

महाराष्ट्र MAHARASHTRA

2023

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प्रधान मुद्रांक कार्यालय, मुंबई  
प.मु.वि.क्र. ८००००९५  
13 FEB 2024  
सक्षम अधिकारी

श्रीमती निवृत्त महाजन

### MASTER SERVICES AGREEMENT

This Master Services Agreement executed on this **16/02/2024** by and between **Balaji Enzyme & Chemical Pvt Ltd**, a Company incorporated in accordance with the laws of India, under the Companies Act 1956, having its registered office at **113, 1<sup>st</sup> Floor, Akshay Mittal Industrial Estate, Building No. 5A, Andheri Kurla Road, Andheri (E), Mumbai-400059, Maharashtra** represented by its Director, **Mr. Abhay Kainya**, hereinafter referred to as Sponsor (which expression, unless repugnant to the subject or context therein, shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents & successors-in interest) of the FIRST PART.

And

College is an organization of the **Guru Nanak Khalsa College of Arts Science and Commerce, Autonomous College** affiliated as an educational institute with University of Mumbai and having its office at **Nathalal Parekh Marg, Opp. Don Bosco School, Matunga, Mumbai – 400019, Maharashtra** represented by its Principal hereinafter referred to as the **R & D centre**, (which expression, unless repugnant to the subject or



Sharma



जाडपत्र-9, 20 FEB 2024, 003885  
अवत प्रतिज्ञापत्राची Only for Affidavit

मुद्रांक विकत-वेगळ्याचे नाव \_\_\_\_\_

मुद्रांक विकत वेगळ्याचे ठिकाणी वजा \_\_\_\_\_

मुद्रांक विकत वेगळ्याची नोंद वही \_\_\_\_\_

**BALASPHENZYME & CHEMICAL PVT LTD**  
113, 1st Floor, Akshay Mittal Industrial Estate,  
Building No. 5A, Andheri Kurla Road,  
Andheri (W), Mumbai-400059, Maharashtra India

मुद्रांक विकत वेगळ्याची \_\_\_\_\_

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मुद्रांक विकत वेगळ्याचे नाव  
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मुद्रांक विकत वेगळ्याची नोंद वही  
मुद्रांक विकत वेगळ्याची \_\_\_\_\_

THE HON'BLE JUSTICE...  
IN MATTER OF...  
BALASPHENZYME & CHEMICAL PVT LTD...  
ANDHERI (W), MUMBAI-400059, MAHARASHTRA INDIA

IN MATTER OF...  
BALASPHENZYME & CHEMICAL PVT LTD...  
ANDHERI (W), MUMBAI-400059, MAHARASHTRA INDIA



context therein, shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents & successors-in interest) of the SECOND PART.

**RECITALS:**

**WHEREAS;**

- i. Sponsor is a Biotechnology company engaged inter alia in the business of manufacturing and/or marketing of various active biotechnological ingredients and biotechnological products in finished dosage forms;
- ii. The R & D centre organization engaged inter alia in the business of undertaking research & development activities, consultancy, projects and services for the pharmaceutical or similar industry.
- iii. The R & D centre has represented and warranted to the sponsor that it has the necessary skill, experience, expertise and necessary facility/infrastructure to provide the services contemplated under this agreement.
- iv. The R & D centre has also represented that it has obtained all and permissions required under law for providing the services contemplated under this agreement and that all such permissions are in full force and effect, at present and during the term of this agreement.
- v. And the sponsor has agreed to engage the R & D centre on a non-exclusive basis for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

NOW THEREFORE, in consideration of the mutual covenants set forth herein the parties agree as follows:

**1. ARTICLE 1: SCOPE OF THE AGREEMENT**

- 1.1. During the term of this agreement, the terms and conditions herein contained shall govern the services to be provided by the R & D centre to the Sponsor under any subsequent individual agreement for specific services to be rendered, referred to as a Project Contract. As a general form of contract, this Agreement allows the parties to contract multiple projects through the issuance of different Project Contracts (template attached, which could be modified from Project to Project that would require such modification necessary to complete the Project) without having to renegotiate the basic terms and conditions contained the quotation for each study will be appended to the respective Project contract.
- 1.2. The specific details of each R & D activity, consultancy, projects and services, including but not limited to timelines and payment schedules shall be negotiated in good faith and agreed upon between the parties from time-to-time and on a product-to-product basis before commencement of R & D activity, consultancy, projects and services with respect to that particular product.

