SPONSOR
JEENA SIKHO LIFECARE LIMITED

CLINICAL RESEARCH ORGANIZATION
MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

MGCTS/24/443

Study Title: "An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

Clinical Study Report

Title Page

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Protocol No.	MGCTS/24/443
Version Number and Date	1.0 DATED 19 Dec 2024
Investigational Product	Shuddhi XS Syrup
Name & Address of Sponsor	Jeena Sikho Lifecare Limited
Name & Affiliation of the Investigator (s)	Name: Dr Mansoor Designation: Principal Investigator Affiliation: CCFT Laboratories E-mail: mansoor25riyaz@gmail.com
Date of First patient in the study	19 April 2025
Date of Last patient follow up	23 May 2025
No. of patients	60
Report Number	MGCTS/24/443
Date of the draft report	11 June 2025
Date of Final Report	12 June 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Jeena Sikho Lifecare Limited no part of it is to be disclosed to the others without prior written permission from Jeena Sikho Lifecare Limited. This study was performed in accordance with ICH E6 R2, Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.

INVESTIGATOR(S) SIGNATURE(S)

A Clinical study titled: “An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation.”

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name: Dr. Mansoor Riyaz **Designation:** Principle Investigator CCFT Laboratories, Meerut	 12-06-2025 SIGNATURE & DATE

STATEMENT OF COMPLAINCE

"An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	**Designation & Address**	**Signature**	**Date (DD MM YYYY)**
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		12-06-2025

STATEMENT OF COMPLAINCE

(DATA SAFETY MONITORING BOARD)

A Clinical study titled: "An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MM YYYY)
1	NIDHI DIXIT Study Director CCFT- Meerut		12-06-2025
2	Ms. Sheetal, Data Management Associate CCFT- Meerut		12-06-2025

REPORT SUMMARY:

Title of the Study	An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation.
Name of Investigational product	Shuddhi XS Syrup
Name of Sponsor	Jeena Sikho Lifecare Limited
SITE	1st Floor room 3, CCFT laboratories, AR multispecialty hospital and research center, Delhi Road, Meerut UTTAR PRADESH
Investigator (s)	Dr. Mansoor Riyaz
Study Objective	**Primary objective:** The primary objective is to study the efficacy and safety of DR. Shuddhi XS Syrup with- • Subject Self-Assessment
Study Phase	NA
Study Design	An open label single arm study. Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed. Patients will be assigned to investigational product for 1 day, following up on 2nd day. The Bristol Stool Form assessment was conducted during Visit 1, and the subject's self-assessment was completed during Visit 2  **Subject Self-Assessment**

	1. Do you agree that this syrup helps relieve constipation? 2. Do you agree that it increases the frequency of your bowel movements? 3. Have you noticed an improvement in abdominal pain? 4. Do you agree that your stool becomes looser after taking the syrup? 5. Do you agree that this syrup does not taste bad? 6. Do you agree that this syrup works quickly? 7. Do you agree that this syrup does not cause any sensitivity?
Sample Size	60 Subjects
Study Inclusion Criteria	**Inclusion Criteria** Subjects must meet all the following criteria to be eligible for participation in the trial: 1. Subject from 18-65 years of age. 2. Subject having problem in passing stool. 3. Subjects that are able to give written informed consent in a manner approved by the institutional ethics committee and comply with the requirements of the study. 4. Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.
Study Exclusion Criteria	**Exclusive Criteria:** • Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids. • Subjects that have participated in any other interventional clinical trial in the previous 90 days. • Heart patients will no enrolled. • Subjects with known sensitivity to any of the constituents of the investigational product. • Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.

	• Chronic illness which may influence the outcome of the study. • Pregnant/nursing mothers
Test Product Study Product, Dose	**Test Product**: Shuddhi XS Syrup **Dose:** 20ml shot before bedtime **Route of Administration:** Oral
Clinical assessment and Laboratory Assessment	• Subject Self- Assessment) • Bristol Stool Form
Outcome Measures	**Primary Outcome Measures:** **Efficacy:** • Change in Subject Self- Assessment [Timeframe 1-2days] **Safety**: • Adverse Events • Tolerability of Shuddhi XS Syrup
SAFETY EVALUATION	Incidence of AE
Statistical Analysis	The study was done as a consumer test based on patient/subjects evaluation only, and therefore the results will be represented as % of population observing the change, and not parameter based, therefore, the actual trial statistics is not applicable for the same.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's Committee. The trial was conducted as per ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.
Efficacy and Safety Results	Out of 60 subjects screened, none were found dropout, no screen failure. 60 subjects who underwent the full trial period. The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study. Data from 60 patients who completed the study were analyzed. A special assessment was done in the first visit for the Bristol stool

	scale to identify and group as per the type of stool. 47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool. The assessment for efficacy involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change. 92% of the users observed that the syrup helps relieving the constipation. 82% users agree that it increases the frequency of their bowel movements. 92% users noticed an improvement in the abdominal pain. 87% users felt their stool to loosen after taking the syrup. 55% users liked the taste of the test product. 92% users felt that it works quickly. 85% users observed no sensitivity post taking the test product. No adverse event was reported during the study. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication. There were no protocol violations and deviations reported. There were no patients who lost to follow up. None of the patients withdrawn the consent.
Conclusion	In conclusion, Shuddhi XS Syrup showed laxative properties, making stool smooth and more frequent along with reduction in the constipation related pain. No, adverse events were observed during the study.
Date of Report	12 June 2025

