosage forms under GMP. • Experience in manufacturing investigational medicinal products (IMPs) for clinical trials. • Capability for blinding/placebo manufacture • Capability for multiple tablet/syrup strengths or weight-based dosing. • Stability studies as per ICH guidelines. • Batch traceability and documentation.	Supported evidence in form of research paper/articles published in peer reviewed journals, or should submit detailed report containing Data of preclinical studies and Undertaking on Proponent's Letter Head, duly signed and stamped by

	• Capacity for nationwide distribution to participating clinical trial sites. • Ability to supply study drug continuously for the entire study period.	the Authorized Signatory Undertaking (As per format – 7)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

13. Disclaimer

i. Technology/Product rights will be owned by ICMR
ii. In case the agency/ company/ entity could not be able to continue the contract or wishes to break the contract, the technology/product rights will be given to any agency/ company/ entity that ICMR would specify.
iii. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
iv. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
v. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
vi. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.
vii. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

14. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.

15. Contacts

In case of any clarification required, please contact:

Dr. Aparna Mukherjee Scientist F and Head, Clinical Studies and Trial Unit Division of Development Research Indian Council of Medical Research Email ID: aparna.sinha.deb@icmr.gov.in	**Dr Priyanka Narad** Scientist-C and Program Officer Division of Development Research, Indian Council of Medical Research Email ID: pnarad.hq@icmr.gov.in

Format-1
Expression of Interest
(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for **Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy**

Ref: No. _____ dated _____

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining the product product, and do hereby express the interest to undertake the development and manufacture/ sale /commercialization of the product as mentioned in the EoI document.

The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	**Documents Required**	**Type of Document Attached**	**Page No.**
1	Authorization Letter	As per **Format–2**	
2	Company Incorporation Certificate/Certificate of Incorporation from ROC/Partnership Deed/LLP Registration, as applicable	Self-attested copy	
3	GST Registration Certificate or GST Exemption Certificate and PAN Card	Self-attested copy	
4	Valid DCGI/CDSCO Manufacturing License for existing products, wherever applicable	Self-attested copy	

5	Proof of Registered Office and Manufacturing Unit in India	Self-attested documentary evidence	
6	DSIR Recognition Certificate (if applicable)	Self-attested copy	
7	Undertaking regarding Blacklisting	As per **Format–3**	
8	Undertaking regarding Non-conviction	As per **Format–4**	
9	Undertaking regarding Functional Manufacturing Facility and Quality Control Laboratory	As per **Format–5**	
10	Valid GMP and/or GLP and/or ISO Certification	Copies of valid certificates	
11	Undertaking regarding Manufacturing Capacity	As per **Format–6**	
12	Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product	As per **Format–7**	
13	Supporting evidence demonstrating formulation development/manufacturing capability, proof-of-concept, or relevant research publications/technical reports	Research papers, technical reports, product dossiers, or equivalent evidence	
14	Proposal for Development and Manufacturing of the Investigational multiple strengths of C-Mn_3O_4 NP Nanodrug Formulations and matching placebo	As per **Format–8**	
15	MSME or recognized start-up	Certificate (if have any)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-2

Authorization Letter

(To be submitted on Company's Letter Head)

To,
The Director General
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory

Ref: No. _____dated _____
Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for the **Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy**.

Mr./Ms./Mrs./Dr…….is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s……. (Company Name)…….., who's signature
is below.

(Specimen Signature of Representative)
Date:
Place:

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-3

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref:

Sir,

It is hereby confirmed and declared that M/s _____(Company Name) currently has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard to Non-Conviction

(To be submitted on Company's Letter Head)

To,

The Director General,

Indian Council of Medical Research,

Ansari Nagar, New Delhi.

Subject: Undertaking regarding Non-Conviction.

Ref: No.

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-5

Undertaking with regard to laboratory facility

(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.

Ref:

Sir,

It is hereby confirmed and declared that M/s……...(Company Name)……. do have-

i. Adequate laboratory infrastructure (equipped laboratory facility) for **Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy**. Please tick GMP/GLP/Quality Control Laboratory/Formulation Development Laboratory/Other* (if other, please specify).

ii. Adequate no. of experienced staff/skilled manpower to undertake to undertake formulation development, analytical testing, manufacturing, quality assurance, quality control, packaging, and commercialization of the investigational **C-Mn_3O_4 NP Nanodrug Formulations**.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

**The Laboratory/ facility requirement will depend on the product*

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.

