IEC
ACEAS-Independent Ethics Committee

ACEAS 001, Aradhya, Ambawadi, Ahmedabad
Gujarat-380015, India.

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+91 79 26460930, Mobile: +91 9327924927,

Vedic Lifesciences Pvt. Ltd.
118, Morya House,
Off New Link Road,
Andheri (W), Mumbai–400 053,
Maharashtra. India

22-JUL-2021

Subject: Review and approval of Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), ACEAS-IEC Protocol Approval No. **VED/P-20/22/JUL/2021,** titled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome".

This has reference to your letter dated 02-JUL-2021 for review and approval of the protocol and other documents of the above clinical study, please note that the approval letter number for this study as **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), titled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome", is **VED/P-20/22/JUL/2021**, for all sites. This is for your information only.

Regards

[redacted]

Sanchita Mitra
Member-Secretary
[redacted]

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

AMAN HOSPITAL & RESEARCH CENTER

15, Shashwat, Opp. E.S.I Hospital, Gotri Road, Vadodara - 390021.
Mob.: +91-8140375047, +91-9904402122, +91-9327925272, +91-9913279515

Study Approval letter

To,
Dr. Aman Khanna,
Aman Hospital and Research Center,
15, Shashwat, Opp. E.S.I Hospital,
Gotri Road, Vadodara-390021.

Date: 14-Jul-2021

Ref: Protocol No: UAS/201003/LPLANTARUMUALP05/IBS

Protocol Name: "A randomized, double-blinded, placebo-controlled, parallel group study of the efficacy and safety of *L. plantarum* UALp-05™ in diarrhea predominant-irritable bowel syndrome."

Sub: Letter no. AHRC/IEC/08/2021

Dear Dr. Aman Khanna,

The Institutional ethics committee of Aman Hospital and Research Center reviewed and discussed your application to conduct the clinical trial entitled "A randomized, double-blinded, placebo-controlled, parallel group study of the efficacy and safety of *L. plantarum* UALp-05™ in diarrhea predominant-irritable bowel syndrome."", an investigator initiated trial, at the IEC meeting held on 10-Jul-2021, 4:00 pm onwards at 15, Shashwat, Opp E.S.I Hospital, Gotri Road, Vadodara-390021.

The following documents were reviewed:

Sr No.	Document	Version No. and Date
1.	NDA / CSA	
2.	ClinicalTrial.gov Registration Certificate	
3.	Cnical Study Protocol	Version 1.0_Dated 23 Apr 2021
4.	Investigator's Brochure	Version 1.0_22 Apr 2021
5.	Source Document- Screening_Randomization to End of visit	Version 1.0_27 Apr 2021
6.	Unscheduled Visit	Version 1.0_27 Apr 2021
7.	Adverse Event Form	Version 1.0_27 Apr 2021
8.	Serious Adverse Event Form	Version 1.0_27 Apr 2021
9.	Protocol Deviation Form	Version 1.0_27 Apr 2021
10.	Subject Discontinuation Form	Version 1.0_27 Apr 2021
11.	Patient Information Sheet- English, Hindi, Marathi,	Version 1.0_27 Apr 2021

	Gujarati	Translated from English to Hindi, Marathi, Gujarati on 21 May 2021
12.	Patient Information Sheet- BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 26 Jun 2021
13.	Informed Consent Form - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 21 May 2021
14.	Informed Consent Form- BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 26 Jun 2021
15.	IBS-SSS Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
16.	IBS-SSS Scale - BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 26 Jun 2021
17.	APS- NRS Scale- Screening and Day0 - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
18.	APS- NRS Scale- Screening and Day0 - BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 26 Jun 2021
19.	BSS-SSS Scale - Screening and Day0 - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
20.	BSS-SSS Scale - Screening and Day0 - BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 26 Jun 2021
21.	IBS-QOL Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021

		Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
22.	IBS-QOL Scale - BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 18 Jun 2021
23.	PSS Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
24.	PSS Scale - BT- Hindi to English and Gujarati to English	Version 1.0_27 Apr 2021 Back Translated from Hindi to English and Gujarati to English on 18 Jun 2021
25.	Diet Recall Chart - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 08 Jun 2021
26.	E-CRF	Version 1.0

Dr. Himanshu Patel chaired the meeting. The list of members who attended the meeting is as follows:-

Name of Members	Position on IEC	Designation	Qualification
Dr. Himanshu Patel	Chairman	Director, International Gastro Institute	M.D. D.N.B
Dr Tushar Sonaiya	Member Secretary	Medical officer and In-charge, Infection Control Committee	M.D., Microbiology
Dr. Shreya Shah	Basic Medical Scientist	Associate Professor, Medical College Baroda	M.D. Pharmacology
Dr. Jigar Modia	Clinician	Physician	M.D., Internal Medicine
Mr. Viral Patel	Legal Expert	Advocate	B.A. L.L.B,
Mr. Piyush Patel	Social Scientist	Social Worker	B.Com.
Mrs. Manjulaben Patel	Lay Person	House wife	B.Com

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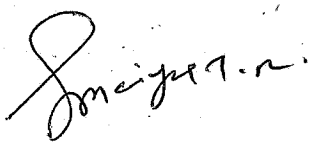
Mob.: +91-8140375047, +91-9904402122, +91-9327925272, +91-9913279515

It is hereby confirmed that neither you nor any of the study team members have participated in the voting /decision making procedures of the committee.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,