Contents

List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
BOCF	Baseline observation carried forward
CI	Confidence interval
CRO	Contract Research Organisation
ECG	Electrocardiogram
CRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IP	Investigational product
IEC	Institutional Ethics Committee
ITT	Intent to treat
MI	Multiple imputation
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over the counter
PP	Per protocol
PRO	Patient-reported outcome
QOL	Quality of Life
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SGA	Subject's global assessment
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
UPT	Urine pregnancy test

Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of the signed informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

Investigators and Study Administrative Structure

Sponsor	Jeena Sikho Lifecare Limited
Principal Investigator (S)	Dr. Mansoor Riyaz
ETHICS COMMITTEE (S)	INSITUTIONAL ETHICS COMMITTEE
SITE(S) ADDRESS	1st Floor room 3, CCFT laboratories, AR multispecialty hospital and research center, Delhi Road Meerut UTTAR PRADESH
NAME AND ADDRESS OF LABORATORY	SAME AS ABOVE

1. INTRODUCTION

1.1. Background

Constipation is a common digestive condition characterized by infrequent, difficult, or painful bowel movements. It often involves passing hard or dry stools and may be accompanied by abdominal discomfort or bloating. Causes can include a low-fiber diet, dehydration, lack of physical activity, or certain medications. While occasional constipation is usually not serious, chronic cases may require medical evaluation to rule out underlying issues. Maintaining a healthy diet, staying hydrated, and exercising regularly can help prevent and manage constipation effectively.

1.2. Rationale of the Trial

To determine the benefits from Dr. Shuddhi XS Syrup with these following ingredients:

1. Cassia fistula
2. Cassia senna
3. Phyllanthus emblica
4. Terminalia chebula
5. Terminalia bellirica
6. Stevia rebaudiana

1.3. Benefit-risk Assessment

The subject population will be composed of healthy volunteers.

The active ingredients in the investigational products are known to be effective for the skin hydration and barrier function. The safety and efficacy profiles for marketed products with these ingredients are well known.

It would be safe to assume that the risk factor in this clinical trial is minimal. However, the trial is designed to record any adverse event that may take place as well as handle any complication that may arise during the trial.

2. TRIAL OBJECTIVES AND PURPOSE

2.1. Primary objective

The primary objective is to study the efficacy and safety of DR. Shuddhi XS Syrup with-

- Subject Self-Assessment

3. TRIAL DESIGN

3.1. Overall Trial Design

An In-vivo study

Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed.

Patients will be assigned to this study for 1 day in which Day 0 (Visit 1/Screening) done for screening purpose and handover the IP to the Subjects, and measure Bristol Stool Form.

The next visits- day 2, only Subject Self-Assessment will be measured.

3.2. Trial Endpoints

3.2.1. Endpoints

Efficacy:

Primary Outcome Measures:

<u>Efficacy</u>:

- Change in Subject Self- Assessment [Timeframe 1-2days]

<u>Safety</u>:

- Adverse Events
- Tolerability of Shuddhi XS Syrup

4. SELECTION OF TRIAL POPULATION

4.1. Subject Population

Subjects (60 in no.) were enrolled for the primary analysis. An individual subject was allowed to participate in the trial one time only.

Each potential subject signed and date an informed consent document before any trial-specified procedures was performed. Subjects were provided authorization for use of their personal data in accordance with the applicable regulations regarding privacy and data protection.

4.2. Inclusion Criteria

Subjects must meet all the following criteria to be eligible for participation in the trial:

- Subject from 18-65 years of age.
- Subject having problem in passing stool.
- Subjects that are able to give written informed consent in a manner approved by the Institutional ethics committee and comply with the requirements of the study.
- Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.

4.3. Exclusion Criteria

- Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids.
- Subjects that have participated in any other interventional clinical trial in the previous 90 days.
- Heart patients will no enrolled.
- Subjects with known sensitivity to any of the constituents of the investigational product.
- Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.
- Chronic illness which may influence the outcome of the study.
- Pregnant/nursing mothers

4.4. Discontinuation of Treatment

In accordance with legal requirements and International Conference on Harmonization (ICH) – Good Clinical Practice (GCP) guidelines, every subject has the right to refuse Further participation in this trial at any time and without providing. A subject's participation is to be terminated immediately upon his/her request. The investigator should seek to obtain the reason and record this on the electronic case report form (eCRF) whenever possible.

