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संख्या/ Enquiry No.: BDG/IICB/R&D/001/2025-26

दिनांक/Date: 27.05.2026

शुद्धिपत्र सूचना
Corrigendum Notice

सभी संबंधित पक्षों को सूचित किया जाता है कि "लिक्विड सस्पेंशन में नए लिपोसोमल एम्फोटेरिसिन बी फॉर्मूलेशन के जीएमपी स्केल-अप और उत्पादन, लियोफिलाइजेशन, कैरेक्टराइजेशन और स्टेबिलिटी चेक" के लिए निविदा एनआईसी सीपीपी पोर्टल (<https://etenders.gov.in/eprocure/app>) पर निविदा आईडी 2026_CSIR_277601_1 के तहत प्रकाशित की गई है। कृपया भाग लेने से पहले निम्नलिखित शुद्धिपत्र पर ध्यान दें। इसकी एक प्रति सीएसआईआर-आईआईसीबी वेबसाइट पर भी अपलोड कर दी गई है।

It is hereby informed to all concerned that the tender for conducting "GMP Scale-up and Production of novel Liposomal Amphotericin B formulation in liquid suspension, lyophilization, characterization & stability check" has been published on NIC CPP Portal (<https://etenders.gov.in/eprocure/app>) vide tender ID 2026_CSIR_277601_1. In this regard following corrigendum may kindly be noted before participating. The copy of the same has also been uploaded on CSIR-IICB website.

1. निविदा दस्तावेज का संशोधित विनिर्देश (अध्याय III जिसमें अनुलग्नक - I शामिल है) सूचना और डाउनलोड के लिए इसके साथ संलग्न है (अनुलग्नक ए)।

A Revised Specification (Chapter III including Annexure - I) of the Tender Document is enclosed herewith as **Annexure-A** for information and downloading.

2. उक्त निविदा अधिसूचना के अन्य सभी नियम और शर्तें अपरिवर्तित रहेंगी।

All other terms and conditions of the said tender notification will remain unchanged.

सभी संभावित बोलीदाताओं से अनुरोध है कि कृपया दिनांक 27.05.2026 का शुद्धिपत्र नोटिस देखें और तदनुसार अपनी बिड/प्रस्ताव/कोटेशन प्रस्तुत करें।

All the prospective bidders are hereby requested to kindly see the corrigendum notice dated 27.05.2026 and submit their bid/ offer/ quotation accordingly.

सीएसआईआर-आईआईसीबी
CSIR-IICB

Chapter III

Technical requirements for conducting of “GMP Scale-up and Production of novel Liposomal Amphotericin B formulation in liquid suspension, lyophilization, characterization & stability check” to be rendered by the Contract Research Organization (CRO) or technical service provider proposed to be engaged in the present case as per the specifications below- One study/package

1. Eligibility Criteria for selection of service provider for conducting the study:

- I. The service provider shall have the necessary in house facility to complete Job A. Job A cannot be outsourced. Service provider should have minimum 2 years of experience in conducting similar services for companies/ public funded or govt/academic institutions and/or have a long standing experience in manufacturing liposomal product as a Pharma company (documents should be provided).
- II. The Consultants/Service Providers must have the registered office in India.
- III. The service provider should have GMP enabled/certified laboratory to perform Job A & B.
- IV. If Jobs B & C are outsourced by the service provider, they should mandatorily have official tie-up/agreement with third party/Sub-contractors (Documents required to be submitted along with the Bid Submission). For Job B, third party/Sub-contractors should have GMP certification. An official agreement on letter head of both parties with clear job responsibility has to be submitted along with the tender document. The Letter of Agreement/MoU/Formal Tie-up, etc. between both (all) parties needs to be submitted along with the Bid Submission".

Bidders should mandatorily provide:

- i. Valid GMP (for Job A & B) certificate as mentioned below in **Annexure I**.
- ii. Laboratory accreditations (as required)
- iii. Pharma companies/Service Providers should submit either evidence of similar work executed in the last 2 years supported by at least 2 purchase orders or long standing experience in manufacturing liposomal product supported by sufficient documents
- iv. Test/manufacturing license for the job
- v. Positive Financial capability documents (Latest 2 financial years)
- vi. Details of subcontractors/tie-ups, valid documents should be provided.
- vii. Commitment to perform work in GMP enabled facilities only (for Job A & B)
- viii. The Bidder may submit additional certifications for quality services
- ix. All certificates are needed as per the guidelines of CDSCO for IND studies, as applicable

2. Scope:

In the proposed project, the selected CRO will conduct GMP Scale-up and Production of novel Liposomal Amphotericin B formulation in liquid suspension, lyophilization, characterization & stability check”.