Member Secretary, Ethics Committee

Date of approval of the study: 14/Jul/2021

Harmony Ethical Research
Dedicated to excellence in healthcare

Harmony Ethical Research Committee

HERC

Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

To,

27 September 2021

Dr. Avadhoot Pandit
Shantaee Nursing Home, Charkop Bhavneet CHS.LTD.,
Ground Floor, A wing, Sector 8, Charkop, Kandivali West
Mumbai- 400 067, Maharashtra

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Avadhoot Pandit,

The meeting of the Harmony Ethical Research Committee (HERC) was held on 25th September 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Study Protocol_ V1.0_Dated 23 Apr 2021
2. IB_ V 1.0_22 Apr 2021
3. SD_ Screening Visit_ V 1.0_27 Apr 2021
4. SD_ Randomization to End of study visit _ V 1.0_27 Apr 2021
5. Unscheduled Visit_ V 1.0_27 Apr 2021
6. Adverse Event form_ V 1.0_27 Apr 2021
7. Serious Adverse Event Form_ V 1.0_27 Apr 2021
8. Protocol deviation form _ V 1.0_27 Apr 2021
9. Subject Discontinuation Form _V 1.0_27 Apr 2021
10. Patient Information Sheet_ English _ V 1.0_27 Apr 2021
11. Informed Consent Form_ English _ V 1.0_27 Apr 2021
12. IBS-SSS Scale_ English _ V 1.0_27 Apr 2021
13. APS-NRS scale _ English _ V 1.0_27 Apr 2021 (Screening and Day 0)
14. BSS Scale_ English_ V 1.0_27 Apr 2021 (Screening and Day 0)
15. IBS-QOL Scale_ English _ V 1.0_27 Apr 2021
16. PSS Scale_ English _ V 1.0_27 Apr 2021
17. Patient Information Sheet_ Hindi- V 1.0_27 Apr 2021
18. Informed Consent Form_ Hindi- V 1.0_27 Apr 2021
19. IBS-SSS Scale_ Hindi- V 1.0_27 Apr 2021
20. APS-NRS scale _ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
21. BSS Scale_ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
22. IBS-QOL Scale_ Hindi- V 1.0_27 Apr 2021
23. PSS Scale_ Hindi- V 1.0_27 Apr 2021

24. Patient Information Sheet_ Marathi- V 1.0_27 Apr 2021
25. Informed Consent Form_ Marathi - V 1.0_27 Apr 2021
26. IBS-SSS Scale_ Marathi- V 1.0_27 Apr 2021
27. APS-NRS scale _ Marathi- V 1.0_27 Apr 2021 (Screening and Day 0)
28. BSS Scale_ Marathi- V 1.0_27 Apr 2021 (Screening and Day 0)
29. IBS-QOL Scale_ Marathi- V 1.0_27 Apr 2021
30. PSS Scale_ Marathi- V 1.0_27 Apr 2021
31. Patient Information Sheet_ Gujarati- V 1.0_27 Apr 2021
32. Informed Consent Form_ Gujarati - V 1.0_27 Apr 2021
33. IBS-SSS Scale_ Gujarati- V 1.0_27 Apr 2021
34. APS-NRS scale _ Gujarati- V 1.0_27 Apr 2021 (Screening and Day 0)
35. BSS Scale_ Gujarati- V 1.0_27 Apr 2021 (Screening and Day 0)
36. IBS-QOL Scale_ Gujarati- V 1.0_27 Apr 2021
37. PSS Scale_ Gujarati- V 1.0_27 Apr 2021
38. Translation certificates - Hindi, Marathi and Gujarati
39. Dr. Avadhoot Pandit's Undertaking
40. Dr. Avadhoot Pandit's Clinical Study Agreement
41. Dr. Avadhoot Pandit's Signed and dated CV
42. Dr. Avadhoot Pandit's Signed and dated MRC
43. Dr. Avadhoot Pandit's Signed and dated GCP
44. Dr. Avadhoot Pandit's Protocol signature page
45. E-CRF- V 1.0

The list of members who attended the meeting is as follows.

- Dr. Vrushali Petkar – Chairperson.
- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
- Dr. Pranali Pandit – Clinician
- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

- Ethics Committee is approving above mentioned study in its presented form, subject to the approval of Drugs Controller General (India) & / or all the regulatory authorities if / as required. Condition if any imposed, by the DCGI or any applicable regulatory authority have to be strictly adhered to. Review and approval of the above mentioned study by HERC is not an endorsement of the study or its outcome.

- Kindly Notify following documents before initiation of the study:
  a) Study Insurance

Harmony Ethical Research Committee HERC

- It is the policy of IEC that, it be informed about any onsite serious adverse event report within 24 hours as per the SAE Reporting Format specified in applicable regulations to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to Chairperson of the IEC and the head of the institution where the trial is being conducted, within 14 days of SAE or death.

- In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the

  Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and provide financial compensation for the clinical trial related injury or death.

- No changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours
Vidulad
29 Sept 21
Ms. Vidula Shevade.
Member Secretary.

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.

Harmony Ethical Research Committee HERC

INSTITUTIONAL ETHICS COMMITTEE
RAHATE SURGICAL HOSPITAL

Near Telephone Exchange Square, 517, Juni Mangalwari, Central Avenue, Nagpur - 440 008.
Tel.: +91 712 2732266, 6536080 Fax : +91 712 2732266 Email : iecrsh@gmail.com

Date :
Date: 19/Jul/2021

To,
Dr. Prashant Rahate
Rahate Surgical Hospital, 517,
Kolbaswami Square, Old Mangalwari,
Nagpur-440008
Maharashtra
India

Ref: Submission letter dated **30 Jun 2021**

Protocol : UAS/201003/LPLANTARUMUALP05/IBS/IEC/001 : A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of *L. plantarum*UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval of Documents.