If, at the time of refusal, a trial product has already been administered, the investigator should advise the subject on follow-up safety evaluations.

In the case of an SAE or development of a condition that would have met the trial safety-related exclusion criteria, the subject should be evaluated by the investigator. The investigator should use his/her discretion to determine whether the subject should continue

treatment with the IP.

A subject may be withdrawn from the trial at any time at the discretion of the investigator. The reasons for early termination are to be fully documented on the CRF.

In addition, sponsor reserves the right to end or suspend the trial at any time.

If a subject withdraws from the trial, all efforts will be made to complete a final evaluation if possible. The withdrawal procedures for subjects who withdraw during the treatment period are the same as those for the End of Treatment visit. Subjects discontinued for an AE will be monitored until the AE is resolved, a reasonable explanation is provided for the event, or the subject is referred to his/her own primary medical doctor. The specific AE in question will be recorded on the appropriate CRF.

4.5. Replacement Policy

After trial enrolment has been completed, subjects who prematurely discontinue the trial after were not replaced.

5. TRIAL TREATMENTS

5.1. Investigational Product

Shuddhi XS Syrup

5.2. Dosing Regimen

20ml shot during bedtime.

5.3. Dose Modification

Subjects classified as clear at on actual visits may stop the treatment at the investigator's discretion. They should remain in the trial and attend visits up to whole trial.

5.4. Packaging, Labeling, and Storage

Medication labels for the IPs will comply with the legal requirements of the country where the trial is performed and be printed in the local language.

The IPs will be supplied by the **Jeena Sikho Lifecare Limited** designated vendor and stored securely at the site under the control of the investigator. The temperature will be monitored and documented.

The cream was supplied to the clinical site. The product to be protected from sunlight,

stored in a cool and dry place at a temperature of 25°C (below 77°F) at the site, and below 25°C (below 77°F) after dispensing to the subject however the product must not be refrigerated.

5.5. Prior, Concomitant, and Prohibited Therapy

All medications, including over-the-counter (OTC) drugs, taken within 30 days prior to the start of the trial were recorded at Screening. Thereafter, a record of all medications and supportive therapy taken during the course of the trial was made. Information regarding the total daily dose, route of administration, start and discontinuation dates, and indication were recorded on the subject's CRF.

5.5.1. Washout of Prohibited Medications Prior to Enrollment

A washout period of up to 2 weeks was completed if the subject has been treated with any medication as specified in the exclusion criteria.

5.5.2. Prohibited Medications during the Trial

Use of any medication that would exclude the subject from participation in the trial (as specified in Section 5.2 Exclusion Criteria) is also prohibited during the treatment which includes medications in the following categories:

Patients should not use any form of the topical interventions

5.5.3. Rescue Medication

In case the patient does not respond to the treatment, any other medication as judged by the Investigator would be better for the subject will be given to subjects. No other concomitant medicine will be allowed except study drug and rescue medication throughout study duration.

5.6. Treatment Compliance

Records of trial product used and dosages administered were kept during the trial. The trial monitor has noted product accountability during site visits and at the completion of the trial.

At all on-treatment visits, the subjects were asked if he/she has used the medication as prescribed. If this is not the case, the degree and nature of noncompliance was specified. In addition, subjects were asked to complete a dosing diary during the treatment period as a

measure of treatment compliance.

Subjects who are consistently noncompliant were counseled.

Subjects were asked to return all used and unused bottles in the outer box at each visit. All returned bottles that had been dispensed to a subject were weighed to determine the amount of the IP used per treatment phase.

6. VISIT SCHEDULE AND ASSESSMENTS

Trial Procedures

The visit schedule and assessments are summarized in Table 1.

Visit	Screening and Visit1(Baseline-Day0/1)	Visit 2 (Follow up-Day 2)
Informed consent	X	
Inclusion/ exclusion criteria	X	
Demographics, medical history	X	
Concomitant medication	X	
Concurrent diagnoses	X	
Physical Exam	X	
Vital signs	X	
Pregnancy test	X	
Subject Self-Assessment		X
Bristol Stool Form Scale	X	
Dispensing IP	X	
AE \ SAE Reporting		
Compliance	X	
Return of all trial Materials		

Table 1: Visit Schedule and Assessments

6.1 Trial Visits and Assessments

Visit 1/Baseline (Day 0):

Screening procedures should be completed no more than 1 days prior to Visit 1/ (Day 0).Visit 1/Screening and Visit 1/Baseline can occur on the same day if no washout of prohibited medications is required. The following screening procedures will be performed at the screening visit:

- Review trial information with subject and obtain written informed consent.
- Review inclusion and exclusion criteria with the subject to determine the subject's eligibility.
- Collect medical history;
    - other allergic history if the subject received concomitant medication for this condition
    - If subject participated in skin related study within last two months
- Review and record any current medical diagnoses.
- Perform the following assessments:
    - Bristol Stool Form Assessment
- Perform a urine pregnancy test (UPT) in female subjects of childbearing potential and instruct these female subjects to use approved form(s) of contraception.
- If the Visit 1Screening or Visit 1/Baseline (Day 0) procedures are being performed on the same day, perform the procedures specified in Table 1:

Visit 2/Day2

Take Vital signs (Body temperature systolic and diastolic blood pressure and heart rate and pulse rate).

Perform the following assessments:

- Subject Self-Assessment

Early Termination

If a subject withdraws from the trial prior to the Visit 2 (End of Treatment) visit, the subject is to return to the site for assessment of any post exposure AE.

Unscheduled Visit and Telephone Calls

An unscheduled visit may be performed at any time during the trial if judged necessary by the Investigator, such as for a severe reaction and clinically significant AE. Details of the event must be recorded in the subject's records.

Investigator Assessments

The investigator assessments are to be performed by a dermatologist, a dermatologist with at least 1 year of experience in dermatology. For dermatologist and dermatologist Assistants who do not fulfill the requirement regarding dermatologist experience and other state licensed professionals who have the ability to diagnose, treat and prescribe medications, the person must be preapproved by the sponsor. The assessments are to be performed as specified in the visit schedule (Table 1).

Assessment of Safety Adverse Events

Adverse Events Assessments

The investigator or designee was responsible for obtaining, assessing, and documenting all AEs during the study. Adverse Events information were collected from the time of the signature of the informed consent form until the end of the study. An AE is an untoward medical occurrence in any subject during the trial which does not necessarily have a causal relationship with the trial drug treatment.

All were will be documented in the CRF, including a description of each AE, AE relationship to trial product administration, start and stop dates, seriousness, severity, action taken and outcome.

Any AE that meets the serious criteria must be reported on the CRF and on a separate SAEs report form. SAEs must be reported to the Ethics Committee within 24 hours of awareness.

Throughout the trial, the occurrence of AEs should be sought by nondirective questioning of the subject at each visit during the trial. Information on AEs can also be obtained from signs and symptoms detected during examination, observations made by the trial site personnel, or spontaneous reports from subjects. Pre-existing conditions that worsen during the trial should also be recorded as AEs.

AEs requiring therapy must be treated with recognized standards of medical care to protect the health and well-being of the subject. Treatment due to an AE will be recorded in the subject's records and on the appropriate CRF.

Any AE that is considered related to the trial product must be followed by the investigator until it is resolved or until the medical condition of the subject is stable; all relevant follow-up information will be reported to the Sponsor/CRO or designee.

The outcome of an AE was classified as recovered, recovered with squeal, recovering/resolving, ongoing, or death.

No AE were observed in the study in either of the arms.

Timing

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and first trial-related activity performed.

Severity of Adverse Events

The investigator is to classify the severity (intensity) of an AE according to the following definitions:

- Mild – The subject was aware of the signs and symptoms but the signs and symptoms were easily tolerated and does not interfere with daily activity.
- Moderate – The signs and symptoms were sufficient to restrict, but did not prevent, usual daily activity for the subject. The subject is still able to function.
- Severe – The subject was unable to perform usual daily activity.

The maximum intensity of an AE (mild, moderate, or severe) will be assessed taking into account the possible range of intensity of the symptom(s).

Relationship of an Adverse Event to Trial Treatment

The investigator is responsible to assess the relationship of an AE to the IP using good clinical judgment and the following definitions:

Not Related	The AE is clearly explained by another cause not related to the trial product administration; the temporal relationship of the AE to IP administration makes a causal relationship unlikely, or, concomitant medication, therapeutics interventions, or underlying condition providea sufficient explanation for the observed AE
Possibly Related	The AE and administration of trial product are temporally related, but the AE can be explained equally well by causes other than the trial product administration
Probably Related	The AE and use of trial product are temporally related, and the AE is more likely explained by trial product administration than by other causes
Definitely Related	The AE and trial product administration are related in time, and a direct association can be demonstrated. Concomitant medication, therapeutics interventions, or underlying conditions do not provide a sufficient explanation for the observed AE

Unexpected Adverse Events

Any AE assessed as related to the IP will be assessed for expectedness by the sponsor or designee. An AE is considered ―unexpected‖ if its nature or severity is not consistent with information in the Investigator's Brochure.