**2. ARTICLE 2: STATEMENT OF WORK**





- 2.1. The R & D centre shall conduct R & D activities, consultancy, projects and services at its research facility, of the products as the Sponsor may specify in writing from time to time, in accordance with this Agreement, Project Contract, Protocol for the study and all applicable laws, rules and regulations and with the standard of care customary in the area of research for biotechnology or similar industry.
- 2.2. Should significant changes to the agreed protocol become necessary or desirable, such changes will only be made following discussion and agreement between the Sponsor and R & D centre.
- 2.3. The protocol will specify the study design, objectives, inclusion and exclusion criteria, procedures for reporting Adverse Events, statistical analysis and other relevant issues.
- 2.4. The R & D centre will at all times exercise independent research judgment as to the compatibility of each Project with the protocol requirements. It is R & D centre's responsibility to promptly notify the Sponsor of any significant deviation from the protocol and any unanticipated or Serious Adverse Event within the timeframe.

### 3. **ARTICLE 3: TERM**

- 3.1. The term of this agreement shall commence from the date of execution and shall be valid for a period of 2 (two) years of execution of this agreement, which may be extended or amended by express mutual consent of the parties conveyed in writing.

### 4. **ARTICLE 4: CONFIDENTIALITY & INDEMNIFICATION**

- 4.1. R & D centre agrees that all unpublished confidential information given to them by the Sponsor shall be kept strictly confidential by its employees, investigators and its agents and shall not be published or disclosed to a third party without the prior written consent of the Sponsor, except as required by law.
- 4.2. The provisions of this agreement shall not prevent the R & D centre from disclosing any information where it can demonstrate and document that such information:  
or
  - 4.2.1. Is or subsequently comes into the public domain other than by breach of its obligations hereunder, or
  - 4.2.2. Is lawfully received by it from a third party without restriction on disclosure or use, or
- 4.3. The obligation of confidentiality shall survive the termination of this Agreement up to 2 (two) years from the date of receipt of such information.

### 5. **ARTICLE 5: TIME FRAME**

Subject to signed acceptance of project contract, shipment and receipt of investigational material, R & D centre shall deliver a copy of the Final Report to the Sponsor as per the timelines specified in the project contract.







## 6. **ARTICLE 6: REGULATORY**

- 6.1. Sponsor shall obtain (wherever necessary) and is solely responsible for all regulatory permissions to the study.
- 6.2. R & D centre agrees to perform the study and prepare its report strictly in accordance to the in-house guidelines of the R & D centre.
- 6.3. The R & D centre certifies that it has not been debarred, and has not been convicted of a crime that could lead to debarment under the local civil laws and that it will use its best efforts not to employ any person or entity that has been so debarred or convicted to perform any services under this Agreement.
- 6.4. The R & D centre shall notify Sponsor within five (5) days in writing of any audit by the regulatory body or other government inspection or inquiry concerning any project contract conducted for Sponsor by the R & D centre.

## 7. **ARTICLE 7: MONITORING**

- 7.1. Sponsor at any time is free to depute its representatives for monitoring / auditing the study conducted at the R & D centre.
- 7.2. The Sponsor reserves the right to review or request copies of data derived from the study at the R & D centre.

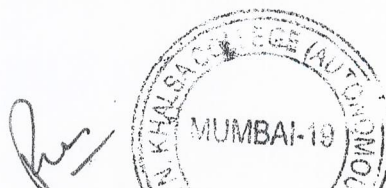
## 8. **ARTICLE 8: PAYMENT**

Sponsor agrees to pay the price and make the payments of the same in accordance with quotation/project contract and as amended from time to time upon mutual agreement and in writing as per the following:-

- a) 50% advance.
- b) 25% after completion of research/ consultancy/ projects /services /analytical part.
- c) 25% after final report.