Dear Sir,

We have received the following documents.

Sr No.	Document	Version No. and Date
1.	NDA / CSA	
2.	ClinicalTrial.gov Registration Certificate	
3.	Cnical Study Protocol	Version 1.0_Dated 23 Apr 2021
4.	Investigator's Brochure	Version 1.0_22 Apr 2021
5.	Source Document- Screening_Randomization to End of visit	Version 1.0_27 Apr 2021
6.	Unscheduled Visit	Version 1.0_27 Apr 2021
7.	Adverse Event Form	Version 1.0_27 Apr 2021
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9.	Protocol Deviation Form	Version 1.0_27 Apr 2021
10.	Subject Discontinuation Form	Version 1.0_27 Apr 2021
11.	Patient Information Sheet- English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 21 May 2021
12.	Informed Consent Form - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 21 May 2021
13.	IBS-SSS Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to

INSTITUTIONAL ETHICS COMMITTEE
RAHATE SURGICAL HOSPITAL

Near Telephone Exchange Square, 517, Juni Mangalwari, Central Avenue, Nagpur - 440 008.
Tel.: +91 712 2732266, 6536080 Fax : +91 712 2732266 Email : iecrsh@gmail.com

Date :

		Hindi, Marathi, Gujarati on 10 May 2021
14.	APS- NRS Scale- Screening and Day0 - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
15.	BSS-SSS Scale - Screening and Day0 - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
16.	IBS-QOL Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
17.	PSS Scale - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 10 May 2021
18.	Diet Recall Chart - English, Hindi, Marathi, Gujarati	Version 1.0_27 Apr 2021 Translated from English to Hindi, Marathi, Gujarati on 08 Jun 2021
19.	E-CRF	Version 1.0
20.	Investigator Undertaking	
21.	CTA	

At the Ethics Committee meeting held through video conference on **19 Jul 2021 at 4:00 PM** your reference letter and above documents were examined and discussed. The EC has approved the submitted documents in its present form for the conduct of study at Rahate Surgical Hospital, 517, kolbaswami square, old Mangalwari, Nagpur-440008

The following member were present during the meeting

Sr.No.	Name of Member	Designation	Gender(M/F)	Scientific/ Non-Scientific	Affiliation with Institute (Y/S)
1	Dr. Sachin Makade	Chairman	M	Scientific	No
2	Dr. Kishore Rewatkar	Member Secretary	M	Scientific	Yes
3	Dr. Manoj Purohit	Clinician	M	Scientific	Yes
4	Adv. Vasant K. Narsapur	Legal Expert	M	Non-Scientific	No
5	Mrinalini Wankhede	Lay Person	F	Non-Scientific	No

INSTITUTIONAL ETHICS COMMITTEE
RAHATE SURGICAL HOSPITAL

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Tel.: +91 712 2732266, 6536080 Fax : +91 712 2732266 Email : iecrsh@gmail.com

Date :

The following members were absent:

1) Dr Suchet Khanzode
   (Member)

2) Dr. Devesh Dattatraya Gosavi
   (Basic Medical Scientist)

3) Mrs. Pushpa Ninave
   (Social Worker)

We confirm that neither you nor your study team members participated in the deliberations of the Ethics Committee & did not vote on the proposal for this study.
You should use copies of the ICD with the signature and seal of IEC Consultants to recruit patients for the study.
If an SAE happens at a study site approved by us, then the investigator should report the same to us within 7 days.
The Ethics Committee is constituted and works as per the ICH-GCP and ICMR guidelines.

We approve the trial to be conducted in its presented form.

Rahate Surgical Hospital
ETHICS COMMITTEE

Yours sincerely,

Authorised Signatory

Dr. Kishore Rewatkar
Member Secretary
Ethics Committee

Ethics Committee Rahate Surgical Hospital
Nagpur

Harmony Ethical Research

Dedicated to excellence in healthcare

Harmony Ethical Research Committee

Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

HERC

To,
Dr. Ramesh Dargad.
Ashokwatika CHS Ltd, Marol Pipeline Road,
Mukund Nagar, J B Nagar, Andheri (East)
Mumbai 400059.

27/05/2021

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Ramesh Dargad.

The meeting of the Harmony Ethical Research Committee (HERC) was held on 22nd May 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Study Protocol_ V1.0_Dated 23 Apr 2021
2. IB_ V 1.0_22 Apr 2021
3. SD_ Screening Visit_ V 1.0_27 Apr 2021
4. SD_ Randomization to End of study visit _ V 1.0_27 Apr 2021
5. Unscheduled Visit_ V 1.0_27 Apr 2021
6. Adverse Event form_ V 1.0_27 Apr 2021
7. Serious Adverse Event Form_ V 1.0_27 Apr 2021
8. Protocol deviation form _ V 1.0_27 Apr 2021
9. Subject Discontinuation Form _V 1.0_27 Apr 2021
10. Patient Information Sheet_ English and Gujarati_ V 1.0_27 Apr 2021
11. Informed Consent Form_ English and Gujarati_ V 1.0_27 Apr 2021
12. IBS-SSS Scale_ English and Gujarati_ V 1.0_27 Apr 2021
13. APS-NRS scale _ English and Gujarati_ V 1.0_27 Apr 2021 (Screening and Day 0)
14. BSS Scale_ English and Gujarati_ V 1.0_27 Apr 2021 (Screening and Day 0)
15. IBS-QOL Scale_ English and Gujarati_ V 1.0_27 Apr 2021
16. PSS Scale_ English and Gujarati_ V 1.0_27 Apr 2021
17. Patient Information Sheet_ Hindi- V 1.0_27 Apr 2021
18. Informed Consent Form_ Hindi- V 1.0_27 Apr 2021
19. IBS-SSS Scale_ Hindi- V 1.0_27 Apr 2021
20. APS-NRS scale _ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
21. BSS Scale_ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
22. IBS-QOL Scale_ Hindi- V 1.0_27 Apr 2021
23. PSS Scale_ Hindi- V 1.0_27 Apr 2021
24. Patient Information Sheet_ Marathi- V 1.0 27 Apr 2021
25. Informed Consent Form_ Marathi - V 1.0_27 Apr 2021