3. The specifications /technical requirements for the proposed outsourcing activity are provided below

Annexure I

Job description - GMP Scale-up and Production of novel Liposomal Amphotericin B formulation in liquid suspension, lyophilization, characterization & stability check

Deliverables

- A. GMP Scale-up Process Development and Production of novel Liposomal Amphotericin B formulation as liquid suspension. This will include 14.4 liters of amphotericin B containing novel liposomal formulation in liquid form plus 3.6 liters of drug free placebo novel liposomal formulation in liquid form. Both amphotericin B containing novel liposomal formulation (4.8 + 4.8 + 4.8 liters) & drug free placebo novel liposomal formulation (1.2 + 1.2 + 1.2 liters) should be made in 3 different batches.

This will include **Set I**- 140 vials of Novel Liposomal Amphotericin B Formulation from each batch with 20 mg/vial stock. Total 420 vials for 3 batches, stock 20 mg/vial.

Set II – 40 vials of Novel Liposomal Amphotericin B Formulation from each batch with 50 mg/vial stock. Total 40 x 3 = 120 vials for 3 batches, stock 50 mg/vial.

From vials of amphotericin B containing novel liposomal formulation, 3 vials from each batch (20 mg/vial, total 9) & 2 vials of 50 mg/vial (3 batches, total 6) will be sent by the service provider to CSIR-IICB, for quality check.

The concentration of amphotericin B should be 1mg/ml.

For the drug free placebo formulation, there should be 15 vials of 20 ml/vial stock (**Set III**) and 18 vials of 50 ml/vial stock (**Set IV**) from each batch. For 3 batches of 1.2 litre each, total vials- 45 vials of 20 ml/vial stock and 54 vials of 50 ml/vial stock of drug free novel liposomal formulation will be manufactured.

From each batch, 5 vials of 20 ml/vial (15 vials from 3 batch) and 2 vials of 50 ml/vial (total 6 vials from 3 batches) will be sent by service provider to CSIR-IICB. The rest of the vials (78 vials) will be lyophilized as mentioned in Job B.

Among the vials of amphotericin B containing novel liposomal formulation, 5 vials from each batch (20 mg/vial) will be used by the service provider for initial check of liposomal integrity and following parameters:

Fill weight, pH, Chloroform content, Lecithin content, Assay (Amphotericin B), Stearylamine (SA), Trehalose, PBS, BET, Sterility, phase behavior, Encapsulation Efficiency, in vitro drug release, particle size analysis using dynamic light scattering and Zeta potential measurement.

All reports and relevant raw data will be delivered to CSIR-IICB within 3 weeks of Production of novel Liposomal Amphotericin B formulation as liquid suspension. Upon successful validation of liposomal integrity at Principal Investigator end, Payment will be released for Job A within 4 week of receiving

the vials upon successful validation

- B. GMP enabled Lyophilization of Novel Liposomal Amphotericin B Formulation in 20 mg/vial and 50 mg/vials stock in glass vials prepared in job A. This will include 100 vials of Novel Liposomal Amphotericin B Formulation from each batch with 20 mg/vial stock. Total 300 vials for 3 batches, stock 20mg/vial. The 2nd preparation will be 38 vials of Novel Liposomal Amphotericin B Formulation from each batch with 50 mg/vial stock. Total 114 vials for 3 batches, stock 50 mg/vial.

The placebo containing drug free novel liposomal formulation will include 30 vials of 20 ml/vial stock & 48 vials of 50 ml/vial stock for lyophilisation. All liquid and lyophilized vials of placebo containing drug free novel liposomal formulation should be sent to CSIR-IICB.

3 vials of Lyophilized Novel Liposomal Amphotericin B Formulation from each batch (Total 9 vials of 20 mg/vial) will be sent by the service provider to CSIR-IICB. Upon successful validation of liposomal integrity & characterization at Principal Investigator end, payment will be released for Job B within 4 weeks of receiving the vials.

- C. Characterization and stability check of novel Liposomal Amphotericin B formulation in liquid form at refrigerated condition, and after lyophilization in different storage conditions as mentioned below.

From the 420 vials produced in **Set I** of Job A, 300 are lyophilized in Job B. The following tests are to be done from these 300 vials.