## 9. **ARTICLE 9: INVESTIGATIONAL PRODUCTS & INDEMNITY**

- 9.1. The Sponsor shall provide, without charge, all investigational materials, working standard to be studied under this Agreement. The investigational materials shall be in appropriately marked containers. It is mutually agreed that R & D centre shall place reliance on Certificate of analysis (COA) given by the Sponsor and indemnify R & D centre against all losses, claims, or damages arising from the usage of the test and reference material within the study or otherwise, except that the foregoing indemnity shall not apply to any liability arising from R & D centre intentional deviation or omission or negligence in the performance of its obligation under this agreement.
- 9.2. The Sponsor shall guarantee that no investigational materials or standards constituting or being part of any shipment now or hereafter made to the R & D centre in connection with the study covered by this agreement will be adulterated or mislabelled. The Sponsor will attest that the investigational materials (including any reference products used in the study) provided by the







Sponsor are identical in content to the description provided in the protocol if blinded formulations are to be used, or are identical to the label description for open-label formulations, if they are to be used.

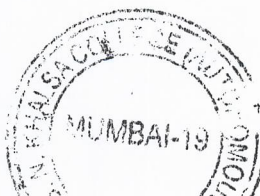
- 9.3. R & D centre agrees to keep all reference and investigational material in a locked, secured area and to maintain complete up to date records showing dispensing and returns of all reference and investigational material. R & D centre will retain samples of the test and reference products submitted by the Sponsor up to the expiry of test or reference whichever is earlier and one year after the expiry. After the retention period of reference or investigational material is completed, the Sponsor shall be offered the choice of
- 9.3.1. Storing the reference or investigational material at R & D centre at an additional cost as mutually agreed upon, or
- 9.3.2. Transporting to Sponsor's location
- 9.3.3. Destroying upon Sponsor's direction at R & D centre.

## 10. **ARTICLE 10: NON-RETENTION OF RECORDS & BIOLOGICAL SAMPLES**

- 10.1. R & D centre acknowledge that all test articles, raw data, documentation, protocols, case report forms, source documents, final reports, analysis instrument system data and biological fluids are the exclusive property of the Sponsor. All raw data, documentation, protocols, case report forms, source documents, analysis instruments system data and final reports must be submitted by R & D centre to the Sponsor on the expiry/discharge of the duties of the under this agreement, and the R & D centre shall not retain any confidential information or data therewith.
- 10.2. If required by any law or applicable guidelines, as updated from time to time, that the R & Centre shall retain the raw data, documentation, protocols, case report forms, source documents, analysis instruments system data and final reports, same shall be permitted in writing by the Sponsor.
- 10.3. In any case otherwise, R & D Centre agrees to return/handover the all the confidential information & data to the Sponsor on the completion of the term of this agreement.

## 11. **ARTICLE 11. TERMINATION**

- 11.1. Either party may terminate this agreement with or without sufficient cause upon serving the written notice to the other party. If the project is postponed or cancelled by Sponsor, the Sponsor will inform R & D centre within one week from the date of execution.
- 11.2. If the Study is terminated by a written notice by the Sponsor prior to completion but subsequent to the start date, then the Sponsor will reimburse R & D centre, all costs, and expenses till date of termination.
- 11.3. If the study is terminated without sufficient cause by R & D centre prior to completion, then R & D centre will refund to the Sponsor all amounts previously received from sponsor for the said project.





11.4. Notwithstanding the above, in case of material breach, either party may immediately terminate this agreement by serving a notice of breach to the other. Breach shall be defined as failure to comply with any material provision of this Agreement. Compensation/costs payable in such a case will be as per mutual agreement or as per the directive of the Arbitrator.

11.5. The termination or curtailment of this Agreement shall not relieve either party of its obligation to the other in respect to:

- 11.5.1. Maintaining confidentiality.
- 11.5.2. Obtaining Consent for Advertising or Publications.
- 11.5.3. Indemnification.
- 11.5.4. Compensation for services Performed.
- 11.5.5. Appropriate Reporting of any Data Obtained.
- 11.6. The R & D centre reserve the right to terminate any study where they deem such termination necessary :
  - 11.6.1. In the interest of subject safety
  - 11.6.2. In order to comply with the decision of any judicial author.
- 11.7. Compensation/costs payable in such a case will be as per mutual agreement or as per the directive of the Arbitrator.
- 11.8. The R & D centre shall return to Sponsor all report/documents /data including but not limited to the leftover/remaining consignments of the Product after the termination of the agreement or as and when required by Sponsor.
- 11.9. Return of Investigational Materials/confidential information:

All investigational materials or documents containing confidential information under this agreement which have been furnished to R & D Centre by the Sponsor shall be promptly returned, accompanied by all copies of such documentation, within five (5) days after receipt by the R & D Centre of a written notice from the Sponsor requesting the return of the Sponsor's Confidential Information.