Harmony Ethical Research Committee ★ HERC

26. IBS-SSS Scale_ Marathi- V 1.0_27 Apr 2021
27. APS-NRS scale _ Marathi- V 1.0_27 Apr 2021 (Screening and Day 0)
28. BSS Scale_ Marathi- V 1.0_27 Apr 2021 (Screening and Day 0)
29. IBS-QOL Scale_ Marathi- V 1.0_27 Apr 2021
30. PSS Scale_ Marathi- V 1.0_27 Apr 2021
31. Translation certificates - Hindi, Marathi and Gujarati
32. Dr. Ramesh Dargad's Undertaking
33. Dr. Ramesh Dargad's Clinical Study Agreement
34. Dr. Ramesh Dargad's Signed and dated CV
35. Dr. Ramesh Dargad's Signed and dated MRC
36. Dr. Ramesh Dargad's Signed and dated GCP
37. Dr. Ramesh Dargad's Protocol signature page
38. E-CRF- V 1.0

The list of members who attended the meeting is as follows.

- Dr. Vrushali Petkar – Chairperson.
- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
- Dr. Pranali Pandit – Clinician
- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

- Ethics Committee is approving above mentioned study in its presented form, subject to the approval of Drugs Controller General (India) & / or all the regulatory authorities if / as required. Condition if any imposed, by the DCGI or any applicable regulatory authority have to be strictly adhered to. Review and approval of the above mentioned study by HERC is not an endorsement of the study or its outcome.

- Kindly Notify following documents before initiation of the study:
  a) Study Insurance

- It is the policy of IEC that, it be informed about any onsite serious adverse event report within 24 hours as per the SAE Reporting Format specified in applicable regulations to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to Chairperson of the IEC and the head of the institution where the trial is being conducted, within 14 days of SAE or death.

- In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the

Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and provide financial compensation for the clinical trial related injury or death.

- No changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Vidula 27/5/2021

Ms. Vidula Shevade.

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.

Harmony Ethical Research Committee ★ HERC

Harmony Ethical Research

Dedicated to excellence in healthcare

Harmony Ethical Research Committee

HERC

Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

27/05/2021

To,
Dr. Sanjeev Khanna.
Dr Khanna Clinic,
E-002, Vishal Apartment, Behind Vishal wedding hall,
Sir M. V. Road, Andheri (East) Mumbai
Maharashtra 400059

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Sanjeev Khanna,

The meeting of the Harmony Ethical Research Committee (HERC) was held on 22nd May 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Study Protocol_ V1.0_Dated 23 Apr 2021
2. IB_ V 1.0_22 Apr 2021
3. SD_ Screening Visit_ V 1.0_27 Apr 2021
4. SD_ Randomization to End of study visit _ V 1.0_27 Apr 2021
5. Unscheduled Visit_ V 1.0_27 Apr 2021
6. Adverse Event form_ V 1.0_27 Apr 2021
7. Serious Adverse Event Form_ V 1.0_27 Apr 2021
8. Protocol deviation form _ V 1.0_27 Apr 2021
9. Subject Discontinuation Form _V 1.0_27 Apr 2021
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12. IBS-SSS Scale_ English and Gujarati_ V 1.0_27 Apr 2021
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17. Patient Information Sheet_ Hindi- V 1.0_27 Apr 2021
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22. IBS-QOL Scale_ Hindi- V 1.0_27 Apr 2021
23. PSS Scale_ Hindi- V 1.0_27 Apr 2021
24. Patient Information Sheet_ Marathi- V 1.0_27 Apr 2021
25. Informed Consent Form _ Marathi - V 1.0_27 Apr 2021

Harmony Ethical Research Committee ★ HERC

26. IBS-SSS Scale_ Marathi- V 1.0_27 Apr 2021
27. APS-NRS scale _ Marathi- V 1.0_27 Apr 2021 (Screening and Day 0)
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31. Translation certificates - Hindi, Marathi and Gujarati
32. Dr. Sanjeev Khanna's Undertaking
33. Dr. Sanjeev Khanna's Clinical Study Agreement
34. Dr. Sanjeev Khanna's Signed and dated CV
35. Dr. Sanjeev Khanna's Signed and dated MRC
36. Dr. Sanjeev Khanna's Signed and dated GCP
37. Dr. Sanjeev Khanna's Protocol signature page
38. E-CRF- V 1.0

The list of members who attended the meeting is as follows.

- Dr. Vrushali Petkar – Chairperson.
- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
- Dr. Pranali Pandit – Clinician
- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

- Ethics Committee is approving above mentioned study in its presented form, subject to the approval of Drugs Controller General (India) & / or all the regulatory authorities if / as required. Condition if any imposed, by the DCGI or any applicable regulatory authority have to be strictly adhered to. Review and approval of the above mentioned study by HERC is not an endorsement of the study or its outcome.

- Kindly Notify following documents before initiation of the study:
  a) Study Insurance

- It is the policy of IEC that, it be informed about any onsite serious adverse event report within 24 hours as per the SAE Reporting Format specified in applicable regulations to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to Chairperson of the IEC and the head of the institution where the trial is being conducted, within 14 days of SAE or death.

