



Clinical Trial Report For Naturamore French Vanilla 50% Protein

CTRI/2019/10/021716 [Registered on: 18/10/2019]



Clinical Trials

- Naturamore is **ONE OF THE VERY FEW BRANDS** in India to conduct **DOUBLE BLIND** rigorous, registered clinical trials of the products.
- Clinical trials provide us the **ASSURANCE** and **CONFIDENCE** that the product is **SAFE** and **EFFECTIVE**
- Studies are conducted following stringent guidelines by **WHO – GCP, ICMR AND OECD GUIDELINES**



Steps in clinical study for Naturamore Products

Safety Study



Efficacy Study



Safety Study

Purpose

To assure total safety of the product for the consumption

Acute

To understand the highest safe dose of the product (As per standard OECD 423 guidelines)

Sub – Acute

To understand safety of the product for long – term consumption (As per standard OECD 423 guidelines)



Acute Toxicity Study

NO SAFETY CONCERNS observed even at 5000 mg / kg body weight dose.

It can be labelled as **SAFE FOR ORAL CONSUMPTION** at recommended dosage



Sub – Acute Toxicity Study

Conducted as Repeated Dose 28-day Oral Toxicity Study as per standard OECD guidelines

NO ADVERSE EFFECT on general health, growth, behavioural, neurological, Haematological, clinical chemistry and urinalysis parameters, organ weights and gross of the tissues / organs of the mice treated at the dose level of 1000 mg/kg body weight.

It can be labelled as **SAFE FOR LONG TERM CONSUMPTION** at recommended dosage



Efficacy Studies

We conducted the Clinical trials in comparison with Market Leader Product

The type of study conducted was a **Double Blind Study** which is considered as **GOLD STANDARD** in clinical trials

Central Registration Number of the trials:
CTRI/2019/10/021716 [Registered on: 18/10/2019]

Study Conducted for 90 days in 100 Subjects
(50 in each group)

Parameters Studied

- Endurance levels (steppers test)
- Perceived stress levels
- Immunity via number of events of recurrent UTI/RTI etc.
- Anthropometric analysis
- HbA1c and glycaemic profile i.e. blood sugar levels
- Regulation of lipid levels
- Sleep Quality, Mood and Behaviour
- Quality of Life
- Digestive Behaviour
- Safety, tolerability and compliance testing