## 12. **ARTICLE 12: FORCE MAJEURE.**

- 12.1. A party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, government action, or power failure ( a "Force Majeure Event" ) provided the affected party gives the other party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected party will be unable to perform its obligations under this Agreement. The affected party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable





continuance of such Force Majeure Event, provided that either party may terminate this Agreement if such Force Majeure Event continues for a period of ninety (90) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event.

### 13. **ARTICLE 13: LIABILITY & INSURANCE**

- 13.1. R & D centre shall secure and maintain in full force and effect throughout the performance of the study, insurance coverage sufficient to cover its exposure for professional indemnity, and general liability in the normal course of business.
- 13.2. Certificates evidencing such insurance will be made available for examination upon request by the Sponsor.
- 13.3. Any other liability and insurance shall be to the account of / covered by the Sponsor.
- 13.4. The R & D centre agrees to indemnify the Sponsor against any and all losses, damages, claims, or expenses incurred or suffered by the Sponsor as a result of the R & D Centre causing the breach of this Agreement.

### 14. **ARTICLE 14: PUBLICATION**

- 14.1. R & D centre may publish the result of scientific investigation involving the project provided that confidential and/or proprietary information of the Sponsor not publicly know is not disclosed and that the Sponsor is provided a copy of the manuscript thirty days prior to submission for publication so that it may offer comments thereon. In the event, the Sponsor asks to defer publication, R & D centre shall not publish or otherwise disclose to any third party any of the information contained in the publication until the Sponsor notifies R & D centre to the contrary.

### 15. **ARTICLE 15: PATENTS & INVENTION**

- 15.1. All data and results of the study shall be the sole and exclusive property of the Sponsor.

### 16. **ARTICLE 16: ENTIRE AGREEMENT AND ORDER OF PRECEDENCE**

- 16.1. This Agreement represents the entire understanding of the parties with respect to the subject matter of this Agreement. In the event of any inconsistency between the articles of this Agreement and the Protocol, the articles of this Agreement shall govern.
- 16.2. The parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favouring or disfavouring any party by virtue of the authorship of any of the provisions of this Agreement. Except where the context otherwise requires, where used, the singular shall







include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense.

16.3. The captions of this Agreement are only for the convenience of reference.

**17. ARTICLE 17: ASSIGNMENT**

This Agreement shall not be assigned by either party without the prior written consent of the other, to any third party.

**18. ARTICLE 18: NO PARTNERSHIP OR AGENCY**

R & D Centre relationship to the Sponsor in the performance of this Agreement is that of an independent R & D Centre. It is understood that this Agreement does not constitute

- (a) R & D Centre as the agent or legal representative of the Sponsor for any purpose whatsoever, or
- (b) R & D Centre is authorized to assume or create any obligation or responsibility, express or implied, on behalf of or in the name of the Sponsor.

**19. ARTICLE 19: SEVERABILITY**

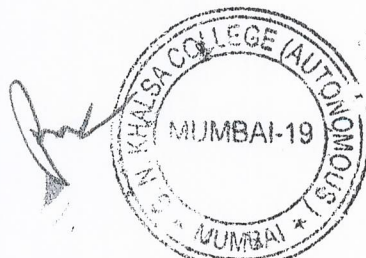
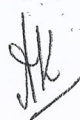
The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

**20. ARTICLE 20: NOTICE**

All Notice given under this agreement shall be in writing and shall be delivered either personally or sent fax or mail to the parties at the addresses set forth below or to such other addresses as the parties may designate in writing and by fax/mail.