―Unexpected as used in this definition, also refers to AEs that are mentioned in the Investigator's Brochure or product prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

Trial Medication Overdose

An overdose of the IP, i.e., a dose that is higher than the highest dose under clinical investigation or the known therapeutic dose, will be fully documented even if no

toxic effects were observed and will be considered as an AE.

Serious Adverse Event

An SAE is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect, or is an important medical event?
- Other serious or important medical event

The death of a subject enrolled in a trial is per se not an event, but an outcome. Any event resulting in a fatal outcome must be fully documented and reported, regardless of the causality relationship to the IP.

Any medical important events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based on appropriate medical judgment, jeopardize the subject, or the subject may require medical or surgical intervention to prevent one of the outcomes listed in the above definitions.

Any pre-planned hospitalizations that are known at the time of signing the ICF will not be recorded as SAEs, however they will be recorded as AEs only.

Any SAE, whether or not deemed drug-related or expected, must be reported immediately to the Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of an SAE). The investigator will document such events in the best possible detail on the SAE Report Form.

A suspected unexpected serious adverse reaction (SUSAR) is an SAE that is both unexpected (not consistent with the current Investigator's Brochure) and for which there is evidence to suggest a causal relationship between the drug and the SAE. The Institutional Ethics Committee (IEC) will be informed of SUSARS according to local requirements. All investigators participating in the trial will also be notified of unexpected SAEs. The sponsor or designee will report SAEs and other events requiring expedited reporting to regulatory authorities as required.

Investigator instructions for reporting SAEs.

Vital Signs

At all the visits, the investigator or designee will take measurements of vital signs, including blood pressure and heart rate (pulse) with the subject in the sitting position with approximately5 minutes rest prior to measurement. The same arm is to be used for all measurements.

Physical Examination

At Visit 1/Baseline the investigator or designee will complete a general physical examination including measurements of height (at screening only) and weight (with indoor clothing and without shoes) and on visit 2, the investigator also takes all the vitals and examine any delayed erythema response on the site.

During the trial, any new clinically significant findings of signs/symptoms that could indicate systemic safety will be reported as AEs.

Appropriateness of Measurements

The assessments to be used in this trial are the standardized and most widely accepted methods for acne testing as per guidelines.

7. Statistical Methods and Analytical Plans

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) was written describing all analyses that will be performed. Data was analyzed using a combination of NCSS & R software version 2.15.0 (R Development core team, R Foundation for statistical computing, Vienna, Austria) with appropriate statistical test. The SAP may contain any modifications to the analysis plan described below.

7.1. Data Sets Analyzed

All eligible patients who are included into the study and receive single dose on same day of the study

7.2. Demographic and Baseline Characteristics

The following demographic variables at screening were summarized by dose level: race, gender, age, height and weight.

7.3. Analysis of Endpoints

All data will be expressed as percentage of subjects with improvement in the condition, with no statistical Safety and tolerability data was summarized by treatment group.

Adverse event rates were coded by body system and MedDra classification term. Adverse events were tabulated by treatment group and include the number of patients for whom the event occurred, the rate of occurrence, and the severity and relationship to study drug.

7.4. Sample Size

Sample size for this protocol is 60. The eligible patients will be assigned to study drug randomly and there is no need of randomization in it.

8. CHANGES IN THE PLANNED TRIAL

8.1. Protocol Amendments

Except for administrative changes, any changes or additions to this clinical trial protocol require a written protocol amendment that must be approved by the IEC before implementation.

These requirements for approval should in no way prevent any immediate action from being taken by the investigator or SPONSOR/CRO in the interests of preserving the safety of all subjects included in the trial. If an immediate change to the protocol is felt to be necessary by the investigator and is implemented for safety reasons, SPONSOR/CRO or designee should be notified and the IEC should be informed according to their reporting requirements.

8.2. Termination or Suspension of the Trial

SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and s about the premature termination or suspension, including the reason for it. In terminating the trial, SPONSOR/CRO and the investigator should ensure that adequate consideration is given to the protection of the subjects' interests.

9. DATA HANDLING AND RECORD KEEPING

9.1. Recording of Data

9.1.1. Source Documents

Source data are all the information in original records and copies of original records of clinical findings, observations, or other activities in the trial, which are necessary for the reconstruction and evaluation of the trial. The identification of any data to be recorded directly on the CRFs is to be considered source data.

Trial data collection procedures must ensure that each data element can be traced with a high level of confidence from its originator or recorder to its representation in the trial database and then to its place in the analysis and report of trial results. Once recorded, the trial data must be protected from unauthorized modification or deletion, and all authorized modifications and deletions must be securely linked in the permanent record with their author, time of change, and reason for change (i.e., the audit trail must be maintained).

The investigator should permit trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records.

The principal investigator should certify the data to be accurate and complete and release the data for transmittal to SPONSOR/CRO or designee.

Source records need to be preserved for the maximum period of time permitted by local requirements. For each subject enrolled, the investigator will indicate in the source record(s) that the subject participated in the trial.