- In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the

Harmony Ethical Research Committee ★ HERC

Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and provide financial compensation for the clinical trial related injury or death.

- No changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Vidula
27/5/2021

Ms. Vidula Shevade.

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.

Harmony Ethical Research Committee ★ HERC

Harmony Ethical Research
Dedicated to excellence in healthcare

Harmony Ethical Research Committee

Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

HERC

To,
Dr. Satish Kulkarni
Samarth Digestive Disease Centre,
405, JK Chambers, Sector 17,
Vashi, Navi Mumbai 400705.

27/05/2021

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Satish Kulkarni.

The meeting of the Harmony Ethical Research Committee (HERC) was held on 22nd May 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Study Protocol_ V1.0_Dated 23 Apr 2021
2. IB_ V 1.0_22 Apr 2021
3. SD_ Screening Visit_ V 1.0_27 Apr 2021
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Harmony Ethical Research Committee ★ HERC

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38. E-CRF- V 1.0

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- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
- Dr. Pranali Pandit – Clinician
- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

- Ethics Committee is approving above mentioned study in its presented form, subject to the approval of Drugs Controller General (India) & / or all the regulatory authorities if / as required. Condition if any imposed, by the DCGI or any applicable regulatory authority have to be strictly adhered to. Review and approval of the above mentioned study by HERC is not an endorsement of the study or its outcome.

- Kindly Notify following documents before initiation of the study:
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- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Vidula
27/5/2021

Ms. Vidula Shevade.

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.

Harmony Ethical Research Committee ★ HERC

Harmony Ethical Research

Dedicated to excellence in healthcare

Harmony Ethical Research Committee

Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

HERC

To,
Dr. Shrikant Deshpande.
Ashirwad Hospital & Research Centre
Near Jijamata Udyan, Maratha Section 32,
Ulhasnagar 4, Mumbai.

27/05/2021

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Shrikant Deshpande,

The meeting of the Harmony Ethical Research Committee (HERC) was held on 22nd May 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

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Harmony Ethical Research Committee ★ HERC

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32. Dr. Shrikant Deshpande's Undertaking
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37. Dr. Shrikant Deshpande's Protocol signature page
38. E-CRF- V 1.0

The list of members who attended the meeting is as follows.

- Dr. Vrushali Petkar – Chairperson.
- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
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- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

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- Kindly Notify following documents before initiation of the study:
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Harmony Ethical Research Committee HERC

- In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and provide financial compensation for the clinical trial related injury or death.

- No changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Vidula 27/5/2021

Ms. Vidula Shevade.

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.

Harmony Ethical Research Committee ★ HERC

IEC
ACEAS-Independent Ethics Committee

ACEAS 001, Aradhya, Ambawadi, Ahmedabad
Gujarat-380015, India.

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iecaceas@gmail.com

+91 79 26460930, Mobile: +91 9327924927,

Dr. Hardik Parikh
Principal Investigator
4th Floor, Sarvopari Mall,
Bhujangdev Circle, C. P. Nagar-1,
Parul Nagar Society,
Ahmedabad, Gujarat-380061.

22-JUL-2021

Dear Dr. Parikh,

Subject: Review and approval of Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), titled,, " A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome".

This has reference to your letter dated 02-JUL-2021 for review and approval of the protocol and other documents of the above clinical study, being sponsored by Chr. Hansen A/S, Human Health Innovation, Kogle allé 6, DK-2970.

With the understanding that the proposed clinical study, is being conducted to assess the **efficacy and safety of *L. plantarum* UALp-05™ in diarrhea-predominant-irritable bowel syndrome, and its report is NOT MEANT FOR SUBMISSON TO DRUGS CONTROLLER GENERAL (INDIA), NEW DELHI, for the purpose of registration of the product**, this ethics committee has reviewed the protocol and other related documents in its meeting held on 22-JUL-2021, in which the following members were participated:

1	Dr. Akshay. O. Parikh Chairman	5	Mrs. Sarita Kapoor, Social Scientist
2	Mrs. Sanchita Mitra, Member Secretary	6	Mrs. Nisha S. Soni, Lay Person /Non-Scientific Person
3	Dr. Anuj Kumar Jain, Clinician	7	Mrs. Kalpana D. Oza, Legal Expert
4	Dr. Parag Bhattacharya, Basic Medical Scientist-Pharmacologist		

Following documents have been reviewed in the meeting:

1. Protocol, Version No. 1.0, Dated 23-APR-2021
2. Investigator Brochure, Version No. 1.0, Dated 22-APR-2021
3. SD- Screening Visit, Version 1.0, Dated 27-APR-2021
4. SD- Randomization to End of study visit, Version 1.0, Dated 27-APR-2021
5. Unscheduled Visit, Version 1.0, dated 27-APR-2021
6. Adverse Event Form, Version No. 1.0, Dated 27-APR-2021
7. Serious Adverse Event Form, Version No. 1.0, Dated 27-APR-2021
8. Protocol deviation Form, Version No. 1.0, Dated 27-APR-2021

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

IEC
ACEAS-Independent Ethics Committee

ACEAS 001, Aradhya, Ambawadi, Ahmedabad
Gujarat-380015, India.

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iecaceas@gmail.com

+91 79 26460930, Mobile: +91 9327924927.

