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SHREE BALAJI TEST LAB PVT LTD

Article 5 General Agreement

Not Applicable

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SHREE BALAJI TEST LAB PVT LTD

ESI INSTITUTIONS

SHREE BALAJI TEST LAB PVT LTD

100

(One Hundred only)





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(Terms and Conditions of MoU to be signed between willing empanelled testing laboratories (PMBI) and ESI Institution for testing of drugs).

 Sample will be sent by speed post/courier from all ESI Institutions pan India at their own cost.

2. ANALYSIS AND REPORTING CONDITIONS:

- (A) (i). Once the Sample test order /dispatch letter is issued to empaneled laboratories, they should furnish the test reports within maximum days as specified under Annexure IX of Tender of PMBI.
- (ii) The confirmation of receipt of samples intended for testing through Sample test order/dispatch letter shall be informed to ESI Institution via e-mail immediately after receipt of samples.
- (iii). For any delay in submitting the reports more than stipulated time as mentioned above, a penalty @ of 1% per day or part thereof, subject to maximum of 10% will be levied irrespective of the fact that whether the ESI Institution has suffered any damage/loss or not, on account of delay in submitting the reports.
- (B). All the test mentioned under current IP/BP/ USP/In-house /other standard reference compendium /Monograph and any other standard mentioned as per Schedule under Drug & Cosmetic Act 1940 and Rules 1945 as well as Schedule V and manufacturer's specification should be carried out for each sample. The results obtained in the test should be mentioned in figures. Test reports not mentioning complete details as per IP/BP/USP/In-house /other standard reference compendium /Monograph etc. will be considered as "Incomplete test report" and the drugs testing laboratory will have to submit complete report for acceptance.
- (i) In case of Surgical/Consumables /Medical Devices the report shall be furnished as per ISO/BIS/CE/In-House/any other references (whichever applicable/as per tender requirement) or as notified under Medical Devices rule 2017.
- (ii) In case of Food Products, the test reports shall be furnished in compliance with FSSAI Guidelines in compliance to latest Recommended Dietary Allowance (RDA)

(iii) In case of Ayurvedic Products, the test reports shall be furnished as per Ayurvedic Pharmacopoeia of India/any other references (whichever applicable/as per tender requirement).

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Note: All the Drug Dosage form (Solid, Semisolid, liquid, gas, Miscellaneous etc) testing shall be done as per Annexures IX. ESI Corporation reserves the right to add/remove test parameters as per requirement.

- (C). "Complies" or "Passes" or "Within Limit" in result column of the test report will also be treated as incomplete test report, if the result has some value the actual value found on analysis is to be reported. Permitted limit shall be incorporated in test report.
- (D). Every test report must have specific remarks as 'Standard Quality', or 'Not of Standard Quality (NSQ).' Any ambiguity/ cutting will not be accepted.
- (E). Test report should have Sr. No., Description of tests, Specification, result, reference, permitted limit as per standard reporting procedure or as required by ESIC under the ambit of law.
- (F). Spectrum/Chromatogram/Dissolution profile, or other work data sheets, wherever applicable, should be attached with the test report. Calculation sheet shall be provided immediately if asked by ESIC in not more than one working day after intimation.
- (G). In case of non-Pharmacopoeial products, the lab shall mention the reference/method of analysis in the test report. ESI Institution may provide Standard testing Procedure (STP)/Method of Analysis (MOA) after collecting same from manufacturer.
- (H) Test report/Certificate of Analysis (COA) must be submitted to ESIC in prescribed format on Form 39 A in compliance to Drugs and cosmetic Act 1940 and rules there under 1945. The test report of the sample passed or failed; the report shall be submitted as per the procedure laid down.
- (I). The original physical copy of test reports shall be submitted in original in triplicate copies in a sealed envelope to ESI Institution within five working days along with all relevant documents duly authorized. However, the scanned copy of Test report to be mailed to ESI Institutions as soon as the report is ready.
- (J) The labs shall have sufficient capacity to cater the testing need of ESIC. They shall have sufficient stock of IPRs, Impurities, Working Standard etc. for the testing of any or all awarded items (if required). Lab will not be entertained at any cost for reporting unavailability of any such standard i.e., IPRs, Impurities, Working Standard etc.
- (K) In case if the sample is delivered /received in damaged condition by the empaneled lab, Lab must not proceed for the testing of such sample and it shall be immediately informed to ESI Institution.

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(L) If Testing Laboratory declares NSQ on Related Substances (RS), then it must ask for placebo & after running the blank samples the impurity has to be confirmed before releasing the final report.