<p><b>For Sponsor</b> <b>Balaji Enzyme &amp; Chemical Pvt Ltd</b></p> <p><b>Name:</b> Mr. Abhay Kainya <b>Designation:</b> Director <b>Address:</b> 113, 1<sup>st</sup> Floor, Akshay Mittal Industrial Estate, Building No. 5A, Andheri Kurla Road, Andheri (E), Mumbai- 400059, Maharashtra <b>Tel:</b> 022-460310666 <b>Direct no.:</b> 98407 58913 <b>Fax:</b> NA <b>E-mail:</b> abhay@becpl.in</p>	<p><b>For:</b> <b>Guru Nanak Khalsa College of Arts Science and Commerce</b></p> <p><b>Name:</b> Prof. Dr. Ratna Sharma <b>Designation:</b> Principal <b>Address:</b> Nathalal Parekh Marg, Opp. Don Bosco School, Matunga, Mumbai – 400019. Maharashtra <b>Tel:</b> 022-24096234 <b>Direct no:</b> 022-24096234 <b>Fax:</b> NA <b>E-mail:</b> ratna.sharma@gnkhalsa.edu.in</p>
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**21. ARTICLE 21: WAIVER**





No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition or any other term, provision or condition of this agreement.

## 22. ARTICLE 22: ARBITRATION

- 22.1. Any dispute/differences or claims under or in relation to this Agreement shall be referred to arbitration in Mumbai in accordance with the provisions of the Arbitration and Conciliation Act, 1996 of the Republic of India.
- 22.2. Arbitration proceedings will be by a sole arbitrator to be nominated by mutual consent and the award shall be final and binding on both the parties. Arbitration proceeding shall be conducted in English language.
- 22.3. Further, this Agreement shall be subject to and interpreted according to the Laws of the Republic of India and any litigation between the parties shall be brought in the court of the City of Mumbai, in India.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed and signed this Agreement as on the date first written.

For and on behalf of

**Balai Enzyme & Chemical Pvt Ltd**

For BALAJI ENZYME & CHEMICAL PVT. LTD

SIGNATURE:

*Abhay Kainya*  
DIRECTOR

NAME: Mr. Abhay Kainya

DESIGNATION: Director

SEAL:



WITNESS:

*Vasudeo Zambare*

NAME: Dr. Vasudeo Zambare

DESIGNATION: R&D Head

For and on behalf of

**Guru Nanak Khalsa College of Arts Science  
and Commerce**

SIGNATURE:

*Ratna Sharma*

NAME: Prof. Dr. Ratna Sharma

DESIGNATION: Principal

SEAL:

WITNESS:

*Gaganjyot Kour*

NAME: Dr. Gaganjyot Kour

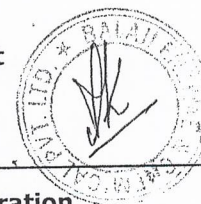
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Annexure - 1 (Project - 1)  
**Protease Cloning, expression, and Activity assay project**



**Project timeline:**

No.	Step	Tentative duration
1	Literature search and clone design	15 days to 1 month
2	Clone ordering	20 days to 1 month
3	Cloning and Transformation	1 to 2 months
4	Protein expression and Characterization	1 month
5	Activity assay analysis	1 month
	Total	5-7 months

**Project costing:**

No.	Step	Materials required	Cost
1	Literature search and clone design	-	10,000
2	Clone ordering	1. Vector - pPICZα - A	40,000
3	Cloning and Transformation	1. X-33 strain of <i>Pichia pastoris</i> 2. Yeast Media 3. Materials for Transformation and plasmid isolation IN <i>E. coli</i> . 4. Materials for Transformation in <i>Pichia pastoris</i>	1,20,000
4	Protein expression and Characterization	1. Materials for Shake flask expression of <i>Pichia pastoris</i> 2. Materials for SDS PAGE	30,000
5	Activity assay analysis (Enzymatic hydrolysis of casein)	1. Casein 2. Propylene glycol 3. Tyrosine 4. Papain	40,000
		Total	2,40,000/-

Note: This cost does not include purchasing X-33 strain of *Pichia pastoris* and vector pPICZα - A. To purchase, the cost will increase significantly.



*[Handwritten Signature]*