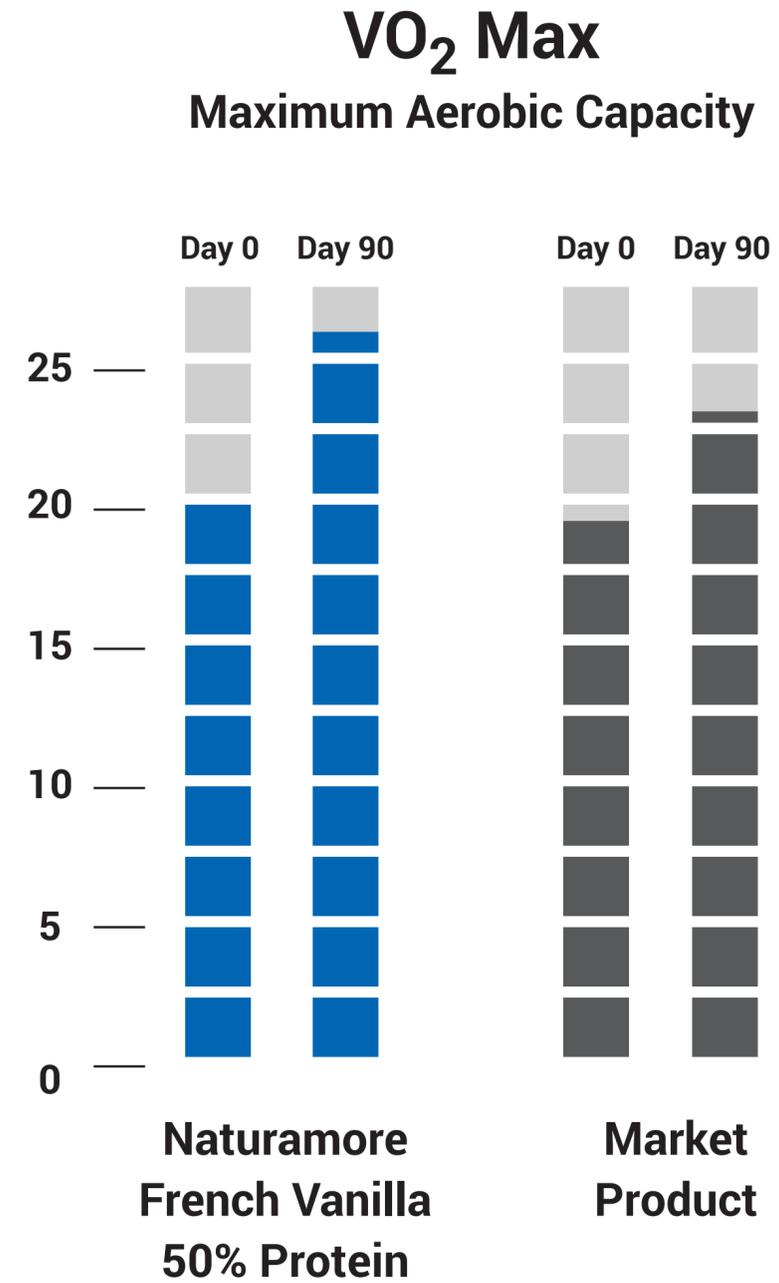
Results & Interpretation



Endurance testing

It is the maximum amount of oxygen you can utilize during exercise. It's commonly used to test the aerobic endurance or cardiovascular fitness.