9.1.2. Case Report Forms

The primary data collection tool for the trial is a CRF designed specifically for the trial. For each subject enrolled in the trial, a CRF was completed by the trial coordinator and signed by the investigator or his/her designate.

The investigator was responsible for ensuring the accuracy of all data entered in the CRFs. All CRFs are to be completed in a timely manner.

Errors occurring in the CRFs were queried. Queries raised by data reviewers must be addressed by site personnel.

On request, the investigator should provide the SPONSOR/CRO with additional data relating to the trial, or copies of relevant source records, duly anonymized (i.e., subject's name is redacted).

9.2. Retention of Documents

The investigator should take responsibility for maintaining adequate and accurate source documents of all observations and data generated during this trial, including any data clarification forms received from the SPONSOR/CRO or designee. Such documentation is subject to inspection by the sponsor or its agents, the FDA and/or other regulatory agencies. The investigator is responsible for retention of essential documents including the Investigator Trial File until SPONSOR/CRO informs the investigator that the documents are no longer to be retained or longer if required by local regulations.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.1. Direct Access to Source Documents

As specified in the investigator's agreement, the investigator agrees to allow trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records, and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any issues.

10.2. Monitoring Procedures

The Clinical Trial Monitor will contact and/or visit the investigator site periodically to verify the adherence to the protocol, the maintenance of trial-related source records, and the completeness and accuracy of all CRF entries compared to source data. The investigator will cooperate with the trial monitor to ensure that any discrepancies that may be identified are resolved.

10.3. Audit and Inspection

The investigator has made all the trial-related source data and records available to a quality assurance auditor mandated by the sponsor, or to domestic or foreign regulatory inspectors, after reasonable notice. The main purposes of an audit or inspection are to confirm that the rights and well-being of the subjects have been adequately protected, and that all data relevant for the evaluation of the IP have

been processed and reported in compliance with GCP/ICH and applicable regulatory requirements.

The investigator has to notify the SPONSOR/CRO or designee immediately of any inspection by regulatory authorities.

11. ETHICS

11.1. Ethical Conduct of the Trial

This trial must be carried out in compliance with the protocol and the applicable laws and regulatory requirements of the appropriate regulatory agency. The trial must be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and amendments and the ICH-GCP guidelines.

11.2. Institutional Ethics Committee (IEC)

This protocol, the proposed informed consent form, and other information for subjects must be reviewed and approved by an IEC, before the start of the trial, in compliance with local regulations. This committee must also approve any amendments to the protocol, other than administrative ones, before initiation of the amendment procedures. This protocol was approved dated 24 December 2024 by ARMHRC Institutional Ethics Committee.

11.3. Subject Information and Consent

Before participation in the trial, each subject or guardian is required to provide written consent to participate in the trial. No trial-specific procedures should be performed before a subject’s informed consent is obtained.

11.4. Disclosure and Confidentiality

11.4.1. Confidentiality of Trial Documentation

By signing the protocol, the investigator agrees to keep all information provided by the sponsor in strict confidence and to request similar confidentiality from his/her staff and the or IEC. Trial documents provided by the trial sponsor (i.e., protocols, Investigators' Brochures, CRFs and other material) should be stored appropriately to ensure their confidentiality. The information provided by the sponsor to the investigator may not be disclosed to others without direct written authorization from the sponsor, except to the extent necessary to obtain informed consent from subjects who wish to participate in the trial.

11.4.2. Privacy of Individual Health Information

The investigator should undertake to protect the privacy of all individually identifiable health information except as specifically authorized by each individual subject through the written informed consent. The Informed Consent document should include a request of the subject's consent to release the collected data for research purposes in such a way that the individual's identity remains masked. While all data records should be identified by the corresponding subject number, the identity of the subject will be held in confidential source documents at the trial site. All trial personnel with access to this information are legally bound not to disclose such information.

11.5. Reporting of Serious Adverse Events and Pregnancies

11.5.1. Contact Person(s) and Number(s)

SAEs and pregnancies must be reported immediately (i.e., not later than 24 hours after first knowledge). The SAE or pregnancy report should be e-mailed or texted to IEC and Sponsor using the following phone number:

Name: Markandey Tiwari

Phone: +91 81270 80666

11.5.2. Reporting Procedures

Serious Adverse Events

For each SAE, the investigator should complete a Serious Adverse Event Report Form and assess the relationship of each SAE to trial treatment. The completed form(s) should be sent electronically to the UBC using the SAE Reporting fax number within 24 hours of first knowledge of the SAE.

Follow-up reports regarding the status of the SAE and the subject's subsequent course should be submitted until the SAE has subsided, the condition stabilized (in the case of persistent impairment), the subject receives alternative therapy, or the subject dies. The form and fax confirmation should be retained. Contacts for reporting SAEs, pregnancies and other safety concerns are provided to each site.