9. Subject Discontinuation Form, Version 1.0, Dated 27-APR-2021
10. Patient Information Sheet, English, Version 1.0, Dated 27-APR-2021
11. Informed Consent Form, English, Version 1.0, Dated 27-APR-2021
12. IBS-SSS Scale English, Version 1.0, Dated 27-APR-2021
13. APS-NRS scale, English, Version 1.0, Dated 27-APR-2021 (Screening and Day 0)
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37. PSS Scale, Gujarati, Version 1.0, Dated 27-APR-2021
38. Translation certificates - Hindi, Marathi and Gujarati
39. Investigator's EC application (Dr Hardik Parikh), Dated 02-JUL-2021
40. Investigator's Undertaking (Dr Hardik Parikh), Dated 03-JUL-2021
41. Investigator's CV (Dr Hardik Parikh), Dated 03-JUL-2021
42. Investigator's MRC (Dr Hardik Parikh), Gujarat Medical Council Registration No. 24452, Dated 29-OCT-2016
43. Investigator's GCP (Dr Hardik Parikh)
44. E-CRF- Version 1.0

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

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Gujarat-380015, India.

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All the 7 of the7 members of the committee, who reviewed the scientific and ethical aspects of the study gave a favorable opinion on the protocol and other documents, as necessary precautionary and safety measures to take care of the rights, safety and wellbeing of the study subjects have been incorporated in the same. we are pleased to grant approval to the conduct of the reviewed clinical study by you at *Vedic Lifesciences Pvt. Ltd., 118, Morya House,Opp. Infinity mall, Andheri (W), Mumbai*, subject to the following conditions:

i. this approval is valid for a period of one-year,
ii. that no subject would be admitted to the trial before necessary regulatory approvals, if required, are obtained, and other necessary documents, as applicable, are submitted to this committee,
iii. that the study will be conducted in full compliance to Good Clinical Practice guidelines and applicable regulatory requirements,
iv. the ACEAS-IEC shall do a continuing review of the progress of the trial, for which you will provide periodic updates on the progress of the same, as a part of your responsibility,
v. the ACEAS-IEC shall provide, according to the applicable regulatory requirements, expedited review and approval/favorable opinion on the minor change(s) in the trial protocol during the course of its conduct, if required,
vi. that no deviations from, or changes in, the protocol would be initiated without prior written ACEAS-IEC approval/favorable opinion on an appropriate amendment, except when necessary, to eliminate immediate hazards to the subjects or when the change(s) involve(s) only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s),
vii. that the investigator would promptly report to the ACEAS-IEC : (a) deviations from, or changes, in the protocol to eliminate immediate hazards to the trial subjects, (b) changes increasing the risk to subjects and/or significantly affecting the conduct of the trial, (c) all serious adverse events, followed by a detailed report with due analysis of the causal relationship of the event with the clinical study as per applicable regulatory requirement, and (d) new information that may adversely affect the safety of the subjects or the conduct of the trial, and
viii. that the ACEAS-IEC would promptly notify in writing the investigator/institution concerning: (a) its trial-related decisions/opinions, (b) the reasons for its decisions/opinions, and (c) procedures for appeal on its decisions/opinions.

Dr. Akshay. O. Parikh,
Chairman 22-07-21

Sanchita Mitra,
Member-Secretary
22nd July 2021

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

ACEAS-Independent Ethics Committee

ACEAS 001, Aradhya, Ambawadi, Ahmedabad
Gujarat-380015, India.

www.aceas.co.in

iecaceas@gmail.com

+91 79 26460930, Mobile: +91 9327924927,

Dr. Jignesh Patel
Principal Investigator
Apex Gastro Clinic and Hospital
B-310, Shivalic Yash,
Naranpura, Ahmedabad,
Gujarat - 380013.

22-JUL-2021

Dear Dr. Patel,

Subject: Review and approval of Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), titled,, " A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome".

This has reference to your letter dated 02-JUL-2021 for review and approval of the protocol and other documents of the above clinical study, being sponsored by Chr. Hansen A/S, Human Health Innovation, Kogle allé 6, DK-2970.

With the understanding that the proposed clinical study, is being conducted to assess the **efficacy and safety of *L. plantarum* UALp-05™ in diarrhea-predominant-irritable bowel syndrome, and its report is NOT MEANT FOR SUBMISSON TO DRUGS CONTROLLER GENERAL (INDIA), NEW DELHI, for the purpose of registration of the product,** this ethics committee has reviewed the protocol and other related documents in its meeting held on 22-JUL-2021, in which the following members were participated:

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2	Mrs. Sanchita Mitra, Member Secretary	6	Mrs. Nisha S. Soni, Lay Person /Non-Scientific Person
3	Dr. Anuj Kumar Jain, Clinician	7	Mrs. Kalpana D. Oza, Legal Expert
4	Dr. Parag Bhattacharya, Basic Medical Scientist-Pharmacologist		

Following documents have been reviewed in the meeting:

1. Protocol, Version No. 1.0, Dated 23-APR-2021
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CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

ACEAS-Independent Ethics Committee

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Gujarat-380015, India.

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9. Subject Discontinuation Form, Version 1.0, Dated 27-APR-2021
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38. Translation certificates - Hindi, Marathi and Gujarati
39. Investigator's EC application (Dr Jignesh Patel), Dated 02-JUL-2021
40. Investigator's Undertaking (Dr Jignesh Patel), Dated 03-JUL-2021
41. Investigator's CV (Dr Jignesh Patel), Dated 03-JUL-2021
42. Investigator's MRC (Dr Jignesh Patel), Gujarat Medical Council Registration No. G-18549, dated 24-NOV-2011
43. Investigator's GCP (Dr Jignesh Patel)
44. E-CRF- Version 1.0

