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प्रधान मुद्रांक कार्यालय, मुंबई.  
 प.मु.वि.क्र. ८०००००३  
 12 OCT 2023  
 सक्षम अधिकारी

श्रीम. एल. एस. सांगळे

**CLINICAL TRIAL AGREEMENT**

This agreement is made on 30<sup>th</sup> Day of January 2024, at Mumbai between M/s. Ipca Laboratories Ltd., a company incorporated under companies Act 1913, and having its registered office at 48, Kandivli Industrial Estate, Kandivli (W), Mumbai-400067 represented by its Managing Director/CFO **Mr. A. K. Jain** (hereinafter referred to as the "Sponsor") which expression shall, where the context so permits include his successors in office and assigns.

And

**Dr. R. Sathish**, Professor, Department Of Oral And Maxillofacial Surgery, JSS Dental College and Hospital Sri Shivarathreshwara Nagar, Mysore, 570015, Karnataka, India (hereinafter referred to as the "Principal Investigator")

And

**Dr. Dhakshaini MR**, Dean and Principal, Faculty of Dentistry, JSSAHER Principal, JSS Dental College and Hospital, Mysore, Karnataka India (hereinafter referred to as the "Institute")

Signature, Stamp and Date:



(Sponsor)

(Investigator)

**Dr. R. SATHISH**  
 Professor

Dept. of Oral and Maxillofacial Surgery,  
 KSDC Reg. No.: 6889-A

**Principal**  
 (Institute)  
 JSS Dental College & Hospital,  
 Mysuru-570 015



जोड़पत्र-9 Annexure - 1

केवल प्रतिभाषासाठी Only for Affidavit (U/T)

मुद्रांक विकत घेणाऱ्याचे नाव \_\_\_\_\_

**Ipca Laboratories Limited.**

मुद्रांक विकत घेणाऱ्याचे रहिवासी पत्ता \_\_\_\_\_

Plot No. 125, Govt. Industrial Estate,  
Charkop, Kandivli (W), Mumbai-400 067

मुद्रांक दि. १२/१०/२०२३ नोंद वही अनु. क्रमांक \_\_\_\_\_

दिनांक \_\_\_\_\_

मुद्रांक विकत घेणाऱ्याची सही \_\_\_\_\_

परवानाधारक मुद्रांक विक्रीत्याची सही

परवाना क्रमांक : ८०००००३

मुद्रांक विक्रीचे नाव/पत्ता : श्री. अशोक रघुनाथ कदम

२९०, शहिद भगत सिंह रोड, लोकमल्ला २/१५, आनंद भुवन, फोर्ट, मुंबई-४०० ००९.

राजकीय कार्यालयासमोर/व्याधालयासमोर प्रतिज्ञापत्र सादर करणेसाठी मुद्रांक

आगवारी आवश्यकता नाही. (शासन आदेश दि. ०१/०७/२००४) तुसार

आ कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यांत त्गपरणे बंधनकारक आहे.

27 OCT 2023

27 OCT 2023

मुद्रांक क्रमांक ८०००००३  
दिनांक १२ OCT 2023  
मुद्रांक विक्री

CLINICAL TRIAL AGREEMENT

This agreement is made on this 12th day of October 2023 in Mumbai between M/s Ipca Laboratories Ltd, a company incorporated under companies Act 1911 and having its registered office at 48, Kandivli Industrial Estate, Kandivli (W), Mumbai-400067 represented by its Managing Director (M.D.) Mr. A. K. Jain (hereinafter referred to as the "Sponsor") whose registered office, where the contract is performed, is at its offices in office and address

And

Dr. R. Sathish, Professor, Department Of Oral And Maxillofacial Surgery, 122 Dental College and Hospital, 25th Cross, Mysore, Karnataka, India (hereinafter referred to as the "Principal Investigator")

And

Dr. Dipakshil Mr. Gan and Principal, Faculty of Dentistry, 122 Dental College and Hospital, Mysore, Karnataka, India (hereinafter referred to as the "Institute")

Dr. R. Sathish  
Professor  
Dept. of Oral and Maxillofacial Surgery  
122 Dental College & Hospital  
Mysore-570 012

Dr. R. SATHISH  
Professor  
Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6689-A



Protocol ID	Ipca/APSP/PIV-21
Protocol Title	Evaluation of Efficacy and Safety of Aceclofenac + Paracetamol + Serratiopeptidase Combination After Impacted Lower Third Molar Surgery: A Randomized, Double-Blind Comparison with Aceclofenac + Paracetamol Combination.
Protocol Version No. & Date	Version Number: 01 Version date: 01.12.2021
Sponsor	Ipca Laboratories Ltd., Mumbai
Principal Investigator	<b>Dr.R. Sathish</b>
Name of Institution	JSS Dental College and Hospital, Sri Shivarathreeswara Nagar, Mysuru-570015, Karnataka, India.