12. INSURANCE

SPONSOR/CRO has taken out appropriate insurance policies covering the subjects in the clinical trial in accordance with applicable laws and regulations.

13. PUBLICATION POLICY

The clinical trial information should be posted on www.ctri.nic.in or www.clinical trial.gov and in accordance with applicable regulations.

All publications (e.g., manuscripts, abstracts, oral/slide presentations, book chapters) based on this trial must be submitted to SPONSOR/CRO for review, as specified in the Clinical Trial Agreement between the institution, investigator, and SPONSOR/CRO or its designee.

14. Results

14.1. Subject disposition:

Out of 60 subjects screened, None were found dropout, no screen failure. 60 subjects who underwent the full trial period.

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	60
2.	No. of subject's screen failure	0
3.	No. of subjects enrolled in the study	60
4.	Number of subjects completed the Study	60
5.	Dropout	60

Table 2: Patient disposition details

S. No	Schedule	Dates
1.	First subject ICF date	19 April 2025
2.	Last subject ICF date	22 May 2025
3.	First subject screening date	19 April 2025
4.	Last subject screening start date	22 May 2025
5.	Date of first subject completed study	20 April 2025
6.	Date of Last subject completed study	23 May 2025

Table 3: Study dates/schedules:

Subjects disposition chart

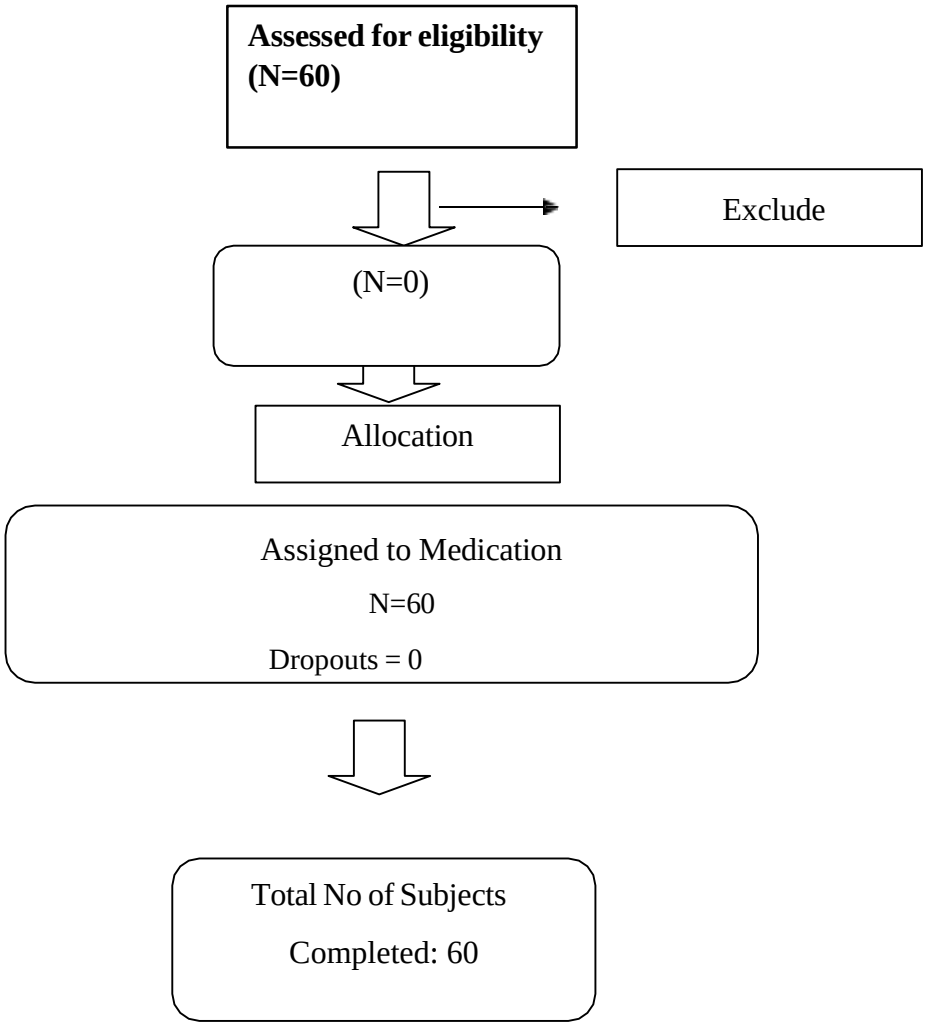
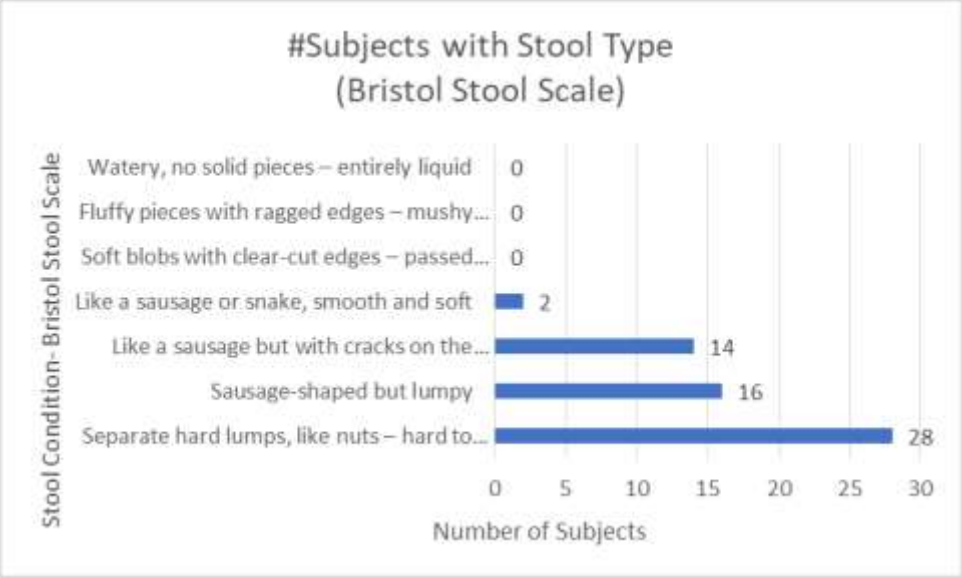


