CLINICAL STUDY REPORT
PROTOCOL NO: CCR/CR/032/24

AN OPEN LABEL CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF AAYUDH ADVANCE IN DENGUE INFECTION.

Phase of Development:	Phase III
Test Product	Aayudh Advance
Indication:	This drug is indicated for the management of Dengue fever.
Study Design:	OPEN LABEL CLINICAL TRIAL
Study Period:	Study Initiation Date:15 July 2024
	Study Completion Date (Date of last subject IP administered): 2 Sep 2024
Date of Report:	1 Oct 2024
This study is conducted in accordance with the principles of Good Clinical Practice laid down in Amended Scheduled of D&C Act, 2005, India and ICH-GCP guidelines.	
Sponsor Name: **PINAQ REMEDIES (INDIA) PVT. LTD**	**205–206 ORBIT PLAZA,** **DR YAGNIK ROAD, RAJKOT** **GUJRAT – 360001**

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1.0 SYNOPSIS

Title of the Study:	An open label clinical trial to evaluate the safety and the efficacy of Aayudh Advance in dengue infection.
Phase of Development:	Phase III
Study Period:	Study Initiation Date: 15 Jul 2024
	Study Completion Date: 2 Sep 2024
Objectives:	Primary Objective: Increase in Platelet Counts as compared to day 0 to Day 7 Secondary Objective: Safety of the drug and improvement of health condition.
Study Design:	Open Labeled, Single Arm, Non-Randomized, Interventional Clinical Study
Number of Subjects:	• No. of subjects planned: 50 • No. of subjects enrolled: 50 • No. of subjects discontinued the study: 00 • No. of subjects included in efficacy evaluation: 50 • No. of subjects included in safety evaluation: 50
Duration of Treatment:	Total duration of study for each subject was of at least 07 days from the day of dose administration (D1).
Investigational Products:	
Test Product (T):	Aayudh Advance
Manufactured by:	**Pinaq Remedies (India) Pvt Ltd**
Administration:	Oral (15 ml for 4 times a day)

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Study Procedures:	An open label single arm non randomized interventional clinical study was conducted to establish the efficacy and safety of Aayudh Advance formula in subjects who were suffering with Dengue Fever. The study protocol was reviewed and approved by an Independent Ethics Committee prior to initiation of trial at the Investigator's site. The patients were evaluated at the time of inclusion in the study. The subjects were screened as per the inclusion and exclusion criteria as prescribed in the study protocol.
	After obtaining written informed consent in presence of the investigator, patients with either gender were enrolled in the study. At the time of taking consent, patient were explained about the study procedure which includes blood sampling at timely interval for evaluating the Investigational Product Aayudh Advance. Baseline assessments were recorded like demographic, medical history, physical examination, vital signs measurement, laboratory assessment and concomitant medications. Eligible patients as per inclusion and exclusion criteria were enrolled in the study. Baseline blood sample was collected for Complete Blood Count that include platelet counts and urine samples. The subjects who were enrolled in the study were dispatched with Investigational product and were instructed on the usage of the Investigational Product. Blood sample for platelet count was collected at Day 3 and at Day 7 the subjects CBC and urine samples were collected at day 7 for end of the study evaluation. Systemic adverse reactions and concurrent medication requirement were assessed throughout the study duration. Usages of any concurrent medication (eg. Paracetamol 500 mg) was recorded through the study. At Day 14 a telephonic call was to enquire about the subject general health and presence of any adverse or severe adverse event.

