



KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED, BENGALURU

7-AMINOCEPHALOSPORANIC ACID (7-ACA) BULK DRUG PROJECT

TENDER REQUEST OF PROCESS CONSULTANT

EXPRESSION OF INTEREST

Request of Process Consultant for Proposed 7-aminocephalosporanic acid (7-ACA) project.

SCOPE OF WORK FOR PROCESS CONSULTANCY/PROCESS ENGINEERING FOR 7-ACA PROJECT

BRIEF ABOUT THE COMPANY

- Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), a Government of India Enterprise, under Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals.
- The company was incorporated in 1981 on the recommendations of the Hathi Committee with an aim of supplying life-saving drugs to the general public at an affordable price.
- The plant started its commercial production in 1984.
- We are an PIC/S GMP Certified, ISO 9001:2015; ISO 14001:2015 & ISO 45001:2018 accredited.
- WHO-GMP approved company since 1985.
- The factory is located in Peenya Industrial Area, Bengaluru.
- The Corporate office is located at Nirman Bhavan, Dr. Rajkumar Road, Bangalore-560 010, which is located 8 km away from the factory site.

OBJECTIVE:

The objective of this document is to define the scope of works to be handled by the Process Consultancy regarding to the Process Engineering and Process Technology Transfer for the project of 7-ACA, started by KAPL-Bengaluru.

This document provides the expected deliverables, roles and responsibilities by the process consultant at various stages of the project.

Minimum Criteria of Process Consultant:

1. Consultant to have minimum 20 years of experience in handling and execution of API projects and fermentation-based production projects. Consultant having experience in the process execution of 7-aminocephalosporanic acid (7-ACA) products shall be given preference.



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2. To have a thorough process know how of biological and fermentation based KSM plant and preferably the complete process know how of 7-ACA.
3. The consultant should have experience in establishing and commissioning of green field projects in the similar lines in India & abroad.
4. The consultant should have handled the projects with investments of not less than 75-100 Crores in API/ Biotechnology projects.
5. The consultant shall have technical and competent man power of not less than 50 personnel for handling the various areas of the project.
6. Process Technology/design shall meet USFDA/EUGMP requirements.

Scope of Consultants during Technology Identification and Scale up

1. Consultant must have knowledge of the product, manufacturing process, project equipment's, product development, project coordination and implementation.
2. The consultant is responsible for the technology from the laboratory, pilot scale and to transfer it to industrial level manufacturing process.
3. The primary scope of the consultancy would be to identify the source of technology/technology provider, verification of the technology at the source end or client R&D Lab, perform the pilot plant manufacturing and then provide support to commercialize the manufacturing process.
4. Support KAPL to generate and finalize the tender document, agreement with technology provider for successful transfer of technical know how
5. Coordinate with the technology provider and KAPL team for identification, procuring of equipment's and establishing pilot plant and other lab equipment's.
6. To provide support KAPL during execution of laboratory scale batches, and scale up of the batches from lab scale to commercial scale.
7. Support KAPL in establishing R&D facility and to co-ordinate with KAPL to hire scientists and R&D resources for the support during the tech development process, and to escalate issues arising to the technology provider the problems identified in the process and systems for prompt corrective actions.
8. Consultant should support KAPL in meeting all the required regulatory requirements during design, planning and execution of the pilot plant manufacturing and commercial project execution.
9. To coordinate with process owners and technology provider to define technology requirements for KAPL and help to design a process vision and plan the execution



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strategy which would help in quick process maturation for immediate product deployment.

10. To act as single point of contact between internal teams and the technology provider in addressing process related enquiries.
11. Coordinate between the tech provider and KAPL to develop the stepwise process, process overview and details and develop the process flow diagrams.
12. The consultant has to coordinate between the technology provider to develop and maintain process development and optimization program and make the process design and development requirements to standardize, improve and redesign the process to meet the business requirements of KAPL.
13. Ensure proper knowledge, documentation transfer from tech provider to KAPL.
14. To develop the process engineering (basic engineering & detailed engineering) package to deliver the capacity desired at industrial level.
15. Ensuring the complete documents hand over to KAPL from the tech provider after the complete execution of the project.
16. The consultant should support KAPL to establish the facility for proper handling and storage of the strain procured from the technology provider and support in establishing the proper procedures for proper handling and use of the strain.