WHEREAS, the "Principal Investigator" has agreed to conduct the "Study", in accordance with the above reference protocol, any subsequent amendments in protocol and after getting prior approval from the Ethical Committee of the Institute, upon the terms and conditions set forth therein.

**NOW THEREFORE IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERE TO AS UNDER: -**

1. That the "Principal Investigator" agrees to ensure that the "Principal Investigator" and the study team will conduct the study in accordance with the Protocol, Good Clinical Practices and all applicable laws and regulations and the Declaration of Helsinki.
2. The "Principal Investigator" agrees that he has adequate time and resources to perform the study according to the quality standard required.
3. That the "Principal Investigator" agrees to enroll and complete 24 subjects, who meet the subject selection criteria described in the protocol. The total budget for this study is **Rs. 7,82,944.16/-** (Seven Lakh Eighty Two Thousand Nine Hundred Forty Four and sixty paise only Including 18% GST). The total agreed budget will be paid to "**Research A/C JSS Dental College and HOSPITAL**" with **PAN no.: AABTJ1350M** including all heads as per mentioned in approved budget.
4. The total budget is for 24 enrolled subjects completing the treatment period. The budget will be adjusted on pro rata basis.
5. **5% of the study budget will be paid at the time of initiation. This amount will be adjusted in the further payments to the site. Ethics Committee fees (with TDS) will be paid at the time of application to Ethics Committee.**
6. TDS will be deducted (as applicable) from your total budget for a transaction done on personal account or private institutes.
7. Principal Investigator has to refund the payment(s) [the gross amount of the Cheque including the TDS] made by the Sponsor if he/she fails to recruit any subject in the study and/or if the site/study members are found to be repeatedly non compliant to the study protocol and/or GCP guidelines.

Signature, Stamp and Date:



(Sponsor)

(Investigator)  
**Dr. R. SATHISH**  
Professor

Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6889-A

Principal Investigator  
JSS Dental College & Hospital,  
Mysuru-570 015



8. Payment will be released based on milestones with respect to number of enrolled patients. Last Installment will be processed after resolving Data Clarification Form and signature on Clinical Study Report.
9. The parties involved in this agreement with the Sponsor need to be a 'regular return filer' as per the GST portal. In case the status of any of the parties show 'default in return filing', the payment of the parties will be kept on hold by the Sponsor till GST compliance status as a 'regular return filer' (if applicable).
10. **Although this CTA is for 24 subjects, initial allotment of the number of subjects to the investigator's site will be at the discretion of sponsor. Also screening and enrollment of the subject will be on competitive basis across different sites and can be halted at the discretion of sponsor.**
11. That the "Principal Investigator" shall ensure the confidentiality of the subjects, protocol, and the Investigational Product (Drug) of "Study".
12. That the "Principal Investigator" shall be responsible for obtaining the clearance from the Ethical Committee of the "Institution" or as mandated by the central licensing authority.
13. The deviations from the "Study" protocol shall not be implemented by the "Principal Investigator" without the prior written approval of the institutional Ethics Committee and sponsor, unless protection of the safety and welfare of "Study" subject requires prompt action during the "Study" and the "Principal Investigator" shall inform the chairman of the Institutional Ethics Committee and sponsor within twenty four hour (24 hours) of the above said deviations. If the "Principal Investigator" feels that in his Clinical Judgment, it is necessary to promptly terminate one or more subject from the "Study", or to promptly implement reasonable alternative to, or deviate from the protocol in consideration of the safety of the "Study" subject, Institutional Ethics Committee and sponsor are to be notified of the terminations, alternatives, deviations and the reasons for such changes, and then these are to be documented in the "Study" records.
14. That once the Institutional Ethics Committee approves this trial the "Principal Investigator" shall try to ensure the recruitment of subjects and the completion of the trial in the specified period of time as are mentioned in the protocol without compromising eligibility criteria and guidelines laid down in the protocol
15. That the "Principal Investigator" shall obtain signed Informed Consent from each subject prior to inclusion of subject into the study.
16. **Payment shall be made only in respect of subjects correctly entered into the trial in accordance with the Protocol, i.e., subjects who satisfy all of the inclusion/exclusion criteria specified in this Agreement and the Protocol and commence the dosing regimen in accordance with the Protocol.**