Efficacy Parameter:	For the assessment, all subjects platelet counts were thoroughly evaluated at an interval of Day 3 and Day 7 and quantity of any required concurrent medication was noted. Data from all the subjects was pooled for analysis. An intention-to- treat and per-protocol analysis was done for efficacy evaluation. Proportions and means in baseline characteristics and outcome were compared between treatments by using Fisher's exact test, two-sample *t* test with pooled variance, or Wilcoxon test, as appropriate. Rescue analgesia parameters, and ease and convenience of using both formulations were compared between the groups using Student's t-test for independent samples. 95% confidential intervals were estimated wherever needed. Side effects between the groups were compared at each time point using chi-square / Fisher's exact test as appropriate. Measurement data was expressed as means and standard deviation, whereas categorical data was expressed as percentages.
Safety Assessment:	Patient safety was evaluated by monitoring vital signs (temperature, blood pressure, pulse rate and respiratory rate) and adverse events during entire study period. The safety outcomes were measured as reported and directly observed adverse events were monitored for after administered dose until post treatment follow up. Safety evaluations were performed by recording treatment-emergent adverse events (adverse events that started or worsened with administration of investigational product during trial). Data from all the centres was pooled for analysis. An intention-to-treat analysis was done for safety evaluation. Treatment safety analysis compared frequencies of occurrence of adverse events. Measurement data was expressed as means and standard deviation, whereas categorical data was expressed as percentages.
Statistical Methods:	The objective of this study was to evaluate the increase in platelet count and compare safety and efficacy of the product under investigation. The difference in the platelet count was measured using 't'- test with confidential intervals of 95% when ever needed. For all statistical tests, significant level (α) was $p < 0.05$.

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Results:	**Baseline Demographics Characteristics:** All the subjects enrolled in the study were of Indian demographics. More males (35 subjects) than females (15 subjects) were enrolled in the study. Overall the mean age of subjects was 41.7 years and mean weight of subjects was 62.2 kg. Overall age ranged from 18 to 65 years and weight ranged from 40 to 89 kg. A total of 50 subjects enrolled in the study, all of them were given the Investigational Product. All (N=50) subjects completed study and were available for efficacy and safety analysis. **Efficacy Evaluation:** The subjects enrolled, the platelet count were evaluated at the Baseline, Day 3 and Day 7. The Mean Platelet Value at the baseline was 60143.5 with a standard deviation of ±8119.5. At Day 3, the Mean Platelet Value increased to 65582 ±8644.4. At Day 7 the Mean Platelet Value increased 76435.98 ±13331.3. These are depicted in proper graphical manner further in the report. **Safety Results:** All enrolled subjects were included for safety analysis and evaluation. Five (05) adverse events were reported during the conduct of study. The adverse event noted were of mild in nature mostly of muscle pain and fatigue which was mild in intensity and unlikely related to the study drug administered as per the investigator.

	No severe, serious or life-threatening adverse events were reported during the course of the study. The investigational products were found to be safe and well tolerated.
Conclusion:	The study concluded that Aayudh Advance formula effectively manages dengue fever. Further it was noticed that none of the subjects showed any Adverse Event or Serious Adverse Event thus making the investigational product safe to use. In total out of 50 subjects only 5 subjects developed muscle pain and fatigue during the course of the study which was very mild in nature and not associated with the Investigational Product. Finally, it can be ascertained that Aayudh Advance Formula gives good result in the management of dengue fever without having any serious adverse events. Aayudh Advance Formula was associated with a reduction in fever within 2–3 days, suggesting a potential role in the symptomatic management of dengue infection.
Date of Report:	1st Oct 2024

2.0 STATEMENT OF COMPLIANCE WITH THE GOOD CLINICAL PRACTICES GUIDELINES

This study was conducted in accordance with the clinical research guidelines established by the basic principles defined in the GCP guidelines issued by the ICMR guidelines for biomedical research on human subjects, Schedule Y (amended version) of CDSCO (Central Drugs Standard Control Organization) and the principles enunciated in the "Declaration of Helsinki" (Ethical Principles for Medical Research Involving Human Subjects, revised by the WMA General Assembly, Seoul).

3.0 LIST OF ABBREVIATIONS AND DEFINITIONS

AE	Adverse Event
ALT	Alanine Aminotransferase
ANOVA	Analysis of Variance
AST	Aspartate Aminotransferase
AUC_{0-t}	Area under the curve from time zero to time of last measurable concentration
$AUC_{0-\infty}$	Area under the curve from time zero to time infinite
BE	Bioequivalence

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