PROJECT MANAGEMENT AND ENGINEERING

17. To provide support KAPL to develop the process engineering package to deliver the capacity desired at industrial level which will be part of Basic Engineering and Detail Engineering.
18. The process consultant should support KAPL to generate the project execution strategy and project procedures, and project controls.
19. The Consultant shall support for preparing the RFP (Request For Proposal) for tender for Engineering consultancy which provides the process engineering, basic engineering and detailed engineering.
20. The consultant shall support KAPL during TBA (Technical bid analysis) and CBA (Commercial Bid Analysis) for engineering consultancy.
21. The process consultancy shall support the KAPL in coordinating with the engineering consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned process engineering aspects .
 - a. Computer aided flows- sheeting for mass and energy balance.



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- b. Process and Instrumentation diagram.
 - c. Utility sizing, requirements and specifications.
 - d. Equipment design, equipment specifications and URS.
 - e. Piping and Instrument specifications.
 - f. Material Specifications.
 - g. Facility layout man and material movement.
22. The process consultancy shall support the KAPL in coordinating with the engineering consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned basic engineering aspects.
- a. Feasibility analysis
 - b. Conceptual design
 - c. Preliminary design
 - d. Economic analysis and cost evaluation and analysis
 - e. Facilities planning
 - f. Site master planning and site selection and entire project outlay.
 - g. Technology evaluations
 - h. Process engineering
23. The process consultancy shall support the KAPL in coordinating with the engineering consultancy and tech provider in reviewing and finalizing the feasibility, concept and safety reports not limiting to the below mentioned detailed engineering aspects.
- a. Civil engineering and architectural engineering
 - b. Structural engineering
 - c. Chemical engineering services
 - d. Specifications for the buildings.
 - e. Piping design and piping engineering
 - f. Electrical and instrumentation engineering
 - g. Equipment selection and specifications
 - h. Process safety and loss prevention
24. The consultant shall support KAPL to select the contractors and vendors as part of procurement assistance.
25. The consultant should help KAPL to establish Building Information Management (BIM) during the initial stages of the project in consultation with the technology provider and engineering consultant.
26. Consultant shall help KAPL to identify the long lead items during basic engineering and help to develop the specifications and coordinate for design development and



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design review with the design builders, and coordinate with the design builders for timely delivery of the long lead items to avoid project delays.

27. Consultant shall coordinate with design consultant and help KAPL to prepare tender documents for different contractors like

- a. Civil contractors
- b. MEP(Mechanical, electrical and plumbing) contractors.
- c. Equipment fabricators and vendors.
- d. Fire safety coordinators.

28. Consultant should coordinate with engineering firm to prepare the tender documents for Construction management scope, identify the construction management firm and different contractors support in TBA and CBA for the construction management firms and contractors and construction management strategy.

29. Consultant should eliminate any major risk in the project from detail design to contraction.

30. Consultant shall support to develop the plot plan and entire project layout in accordance with the building regulations and code meeting USFDA/ EUGMP requirements.

31. The consultant should provide support KAPL to create suitable ware house, solvent storage, explosive yard, scrap yard, acid and alkali management system, and also provide support to create a safe and GMP compliant industrial plant for KAPL.

32. The consultant should support KAPL to create infrastructure of plant with mechanization and instrumentation which would reduce the excess manpower engagement and help in optimum man power utilization.

33. The consultant shall support KAPL to establish Effluent treatment Plant (ETP) and Zero Liquid Discharge Plants in coordination with the design team to meet the required clearance norms.

34. The consultant shall act as single point of contact between KAPL and Engineering consultants during process engineering, basic engineering and detailed engineering stages.

35. The consultant shall ensure to capture all the critical process parameters and to help to resolve the any issues in coordination with the technology provider and engineering consultancy arising during the design phase.

36. The consultant shall support KAPL during review meeting with the technology provider during water trials and commissioning and shall assist KAPL in



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manufacturing of 3 exhibit batches and certifying the yield as per the pre designed process specifications.