Signature, Stamp and Date:



(Investigator)

**Dr. R. SATHISH**  
Professor

Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6889-A

Principal

JSS Dental College & Hospital,  
Mysuru-670 015




17. That for any reason, if the "Study" trial is prematurely terminated or suspended by the "Principal Investigator" he/she is responsible to inform the "Study" subject and the Institutional Ethics Committee with valid reasons.
18. The "Study" may be terminated with immediate effect upon written notice from the "Sponsor" to the "Principal Investigator" for the following reasons: -
- a. Notification to the "Sponsor" from Central or state regulatory authorities to terminate the said "Study"
  - b. Determination by the "Sponsor" that the "Principal Investigator" is not performing the "Study" as required in the protocol or if there is poor rate of randomization/ repetitive wrong enrollment/repetitive protocol violations of subjects at the site & not enrolling agreed number of subjects in stipulated time frame.
  - c. Inability or failure to perform any of the responsibilities assigned to the "Principal Investigator"

Upon receipt of notice of termination, the "Principal Investigator" shall immediately cease any study subject recruitment, follow the specified termination procedures, ensure that any required study subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and "Sponsor" shall make a final payment according to payment schedule. However, Last Installment of this final payment shall be withheld until final acceptance by "Sponsor" of all subject CRF and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

19. That the "Principal Investigator" shall review the Investigator Brochure for & on behalf of the "Sponsor", and any up to date information on the trial drug.
20. That the "Principal Investigator" shall enter the personal details of the subjects to different register/logs and will ensure that only study drug code/number assigned to subject is mentioned on the study related documents to ensure the confidentiality of study subjects.
21. That the "Principal Investigator" shall review and sign all the Case Record Forms at the appropriate space provided in the Case Record Form.
22. That any corrections in the Case Record Form are to be properly verified, signed & dated.
23. That the "Principal Investigator" shall hand over all the unfilled Case Record Forms (wherever applicable), Informed Consent Forms and the Unused Investigational Product (Drug)/Medication after the completion of the study to "Sponsor".
24. That the personal data regarding the subject being confidential in nature shall be kept in Institution.
25. That the "Principal Investigator" shall ensure the adequate facilities for subject follow-up examinations.

Signature, Stamp and Date:



  
(Investigator)  
**Dr. R. SATHISH**  
Professor

Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6889-A

  
Principal  
(Institute)  
**JSS Dental College & Hospital,**  
Mysuru-570 015



26. That the "Principal Investigator" shall ensure the adequate facilities for retention of study related documents of every subject entered in the "Study".

27. (a) That in the event of serious/severe or unexpected adverse event, the adverse reaction experiences or in the case of death of the subject, whether related to the use of Investigational product or not, the "Principal Investigator" shall be responsible for notifying "Sponsor", Chairman of the respective Institutional Ethics Committee, Head of the Institute, Central Licensing Authorities as applicable within timeline as per regulatory guidelines.

(b) That in case of occurrence of any events is stated in Clause 27 (a) the "Principal Investigator" shall inform the same to:

Dr. Anil Pareek  
President – Medical Regulatory Affairs & Clinical Research  
Ipca Laboratories Ltd.,  
142 AB, Kandivli Industrial Estate,  
Kandivli (West), Mumbai 400 067.  
Tel: 022-66474641  
Fax: 022-28686954

28. That the "Principal Investigator" shall replace the enrolled subjects who fail to complete the "Study" because they choose to drop out of the investigations, fail to keep their specified appointments, protocol violations or are discontinued by the investigator/sponsor for administrative reasons unrelated to the investigation of the drug.

29. That the "Principal Investigator" shall assure that the "Study" medication will be dispensed or administered only to subjects in the study and under his/her personal supervision, or under the supervision of an authorized co-investigators/personnel responsible to him/her.