Figure 1: Subject disposition chart details

14.2. Demographic and Other Baseline Characteristics

The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study.

A special assessment was done in the first visit for the Bristol stool scale to identify and group as per the type of stool.



47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool.

14.3. Efficacy Evaluations

Data sets Analyzed. Data from 60 patients who completed the study were analyzed.

Treatments	Test Product(s)
Total screened	60
Enrolled	60
No. of patients completed	60

Table 4: Data sets analyzed

Efficacy Results and Tabulations of Individual Patient Data

14.3.1. Change in Subject's Global Assessment (Questionnaire):

The assessment involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change.

Below were the data points and results.

	Questionnaire	%users
Subject's Self-Assessment	**Do you agree that this syrup helps relieve constipation?**	92%
	Do you agree that it increases the frequency of your bowel movements?	82%
	Have you noticed an improvement in abdominal pain?	92%
	Do you agree that your stool loosens after taking the syrup?	87%
	Do you agree that this syrup does not taste bad?	55%
	Do you agree that this syrup works quickly?	92%
	Do you agree that this syrup does not cause any sensitivity?	85%

- 92% of the users observed that the syrup helps relieving the constipation.
- 82% users agree that it increases the frequency of their bowel movements.
- 92% users noticed an improvement in the abdominal pain.
- 87% users felt their stool to loosen after taking the syrup.
- 55% users liked the taste of the test product.
- 92% users felt that it works quickly
- 85% users observed no sensitivity post taking the test product.

14.3.10 Adverse events and other safety assessments:

The adverse events reported was none during the treatment. No such issue reported.

S. No.	AE	Test (N=60)
1	No. of AEs	0
2	SAE	0

Table 6: Adverse Events list

As per the protocol the r esults are represented as % of Panel found No-side effects; i.e, 100% of subjects found No-side effects.

14.3.12. Other concomitant medications:

All standard treatments were given to the subjects as deemed necessary by the Investigator. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

15. Discussion:

Out of 60 subjects screened, none were found dropout, no screen failure. 60 subjects who underwent the full trial period.

The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study. Data from 60 patients who completed the study were analyzed.

A special assessment was done in the first visit for the Bristol stool scale to identify and group as per the type of stool. 47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool.

The assessment for efficacy involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change. 92% of the users observed that the syrup helps relieving the constipation. 82% users agree that it increases the frequency of their bowel movements. 92% users noticed an improvement in the abdominal pain. 87% users felt their stool to loosen after taking the syrup. 55% users liked the taste of the test product. 92% users felt that it works quickly. 85% users observed no sensitivity post taking the test product.

No adverse event was reported during the study.

Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported. There were no patients who lost to follow up.

None of the patients withdrawn the consent.

16. Conclusion:

In conclusion, Shuddhi XS Syrup showed laxative properties, making stool smooth and more frequent along with reduction in the constipation related pain.. No, adverse events were observed during the study.

17. Reference List

1. Pediatric and Adolescent Sexuality and Gynecology: Principles for the Primary Care Clinician. Hatim A. Omar, Donald E. Greydanus, Artemis K. Tsitsika, Dilip R. Patel, & Joav Merrick, (Eds.).
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