Subject ID: Subject Initials:

SUBJECT INFORMATION & CONSENT FORM

STUDY TITLE: A randomized, double blind, Placebo controlled, single center, study to evaluate the efficacy of herbal sports nutrition for physical endurance in healthy volunteers.

Following pages give the details of this particular study. Read this carefully. If have any questions, please ask

Subject Information	
Name	First name Middle name Last name
Subject Initials	
Subject ID	
Gender	
Age/Date of Birth	
Date & Time	

Subject ID: Subject Initials:

This Informed Consent Document has two parts:

I. Information Sheet /PIS(to share information about the research with you)

II. Certificate of Consent/ICF (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Document

I. Information Sheet

You are being invited to take part in this research study. This consent form has information to help you decide if you want to participate. Take your time, read this form carefully, and ask the study doctor or staff any questions you may have.

The study doctor (or Institution) will be paid by the CRO, Agile Pharma Service for conducting this study.

1. Introduction

Sports Nutrition is the study and practice of nutrition and diet as it relates to athletic performance. It is concerned with the type and quantity of fluid and food taken by an athlete, and deals with nutrients such as vitamins, minerals, supplements and organic substances such as carbohydrates, proteins and fats. Although an important part of many sports training regimens, it is most popular in strength sports (such as weight lifting and bodybuilding) and endurance sports (for example cycling, running, swimming, rowing).

2. Purpose of the research

The purpose of the study is to study to evaluate the efficacy of herbal sports nutrition for physical endurance in healthy volunteers.
Details of the Investigational product

NAME OF THE PRODUCT
Herbal Sports Nutrition
THERAPEUTIC INDICATIONS
Physical endurance
ROUTE OF ADMINISTRATION
Oral

Subject ID: Subject Initials:

Participant selection

Inclusion Criteria:

- Male healthy adult subjects ranging in age from 18 to 55 years (both inclusive) normotensive, physically active but not exercise trained.
- Willingness to follow the protocol requirements as evidenced by written, informed consent.
- Agree not to use any medication including vitamins and minerals, during or before the course of this study.
- Subjects whose blood chemistries are within a normal range or not considered clinically significant if outside the normal range.
- Non smokers and non-alcoholics.
- Willing to come for all follow-up visits

Exclusion Criteria:

- Any clinically significant medical history, medical finding or an ongoing medical or psychiatric condition exists which in the opinion of the Investigator could jeopardize the safety of the subject, impact validity of the study results or interfere with the completion of study according to the protocol
- Significant abnormal findings as determined by baseline history, physical examination, vital signs (blood pressure, pulse rate, respiration rate, temperature) hematology, serum chemistry.
- History of hypersensitivity reactions.
- Smokers and alcoholics
- History of migraine, asthma
- Participation in a clinical study during the preceding 90 days.
- Evidence of ischemic heart disease by history or abnormal resting or exercise electrocardiogram (ECG) (> 1mm ST segment depression), regional wall motion abnormalities, left ventricular systolic dysfunction or significant valvular disease.
- Blood or blood products donated in past 30 days prior to study supplement administration.

3. Study procedure

Part 1: Subjects enrolled in 24 hours Pharmacokinetic study. Blood samples (5 ml) will be collected at Pre dose 0.00.0.50,1.00,2.00,3.00,4.00,5.00,6.00,7.00,8.00,9.00,10.00,11.00,12.00 and 24.00 hrs Post dose.
Part 2: All the eligible subjects enrolled into the study shall have to visit the study site on Days 0 (In house Part I), 22 days after 2 to 4 days from the day of screening visit. Physical examination, demographics, vitals will be recorded on all visits. Adverse events and concomitant medication will be recorded. Serum chemistry, haematology, Lactate levels – pre & post exercise, heart rate, Time to exhaustion, 12 lead -Electrocardiogram (ECG) for arrhythmia patterns, ST and RR segments (efficacy assessments), Exercise test on treadmill (Bruce treadmill test), plasma and saliva NO_3 and NO_2 levels at pre and post exercise will be conducted on screening and final visit. A buffer period of ± 2 days will be allowed for every visit and beyond which it will be considered as a protocol deviation.

4. No of Subject/Patient participating in the clinical trial

24 (1:1 ratio i.e., 12 subjects will receive active and 12 placebo)

5. Duration of Study

The research takes place 22 days in total. During that time, it will be necessary for you to come to the clinic/hospital.

Expected benefits and risks

No risks will be foreseen by participating in this study;

Other than the treatment benefit and free investigations/tests, you are not expected to get any benefit from being on this research study. The results of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefit to future patients.