30. That the "Principal Investigator" shall maintain all the relevant Logs mentioned in the protocol and / communicated at the time of initiation /progress of the study.

31. That the "Principal Investigator" shall maintain trial master file containing all the essential documents related to the "Study".

32. That "Sponsor" shall inform the "Principal Investigator" for any new information about the drug, which may affect subject's welfare or may influence the subject's decision to continue participation in the "Study".

33. That "Sponsor" shall provide to the "Principal Investigator" the most up to date editions of the clinical Investigator's Brochure (IB) for the Investigational Products, the protocol and a full set of Case Report Forms for each subject entered into the "Study" to document the "Study" evaluation parameters.

34. The "Sponsor" shall provide Investigational product (drug) labeled and packed for the use of investigator.

Signature, Stamp and Date



  
(Investigator)  
**Dr. R. SATHISH**  
Professor  
Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6889-A

  
Principal  
(Institute)  
**JSS Dental College & Hospital,**  
Mysuru  
Page 7 of 15

Confidential

35. That in case of trial related injury; free medical management will be provided to the subject by the sponsor as long as required and advised by the treating physician and central licensing authority. In case of trial related death and / or injury, compensation will be provided by the sponsor as recommended by the regulatory authority. The "Sponsor" will reimburse the cost of extra unanticipated tests, treatments, hospitalizations of subjects required as a result of adverse events which the "Sponsor" determines with reasonable medical certainty, to have resulted from substances dispensed or administered properly and in accordance with study protocol. The "Principal Investigator" will obtain promptly for "Sponsor," all record of such extra tests and treatments.
36. "The premium for insurance coverage shall be paid by the Sponsor as per applicable laws for the subject's injury/death including insurance through Government agency as applicable during the study".
37. That "Sponsor" shall pay all present and future liabilities in connection with the said study and shall also indemnify the "Principal Investigator" and the institution against all actions, proceedings, claims, damage, demand and expenses in relation thereto including cost, damages and expenses whatsoever in connection with any proceedings which may be taken against the "Principal Investigator" and the Institution with reference to this "Study".
- This however does not cover the act of negligence on part of the "Principal Investigator" or any other "Study" Personnel.
38. The "Sponsor" shall be free to use the results of the "Study" as it seems fit in the discovery and development of the pharmaceutical product. Other than that, no party conveys intellectual property of any kind to any other.
39. That any publication generated from the "Study" would be published with the consent of all the Investigators, and after mutual discussion and consent of the "Sponsor" and "Sponsor" will be duly acknowledged in the publication.
40. That in case of any dispute the court in Mumbai shall solely have the jurisdiction to try the matter.

Signature, Stamp and Date:



  
(Investigator)  
**Dr. R. SATHISH**  
Professor  
Dept. of Oral and Maxillofacial Surgery  
KSDC Reg. No.: 6889-A

  
Principal  
JSS Dental College & Hospital,  
Mysuru-570 015



IN WITNESS WHERE OF the Seal of M/s. Ipca Laboratories Ltd. The parties to this agreement have set their hands on the date aforementioned and Common Seal of M/s. Ipca Laboratories Ltd. has been affixed herewith. A true copy thereof signed by all the parties has been delivered to the "Principal Investigator."

**WITNESS:**

Sd/-

1. Name: **Mr. A. K. Jain,**  
Designation: **Managing Director/CFO,**  
Address: **For & On behalf of**  
**M/s. IPCA Laboratories Ltd.**  
**48, Kandivli Industrial Estate,**  
**Kandivli West, Mumbai- 400067.**

For Ipca Laboratories Ltd.

  
**A. K. JAIN**  
**Managing Director**

**30<sup>th</sup> January, 2024.**  
(Signature, Date and Stamp)



Sd/-

2. Name: **Dr. R. Sathish,**  
Designation: **Professor,**  
Address: **Department of Oral And Maxillofacial**  
**Surgery, JSS Dental College and Hospital**  
**Sri Shivarathreeshwara Nagar, Mysore,**  
**570015, Karnataka, India**


  
(Signature, Date and Stamp)

**Dr. R. SATHISH**  
**Professor**

**Dept. of Oral and Maxillofacial Surgery**  
**KSDC Reg. No.: 6889-A**

Sd/-

3. Name: **Dr. Dhakshaini.M R,**  
Designation: **Dean, Principal,**  
Address: **Faculty of Dentistry, JSS Dental College**  
**and Hospital , Mysore-570015,**  
**Karnataka India**