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All the 7 of the7 members of the committee, who reviewed the scientific and ethical aspects of the study gave a favorable opinion on the protocol and other documents, as necessary precautionary and safety measures to take care of the rights, safety and wellbeing of the study subjects have been incorporated in the same. we are pleased to grant approval to the conduct of the reviewed clinical study by you at *Vedic Lifesciences Pvt. Ltd., 118, Morya House,Opp. Infinity mall, Andheri (W), Mumbai*, subject to the following conditions:

i. this approval is valid for a period of one-year,
ii. that no subject would be admitted to the trial before necessary regulatory approvals, if required, are obtained, and other necessary documents, as applicable, are submitted to this committee,
iii. that the study will be conducted in full compliance to Good Clinical Practice guidelines and applicable regulatory requirements,
iv. the ACEAS-IEC shall do a continuing review of the progress of the trial, for which you will provide periodic updates on the progress of the same, as a part of your responsibility,
v. the ACEAS-IEC shall provide, according to the applicable regulatory requirements, expedited review and approval/favorable opinion on the minor change(s) in the trial protocol during the course of its conduct, if required,
vi. that no deviations from, or changes in, the protocol would be initiated without prior written ACEAS-IEC approval/favorable opinion on an appropriate amendment, except when necessary, to eliminate immediate hazards to the subjects or when the change(s) involve(s) only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s),
vii. that the investigator would promptly report to the ACEAS-IEC : (a) deviations from, or changes, in the protocol to eliminate immediate hazards to the trial subjects, (b) changes increasing the risk to subjects and/or significantly affecting the conduct of the trial, (c) all serious adverse events, followed by a detailed report with due analysis of the causal relationship of the event with the clinical study as per applicable regulatory requirement, and (d) new information that may adversely affect the safety of the subjects or the conduct of the trial, and
viii. that the ACEAS-IEC would promptly notify in writing the investigator/institution concerning: (a) its trial-related decisions/opinions, (b) the reasons for its decisions/opinions, and (c) procedures for appeal on its decisions/opinions.

Dr. Akshay. O. Parikh,
Chairman 22-07-21

Sanchita Mitra,
Member-Secretary
22nd July 2021

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

IEC
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Dr. Rajendra P. Kushwaha
Principal Investigator
Rajsukh Medical Care Unit,
1st Floor, Om Laxmi Shopping Centre,
Opp. Radha Krishna Hotel,
Nallasopara, (E), Palghar – 401209.

11-NOV-2021

Dear Dr. Kushwaha,

Subject: Review and approval of Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), titled,, " A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome".

This has reference to your letter dated 02-NOV-2021 wherein you requested this committee to review and approve the site of **Dr. Rajendra P. Kushwaha's** for conduct of this trial along with the Protocol and related documents of the above referred clinical study. Based upon the initial approval granted to the study by this committee on 22-JUL-2021, we have reviewed:

following site related documents:

1. Application Letter, Dated 02-NOV-2021
2. Investigator Undertaking, Dated 09-NOV-2021
3. CV of the investigator
4. Registration Certificate of Maharashtra Council of Indian Medicine, Mumbai, Registration No. I-21663, Dated 02-FEB-2008
5. GCP training record

The above documents have been found to be in order. Therefore, ACEAS-IEC is pleased to approve the site related documents and accord its concurrence to the conduct of the above clinical trial project using the documents detailed above. All the conditions of this approval remain the same as those mentioned in our letter dated 22-JUL-2021.

Akshay Parikh

Dr. Akshay. O. Parikh,
Chairman
11-11-21

Sanchita

Sanchita Mitra,
Member-Secretary
11TH NOV 2021

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

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Dr. Sushil Narang
Principal Investigator
SN Gastro and Liver Clinic
403-404, Maple Trade Center,
Thaltej, Ahmedabad,
Gujarat – 380054.

22-JUL-2021

Dear Dr. Narang,

Subject: Review and approval of Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**, (Version 1.0, 23-APR-2021), titled„ " A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome".

This has reference to your letter dated 02-JUL-2021 for review and approval of the protocol and other documents of the above clinical study, being sponsored by Chr. Hansen A/S, Human Health Innovation, Kogle allé 6, DK-2970.

With the understanding that the proposed clinical study, is being conducted to assess the **efficacy and safety of *L. plantarum* UALp-05™ in diarrhea-predominant-irritable bowel syndrome, and its report is NOT MEANT FOR SUBMISSON TO DRUGS CONTROLLER GENERAL (INDIA), NEW DELHI, for the purpose of registration of the product**, this ethics committee has reviewed the protocol and other related documents in its meeting held on 22-JUL-2021, in which the following members were participated:

1	Dr. Akshay. O. Parikh Chairman	5	Mrs. Sarita Kapoor, Social Scientist
2	Mrs. Sanchita Mitra, Member Secretary	6	Mrs. Nisha S. Soni, Lay Person /Non-Scientific Person
3	Dr. Anuj Kumar Jain, Clinician	7	Mrs. Kalpana D. Oza, Legal Expert
4	Dr. Parag Bhattacharya, Basic Medical Scientist-Pharmacologist		

Following documents have been reviewed in the meeting:

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40. Investigator's Undertaking (Dr Sushil Narang), Dated 06-JUL-2021
41. Investigator's CV (Dr Sushil Narang), Dated 06-JUL-2021
42. Investigator's MRC (Dr Sushil Narang) Gujarat Medial Council Registration No. G-19663, Dated 06-MAY-2013
43. Investigator's GCP (Dr Sushil Narang)
44. E-CRF- Version 1.0

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iv. the ACEAS-IEC shall do a continuing review of the progress of the trial, for which you will provide periodic updates on the progress of the same, as a part of your responsibility,
v. the ACEAS-IEC shall provide, according to the applicable regulatory requirements, expedited review and approval/favorable opinion on the minor change(s) in the trial protocol during the course of its conduct, if required,
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viii. that the ACEAS-IEC would promptly notify in writing the investigator/institution concerning: (a) its trial-related decisions/opinions, (b) the reasons for its decisions/opinions, and (c) procedures for appeal on its decisions/opinions.