6. Side effects or Adverse reactions and special warnings and precautions

Contraindications: None established.

Special Warnings and Special Precautions for Use: None established.

Interactions: No established interactions.

Use during Pregnancy and Lactation: Not known.

Overdose: No established evidence available.

7.Alternative procedures or therapies available to the subject

Your options include: The other drugs were already in the market for bone health.

You do not need to take part in this study to be treated for bone health. The study doctor can discuss these options with you.

8. Compensation for participation in the study

You will not be paid to take part in this study. At the same time, you will not have to pay for consultations or test done as part of this study. Insurance for the study subjects has been taken by the sponsor to cover complications that may arise in the course of the study.

9. Statement for subject withdrawal

Clinical trial subject enrollment is subject to the norms of the Informed Consent Form which is prepared in compliance with all applicable laws of the regulatory bodies. The participation of a test subject may only be discontinued by the Investigator in the event of the following:

- The participant has recently consumed or has started treatment with a drug which causes interference with the effects of the test drug.

- Participant has not disclosed and therefore has without prior knowledge of the clinical trial authorities a condition which requires special medical care or a medication which may interfere with the test drug and its effects.
- Participant has failed to furnish all required details to the recruiter and has therefore been selected without compliance with inclusion criteria.
- Participant wishes to discontinue due to dissatisfaction with the trial procedure and drug administration.
- Inability of the participant to adhere to the prescribed dosing regimen and special requirements of the trial.
- In case informed consent given without proper examination of details furnished in the ICF.

10. Privacy of Subject's/Patient's medical records

Information about study subjects will be kept confidential.

11. Responsibility of Subject/Patient

- Able to sign voluntarily consent and Audio video visual consent
- Subjects must understand risks and benefits of the protocol
- If female, should be negative in pregnancy test. Female of child bearing potential, should agree to follow an acceptable method of birth control for the duration of the study.

12. Confidentiality of study participants

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document. The study doctor, the sponsor or persons working on behalf of the sponsor and under certain circumstances Institutional Review Board (IRB/IEC), will be able to inspect and copy confidential study-related records which identify you by ID / initial. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

13. Whom to Contact

For further questions/problems and in case of any emergency you may contact the following persons (Investigator's/ designee's details to be filled)

Investigator		
Name	**Contact Address**	**Telephone/Mobile Number**

14. Ethics Committee details

For any questions regarding your rights as a research subject, you may contact the following from the Ethics Committee

Ethics Committee		
Name	**Contact Address**	**Telephone/Mobile Number**

Subject ID: Subject Initials:

II. CERTIFICATE OF CONSENT

STUDY TITLE: A randomized, double blind, Placebo controlled, single center, study to evaluate the efficacy of herbal sports nutrition for physical endurance in healthy volunteers.

Subject Name:	**Subject Initials:**
Date of Birth/Age :	**Subject Id:**
Address:	**Qualification:**
Mobile No.:	**Annual Income (Optional)**
Occupation: Student / Self employed / Service / Housewife / Others (Please tick appropriate)	

By signing below I agree that:

S. No.	Description	Initial
1	I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to book at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	
4	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	

5	I agree that I may have to leave the study without my consent if I needs other treatment, do not follow the study plan, have a study related injury, or for any other reason.	
6	I agree that if I leave the study for any reason, the study doctor may ask me to have some end-of study test	
7	I agree to take part in the above study.	

SIGNATURE OF SUBJECT:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

_____	_____	_____
Name of the Subject	Signature or Thumb Impression	Date (DD-MMM-YYYY)

SIGNATURE OF LEGALLY ACCEPTABLE REPRESENTATIVE:

_____	_____	_____
Name	Signature	Date (DD-MMM-YYYY)

_____

Relationship with Subject

SIGNATURE OF INVESTIGATOR TAKING CONSENT:

_____	_____	_____
Name of the Study Investigator	Signature	Date (DD-MMM-YYYY)

Subject ID: Subject Initials:

SIGNATURE OF IMPARTIAL WITNESS:

As an impartial third party, I wished the entire consent discussion and the subject's signature on this form.

_____	_____	_____
Name of Witness (If applicable)	Signature	Date (DD-MMM-YYYY)

Subject ID: Subject Initials:

STATEMENT BY THE INVESTIGATOR TAKING CONSENT

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this filled ICF has been provided to the participant or his/her attendant.

Name of the Investigator	Signature	Date (DD-MMM-YYYY)