  
**Principal 15. 2. 24.**  
(Signature, Date and Stamp),  
**Mysuru-570 015**



Protocol ID: Ipcal/APSP/PIV-21

## Study Budget



Study Title Evaluation of Efficacy and Safety of Aceclofenac + Paracetamol + Serratiopeptidase Combination After Impacted Lower Third Molar Surgery: A Randomized, Double-Blind Comparison with Aceclofenac + Paracetamol Combination

Protocol ID: Ipcal/APSP/PIV-21

Name of Investigator: Dr. R. Sathish

Name of Institution: JSS Dental College &amp; Hospital

Number of patients (24)		Proposed Amount (Rs.) (01-24)
Heads	Investigator's Fees (Rs. 9,363.33/- per patient )X24	2,24,720.00
1	ECG (Rs. 1*100)	2400.00
2	X-ray of mandible (Rs. 1*1500)	36000.00
4	Cost of study staff	1,00,000.00
5	Phlebotomist remuneration	24000.00
6	Procedures and Consumables	38,400.00
7	Patient Conveyance and other allowance (Rs. 300*7 visits*24)	50400.00
8	Total	475920.00
9	EC fees	40000.00
10	Institutional Overhead - 10% (on Total Budget)	47592.00
11	Archival Fees (Per box 10000*2 boxes) 5 Years	100000.00
12	Total (8+9+10+11)	663512.00
13	GST @18%	119432.16
14	Grand Total(12+13)	782944.16

Note

1	The total budget is for 24 enrolled patients completing the treatment period.
2	5% of the study budget will be paid at the time of initiation. This amount will be adjusted in the further payments to the
3	Ethics Committee fees will be paid at the time of application to Ethics Committee
4	Principal Investigator has to refund the payment(s) [the gross amount of the Cheque including the TDS] made by the Sponsor if he/she fails to recruit any patient in the study and/or if the site/study members are found to be repetitively non-compliant to the study protocol and/or GCP guidelines.
5	ESR and ECG examination will be performed at the site by investigator. Cost of ECG is included in the proposed budget & will be paid as per actual visit completed by patient as mentioned in the protocol. ESR tubes will be provided by central laboratory.
6	All other investigations as per the protocol will be performed by the central laboratory and cost for the same will be paid by sponsor of the trial.
7	Blood smears, if applicable, have to be prepared at the site by investigator's study staff.
8	For laboratory investigations, site has to send the blood and urine samples to central laboratory as per the laboratory requirement. (Sample pick-up will be arranged by central lab.)
9	TDS will be deducted (as applicable) from your total budget for a transaction done on personal account or private institutes.
10	The trial will be conducted on the competitive basis for enrollment of patient at all centers.
11	The study may be terminated at sponsor's discretion, if there is poor rate of randomization/ repetitive wrong enrollment/repetative protocol violations of patients at the site.
12	The initial allotment of number of patients to the site will be at the discretion of the sponsor.

Dr. R. Sathish

Investigator's Signature, Date &amp; Stamp

Dr. R. SATHISH

Professor

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Protocol ID: Ipcal/APSP/PIV-21



Sr. No	No. of Installment	Amount As Per Installment	GST	Installment With GST	Schedule
1	1st Installment	40000.00	7,200.00	47,200.00	EC Fees
2	2nd Installment	26175.60	4,711.61	30,887.21	At the time of initiation
3	3rd Installment	78526.80	14,134.82	92,661.62	After recruitment of 08 Patients
4	4th Installment	183229.20	32,981.26	2,16,210.46	After recruitment of 16 Patients
5	5th Installment	183229.20	32,981.26	2,16,210.46	After recruitment of 24 Patients
6	6th Installment	100000.00	18,000.00	1,18,000.00	Archival Fees
		52351.20	9,423.22	61,774.42	After resolution of all DCF & Signature of PI on CSR
<b>Total</b>		<b>6,63,512.00</b>	<b>1,19,432.16</b>	<b>7,82,944.16</b>	

Dr. R. Sathish



Investigator's Signature, Date & Stamp

**Dr. R. SATHISH**  
Professor

Dept. of Oral and Maxillofacial Surgery  
NSDC Reg. No.: 6889-A