37. The consultant shall support KAPL for the expansion of installed capacity and future integration plant requirements if required.
38. The consultant should visit vendor sites during fabrication of the equipment's, and coordinate with the procurement teams for on time delivery of the materials to avoid delay of the long lead items.
39. The consultant should help KAPL to develop strategy for procurement of the material to avoid unnecessary over expenditure of capital and help to reduce overhead expenses.
40. The consultant should support KAPL team in FAT (Factory acceptance testing), SAT (Site acceptance test), CQV (Commissioning, qualification and validation) of the equipment's.
41. The consultant should help KAPL to prepare VMP (Validation Master Plan) and to identify the commissioning boundaries and to coordinate between the construction team and turnover team for smooth transition from construction to commissioning.
42. Consultant has to support the KAPL team in commissioning and qualification protocols (IQ, OQ, PQ) and support to design SOP for all the procedures and equipment's for safe operation of the commissioned plant.
43. The consultant should review the fire safety basic data and fire safety requirements and to provide the inputs to the vendors for design, supply and installation of the same as per the process requirements.
44. The consultant should review/check and design details/drawings provided by the equipment vendor for finalizing the basic engineering of the facility.
45. The consultant shall support KAPL to establish the safety measures required to be installed and also support in designing the safety plan and to identify the contractor providing the installation and commissioning of the safety equipment.
46. The consultant should help KAPL to establish ETP plant and help in design as per the process, detailed designing of the complete ETP complying with the statutory requirements and review the vendors detailed engineering drawings and specifications of the plant.

**SUPPORT IN ESTABLISHING SUPPORTING AND ANCILIARY
DEPARTMENTS.**

47. The consultant should provide support for establishing the Quality control and Microbiology departments and support in identification of the equipment's and



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instrument requirements, provide the specification of the instruments and help in procuring and installation and qualification of the instruments.

48. The consultant shall support KAPL to establish a state of the art laboratory which would meet all the regulatory and laboratory compliance with all the safety requirements.
49. The consultant shall support KAPL to establish the SOP (Standard Operation Procedures) in Production, engineering, safety and quality departments etc.
50. Consultant should support the quality team to establish analytical methods of the product and support in preparation of any product related, critical analytical documents.
51. The consultant shall support KAPL in training of the hired staff in the production, engineering and Quality departments.
52. The consultant shall provide post commissioning support for a period of 1 year.
53. The consultant should support KAPL team for preparing Quality Manual and Site Master File, product specifications and testing procedures.
54. The consultant shall help KAPL to establish the specifications for materials and their testing specifications and testing procedures.
55. Support in preparing training manual, calendar and implementation of QMS systems like risk analysis & management, CAPA procedures as per cGMP requirements.
56. The consultant should support in qualification of equipment's, area, validation of procedures and QbD (Quality by Design) approach for process and cleaning validation activities.
57. Consultant should support in Computer system validation, gap analysis, audit, training, risk assessment, life cycle approach and updation.
58. The consultant should support to establish Quality culture development and build up across the site.
59. Consultant should support and guide KAPL in obtaining all the necessary regulatory permissions and approval required during various stages of the project.

SUBMISSION OF BIDS:

1. Interested parties shall submit their bids in two separate sealed envelopes
2. Technical bid shall be sent in a separate sealed envelope super scribed as "TECHNICAL BID" along with the Tender Number and date on the top of the envelope.



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3. Commercial bid shall be sent in a separate sealed envelope super scribed as “COMMERCIAL BID” along with the Tender Number and date on top of the envelope.
4. If technical and commercial bids are submitted in a single sealed envelope such bids will be rejected.
5. Selected vendors shall be informed to pay Earnest Money Deposit (EMD) of Rs 5.0 Lakhs within in 10 days after selection of Technical Bid. Any vendor, who is not submitting EMD, will be disqualified.
6. EMD shall be sent in the form of Demand Draft in favour of “KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED” payable at Bengaluru.
7. Technical Bid and Commercial Bid should reach us on or before 05.06.2021.
8. All bids shall be addressed to

**“The Company Secretary & Asst. General Manager(Admn)”
Karnataka Antibiotics and Pharmaceuticals Limited
Nirman Bhavan, Dr. Rajkumar Road
1st Block, Rajajinagar
Bangalore-560010, India.**

Any Tender which does not comply with the requirements of the request for Tender including these Conditions of Tender may be rejected at the KAPL’s sole discretion.