Ref:

Sir,

It is hereby confirmed and declared that **M/s. _____ (Company Name)_____** has the capacity in all respects (including infrastructure, funds, materials, equipment, and skilled manpower) for the **Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy**.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-7

Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product

(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding uninterrupted supply and maintenance of reserve stock of the investigational product.

Ref: EoI No. _____ dated _____

Sir,

It is hereby agreed and declared that M/s. _____ (Company Name)_____ shall ensure uninterrupted manufacture, supply, and maintenance of adequate reserve stock of the multiple strengths **of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy**.

It is also agreed that M/s. _____ (Company Name)_____ shall manufacture and supply additional quantities of the investigational product, if required by ICMR during the conduct of the clinical trial, within the agreed timelines and in accordance with the applicable quality and regulatory requirements.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-8

Proposal for Development and Manufacture of Multiple Strengths of C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo for Clinical Trial Batches for Neonatal Hyperbilirubinemia and Associated Neurotoxicity or Bilirubin Encephalopathy

A. About the Product / Formulation

- Brief description of the proposed multiple strengths of investigational **C-Mn_3O_4 NP Nanodrug Formulations and Matching Placebo**
- Proposed dosage form(s) (tablet/capsule or other oral dosage form), strength(s), and formulation approach.
- Manufacturing process and any novel formulation features, if applicable.
- Proposed packaging and labelling suitable for use in a multicentre clinical trial.

B. Work Done So Far

- Experience in formulation development of oral solid dosage forms.
- Experience in manufacturing Nanodrug Formulations or similar pharmaceutical formulations.
- Analytical method development and validation experience.
- Stability studies and pilot/commercial batch manufacturing experience, if available.

C. Product Development Readiness

- Current stage of formulation development.
- Availability of formulation development data, analytical methods, and manufacturing process.
- Estimated timeline for development, validation, manufacturing, and supply of the investigational product.

D. Intellectual Property & Publications

- Status of patents, if any, related to the proposed formulation or manufacturing process.
    - Status of IP: patents filed/granted (national and international).
- Relevant publications or technical reports related to formulation development and manufacturing.

E. Company Profile & Experience

- Experience in formulation development and manufacturing of oral pharmaceutical products.
- Experience in manufacturing investigational medicinal products (IMPs) for clinical trials.
- Past collaborations with national or international health agencies (ICMR, DBT, WHO, CEPI, etc.).

F. Capacity and Infrastructure

- GMP-compliant manufacturing facilities.
- Formulation development, analytical, quality control, and quality assurance laboratories.
- Manufacturing capacity and batch size.
- Stability testing facilities.
- Packaging, labelling, storage, and distribution capabilities for clinical trial materials.

G. Analytical & Quality Control Capabilities

- Availability of validated analytical methods.
- Batch release testing facilities.
- Stability testing capability.
- Quality assurance and quality control systems.

H. Regulatory & Compliance Readiness

- Experience with CDSCO/DCGI regulatory requirements.
- Experience in manufacturing investigational medicinal products for clinical trials.
- GMP certifications and regulatory inspections.
- Ability to comply with applicable GCP, GMP, and regulatory requirements.

I. Timelines & Project Management

- Proposed timelines for formulation development, analytical method validation, manufacturing, packaging, and supply.
- Availability of dedicated technical and project management teams.
- Risk mitigation strategies to ensure uninterrupted supply.

J. Supply Chain & Resource Mobilization

- Availability of raw materials and supply chain management.
- Storage and transportation facilities.
- Availability of skilled manpower.
- Capacity to ensure uninterrupted manufacture and supply throughout the study period.

K. Support Required from ICMR

- Technical discussions regarding formulation requirements.
- Support related to the proposed multicentre clinical trial.
- Regulatory coordination, where applicable.
- Any other support required from ICMR.

L. Compliance & Declarations

- We have gone through the complete EoI document No. _____ dated _____ and have understood all the terms and conditions.
- We have understood the purpose and objectives of this EoI.
- We hereby declare that the information furnished in this proposal is true and correct.
- We will not be deviated from the any of the commitment proposed in this proposal.
- We agree to abide by the roles and responsibilities as outlined by ICMR in this EoI.
- We accept that ICMR reserves the sole right to accept or reject any proposal without assigning any reason thereof.

Authorized Signatory
(Name, Designation, Seal, Date)