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)