3. PAYMENT PROVISIONS:

- A) No advance payment towards any analysis will be made to empaneled Laboratory.
- B) No payment will be made for incomplete analysis or incomplete report.
- C) Payments towards the analysis/testing of sample will be made within 45 days from the date of receipt of invoice and submission of Test Report.
- D)All bills/Invoices should be raised in triplicate and the bills should be drawn as per GST Rules in the name of Medical Superintendent/Dean/DIMS etc of respective ESI Institution.
- E) If at any time during the period of contract, the price/testing charges of items is reduced or brought down by any law or Act of the Central or State Government or by the Testing Laboratory itself, the Testing Laboratory shall be bound to inform the ESIC Hqrs and ESI Institution immediately about such reduction in the contracted prices.
- 4. As per Clause No. 13.1.2. , L-1 Rates of Testing are exclusive of GST as per terms and conditions of the Tender Enquiry No. PMBI/Empanelment/Drug Testing Laboratory/10-2023 date: 28.12.2023 published by PMBI.
- 5. Invoice/bill must be received in ESI Institutions within 3 months. After 3 months ESI Institutions shall not be liable to pay the invoice. Each invoice shall be generated with L-1 rate as described, if rate on laboratory invoice exceed with L-1 rate, that invoices shall be considered as cancelled.
- No suit, prosecution or any legal proceedings shall lie against the ESI
 Corporation or any person for anything that is done in good faith or intended to
 be done in pursuance of the contract/agreement.
- 7. ARBITRATION AND JURISDICTION: Normally, there should not be any scope of dispute between the ESI Corporation and the empaneled Drug Testing Laboratory after entering a mutually agreed valid contract/agreement. However, due to various unforeseen reasons, problems may arise during the progress of the contract/agreement leading to disagreement, ESIC and the Testing Laboratory shall first try to resolve the same amicably by mutual Consultation. If the parties fail to resolve the dispute by such mutual consultation within twenty-one days, then, depending on

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the position of the case, either the ESIC or the empaneled Drug Testing Laboratory shall give notice to other party of its intention to commence Arbitration procedure as per Indian Arbitration and Conciliation Act, 1996. Such disputes/differences shall be referred to Sole Arbitrator to be appointed by the Director General, ESIC. The venue of Arbitration Shall be at New Delhi. The award published by the Arbitrator shall be final and binding on the parties.

- B) And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any Para herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of Director General, ESIC in the matter shall be final and binding on both parties.
- C) All disputes under this Agreement shall be resolved as follows. Within 15 days after written notification of the dispute, principals, or officers of Laboratory and ESIC shall meet to make an effort to resolve the dispute. If the dispute remains unresolved, the parties shall participate in a facilitated mediation pursuant to the rules of the Indian Arbitration and Conciliation Act, 1996, Such disputes/differences shall be referred to Sole Arbitrator to be appointed by the Director General, ESIC in accordance with the provisions of Arbitration Act, 1996.

 D) If any of the provisions of this agreement are held to be invalid or unenforceable in any respect, the remaining terms will remain effective, and the agreement will be construed as if the invalid or unenforceable matters were never included in it. No waiver of any default will be a waiver of any future default. Neither party shall be liable for nonperformance caused in whole or in part by Acts of God, civil unrest, and war.
- 8. PERFORMANCE SECURITY DEPOSIT: Performance Security Deposit @ 3 % will be deducted from each running bill against the total value in the Purchase Order/Testing Order and accumulated security deposit will be refunded without any interest by ESI Institution to the Testing Laboratory within 60 days following the date of completion of tenderers performance obligations under the contract/agreement.
- 9. The Testing Laboratory shall comply with, abide by, and accept without variation, deviation, or reservation all terms and conditions of the Tender Enquiry No. PMBI/Empanelment/Drug Testing Laboratory/10-2023 date: 28.12.2023 published by PMBI. If mentioned elsewhere in this MoU, contrary terms and conditions shall not be recognized and shall be considered as null and void.







The Memorandum will commence on 16(9), 2025 and will remain in force for 01 year or validity of contract of Testing Laboratory with PMBI or till finalization of Empanelment of ESI Institutions whichever is earlier. Either Party may terminate this Memorandum forthwith by providing 60 days prior notice in writing to the Other Party.

The parties have caused this MOU to be signed and executed on $\frac{16/9}{}$, 2025.

On behalf of ESI Institution

On behalf of PMBI's Empaneled Testing Laboratory

Signed By toye / Dr. Bheiren Deshmukh

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Signed by:

In the presence of (Witnesses)

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