- Accelerated Conditions: Store at 40°C ± 2° C/75% RH ± 5% RH for 1 month, 2 months, 3 months, 6 months, 9 months (5 time points)
 - Real-Time Conditions: Store at 30°C ± 2° C/75% RH ± 5% RH for 1 month, 2 months, 3 months, 6 months, 9 months. (5 time points)
 - Refrigerated Conditions: Store at 2-8°C for initial, 1 month, 2 months, 3 months, 6 months, 9 months. (6 time points)

15 vials from 3 batches (5 vials/batch) for a total 16 time points at 3 different storage conditions as mentioned above will be evaluated for liposomal integrity and following parameters:

Fill weight, pH, Chloroform content, Lecithin content, Assay (Amphotericin B), Stearylamine (SA), Trehalose, PBS, BET, Sterility, phase behavior, Encapsulation Efficiency, in vitro drug release, particle size analysis using dynamic light scattering and Zeta potential measurement. All reports and relevant raw data will be delivered to CSIR-IICB within 3 weeks after completion of each time point.

Total no. of lyophilized vials will be evaluated 16 x 15= 240 vials. The remaining vials are to be sent to CSIR-IICB.

Liquid amphotericin B containing novel liposomal formulation (3 vials of 20 mg/vial from each batch) will also be checked for Characterization and stability at refrigerated temperature for initial, 3 & 6 months. The remaining vials are to be sent to CSIR-IICB.

Total vials for 3 set = 3 x 3 x 3= 27 vials.

Terms & conditions

1. Service provider should have minimum 2 years of experience in conducting similar services for companies/ public funded or govt/academic institutions and/or have a long standing experience in manufacturing liposomal product as a Pharma companies

- (documents should be provided). The Institute will have the right to have its authorized personnel visit the manufacturing site.
2. The service provider shall mandatorily complete Job A. The upscaling of liposomal preparation and lyophilization should be done in GMP certified laboratory. The service provider should provide valid GMP enabled laboratory certification.
 3. The manufacturer should procure stearylamine and phosphatidylcholine from commercial sources with highest purity and should be characterized for purity and structural verification before proceeding with the GMP upscaling of the amphotericin B liposomal formulation.
 4. All ingredients should be purchased by the manufactures from commercial sources with highest purity.
 5. Non Disclosure Agreement (NDA) will be executed with the selected service provider for process development and Production of novel Liposomal Amphotericin B formulation
 6. The manufacturer should provide data for encapsulation efficiency (equal or greater than 88%) of liquid formulation before proceeding for lyophilization.
 7. The manufacturer should provide sterility, composition, and physical and chemical stability data to claim the integrity of the formulation both before & after lyophilization. The party should provide characterization certificate for the proper stability of the product. Vials of both liquid and lyophilized liposomes will be shared with the PIs for validation prior to release of payment.
 8. The payment will be done to the party only if the lyophilized formulation is sterile, pure and physically and chemically intact.
 9. The service provider shall mandatorily complete Job A. Only lyophilization (Should be GMP enabled for job B) & liposomal integrity and characterization (Job C) may be out sourced from a third party/Sub-contractors.
 10. The selected Service Provider can also outsource jobs B and C from a third party/Sub-contractors (Should be GMP enabled for job B) provided they should have an official tie up/collaboration with the third party and valid documents of official tie up/collaboration should be provided along with GMP certificates.
 11. The selected service provider shall be solely responsible for completion of Job A, B and C as per the scope of work.

CSIR-IICB reserves the right to ask the service provider to submit the shortfall documents pertaining to their eligibility criteria etc. mentioned in the tender document after opening of the technical offer (under Two Bid Format) within the stipulated time failing which their technical offer may be considered as non-responsive.

Any clarification on technical points asked by the technical committee of CSIR-IICB will be for the clarity of the service for arriving at a proper decision. Any clarification from the vendor of such nature which modifies the original quote in order to suite the technical specifications of CSIR-IICB after opening of bids will not be accepted

DELIVERY PERIOD

For Job A- 60 Days from date of PO / contract or earlier

For Job B- 45 days after completion of Job A

For Job C- Month-wise as mentioned in Technical Specifications in Annexure I

Payment condition: Payment will be made phase-wise on the completion of each job (A followed by B followed by C) and after providing the satisfactory data for each job under the scope of work. For job C, payment will be made after each time point after providing the data for liposomal integrity as mentioned in point C under the scope of work. For Job C, if the formulation is found unstable at a particular time point in either Accelerated, Real-Time and Refrigerated Conditions, no subsequent

characterization will be performed by the service provider at that particular condition for subsequent characterization. Accordingly, payment will not be done for subsequent particular time point and condition (Accelerated, Real-Time & Refrigerated Conditions)

Payment Terms: Payment shall be made on milestone basis. The first milestone payment of up to 32% will be released after completion of liquid formulation (Job A). The second milestone payment of up to 18% will be released on satisfactory completion of lyophilization (Job B). Finally, after submission of stability and characterization data study/work subject to its approval and acceptance by CSIR-IICB project team, the rest of the payment upto 50% shall be released on monthly basis according to Job C.