Akshay Parikh

Dr. Akshay. O. Parikh,
Chairman 22-07-21

Sanchita

Sanchita Mitra,
Member-Secretary
22nd July 2021

CDSCO Reg. No. : ECR/281/Indt/GJ/2017/RR-21 Date : 04/02/2021 & OHRP US DHHS Reg. No. IRB00011046

Harmony Ethical Research
Dedicated to excellence in healthcare

Harmony Ethical Research Committee
Shree Hospital, Kavan 70M (Central Avenue) Near Station,
Ambedkar Garden, 19th road, M. S. D. Marg, Chembur,
Mumbai, Maharashtra 400 071

HERC

To,

27 July 2021

Dr. Kapil Rathi.
Room no. 04, Ground floor, B-4
Ground Nest Society, Marol Naka,
Mumbai- 400059

Reference: Protocol Code: UAS/201003/LPLANTARUMUALP05/IBS

Study Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome

Subject: Ethics Committee Approval for above reference study

Dear Dr. Kapil Rathi,

The meeting of the Harmony Ethical Research Committee (HERC) was held on 24nd July 2021 at Shree Ethics Committee office, in the Shree Hospital with Dr. Vrushali Petkar as Chairperson.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Study Protocol_ V1.0_Dated 23 Apr 2021
2. IB_ V 1.0_22 Apr 2021
3. SD_ Screening Visit_ V 1.0_27 Apr 2021
4. SD_ Randomization to End of study visit _ V 1.0_27 Apr 2021
5. Unscheduled Visit_ V 1.0_27 Apr 2021
6. Adverse Event form_ V 1.0_27 Apr 2021
7. Serious Adverse Event Form_ V 1.0_27 Apr 2021
8. Protocol deviation form _ V 1.0_27 Apr 2021
9. Subject Discontinuation Form _V 1.0_27 Apr 2021
10. Patient Information Sheet_ English _ V 1.0_27 Apr 2021
11. Informed Consent Form_ English _ V 1.0_27 Apr 2021
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13. APS-NRS scale _ English _ V 1.0_27 Apr 2021 (Screening and Day 0)
14. BSS Scale_ English_ V 1.0_27 Apr 2021 (Screening and Day 0)
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16. PSS Scale_ English _ V 1.0_27 Apr 2021
17. Patient Information Sheet_ Hindi- V 1.0_27 Apr 2021
18. Informed Consent Form_ Hindi- V 1.0_27 Apr 2021
19. IBS-SSS Scale_ Hindi- V 1.0_27 Apr 2021
20. APS-NRS scale _ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
21. BSS Scale_ Hindi- V 1.0_27 Apr 2021 (Screening and Day 0)
22. IBS-QOL Scale_ Hindi- V 1.0_27 Apr 2021
23. PSS Scale_ Hindi- V 1.0_27 Apr 2021

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24. Patient Information Sheet_ Marathi- V 1.0_27 Apr 2021
25. Informed Consent Form_ Marathi - V 1.0_27 Apr 2021

26. IBS-SSS Scale_ Marathi- V 1.0_27 Apr 2021
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38. Translation certificates - Hindi, Marathi and Gujarati
39. Dr. Kapil Rathi's Undertaking
40. Dr. Kapil Rathi's Clinical Study Agreement
41. Dr. Kapil Rathi's Signed and dated CV
42. Dr. Kapil Rathi's Signed and dated MRC
43. Dr. Kapil Rathi's Signed and dated GCP
44. Dr. Kapil Rathi's Protocol signature page
45. E-CRF- V 1.0

The list of members who attended the meeting is as follows.

- Dr. Vrushali Petkar – Chairperson.
- Ms. Vidula Shevade- Member Secretary.
- Dr. M. Mahajan- Basic Medical Scientist.
- Dr. Rohan Deshmukh- Clinician.
- Dr. Pranali Pandit – Clinician
- Ms. Manali Srikrushna – Social Worker.
- Mr. Eshan Khaire – Legal person.
- Ms. Anita IP – Lay Person

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC hereby gives approval to the proposal entitled, "A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of L. plantarum UALp-05™ in diarrhea-predominant-irritable bowel syndrome."

- Ethics Committee is approving above mentioned study in its presented form, subject to the approval of Drugs Controller General (India) & / or all the regulatory authorities if / as required. Condition if any imposed, by the DCGI or any applicable regulatory authority have to be strictly adhered to. Review and approval of the above mentioned study by HERC is not an endorsement of the study or its outcome.

- Kindly Notify following documents before initiation of the study:
  a) Study Insurance

Harmony Ethical Research Committee HERC

- It is the policy of IEC that, it be informed about any onsite serious adverse event report within 24 hours as per the SAE Reporting Format specified in applicable regulations to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to Chairperson of the IEC and the head of the institution where the trial is being conducted, within 14 days of SAE or death.

- In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the

  Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and provide financial compensation for the clinical trial related injury or death.

- No changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

- For all studies undertaken by you, you will have to submit the yearly progress report for continuing assessment of the study.

A copy of the final study report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, New CT Rules 2019, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Vidula 28/07/21

Ms. Vidula Shevade.
Member Secretary.

Harmony Ethical Research Committee ★ HERC

Member Secretary
Harmony Ethical Research Committee
Shree Hospital, Chembur,
Mumbai - 400 071.