More value is considered better

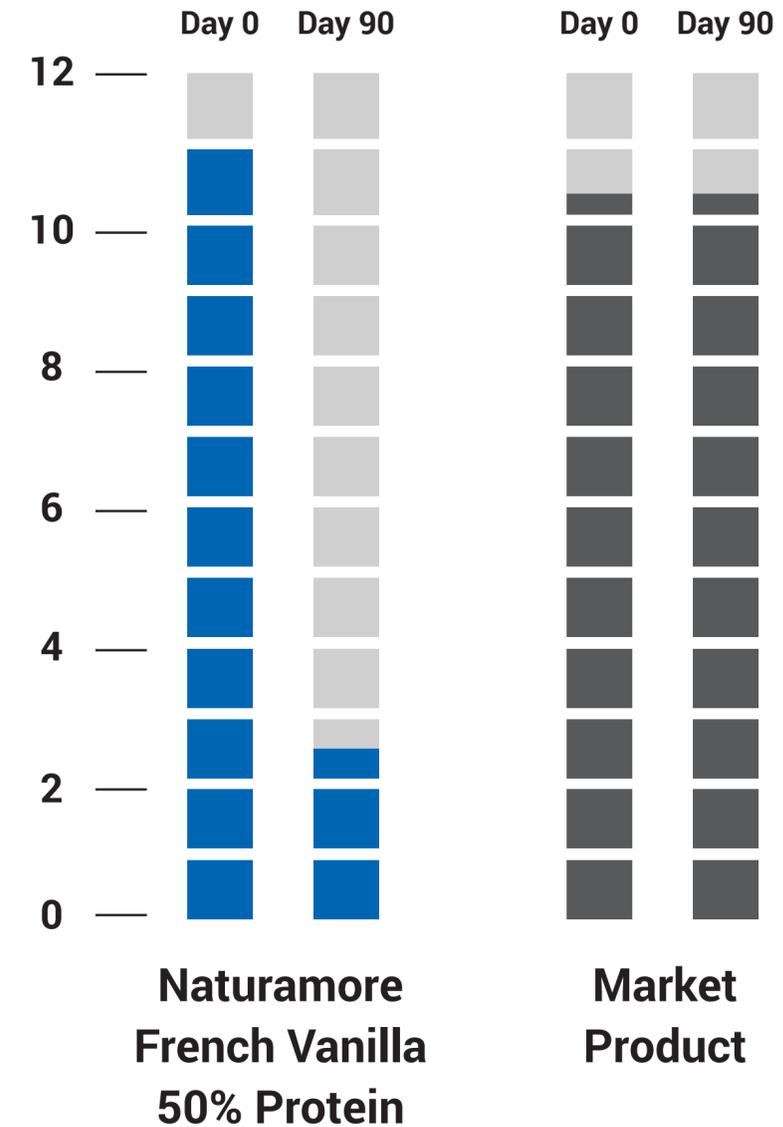


Sleep Testing

It is to check your overall sleep quality using Pittsburgh Sleep Quality Index.

Less value is considered better

Pittsburg Sleep Quality Index

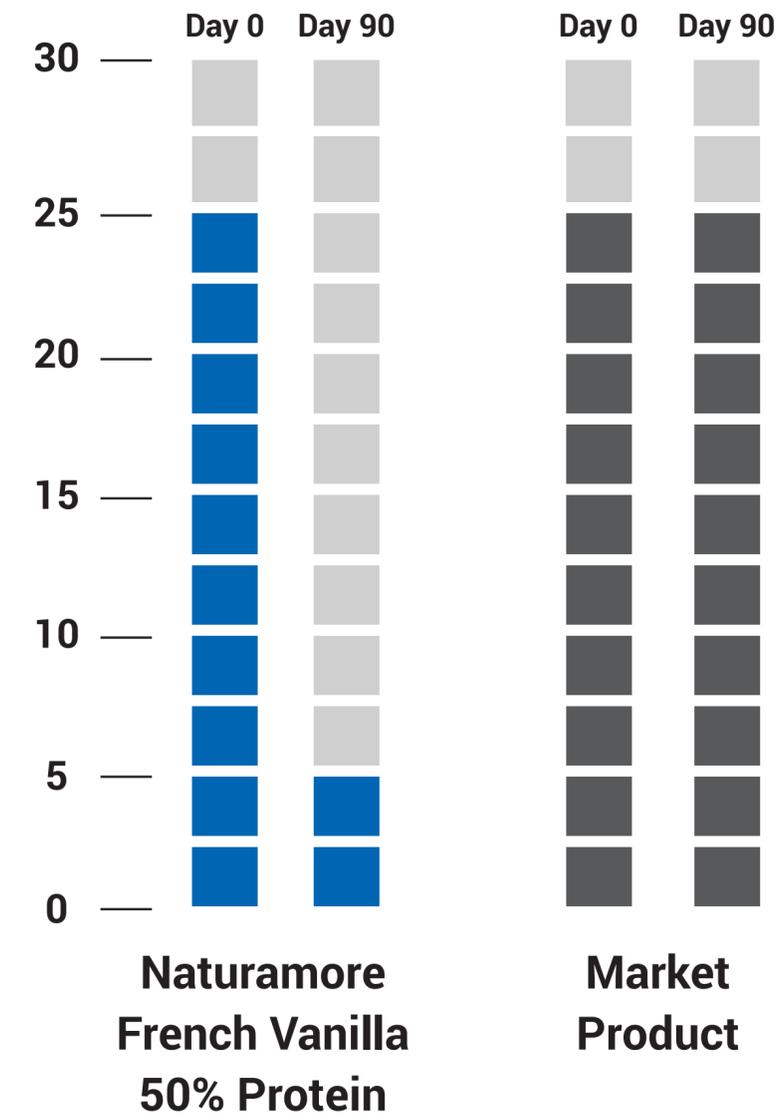


Perceived Stress Testing

It is to check your feeling of overall mental stress.

Less value is considered better

Perceived Stress Score

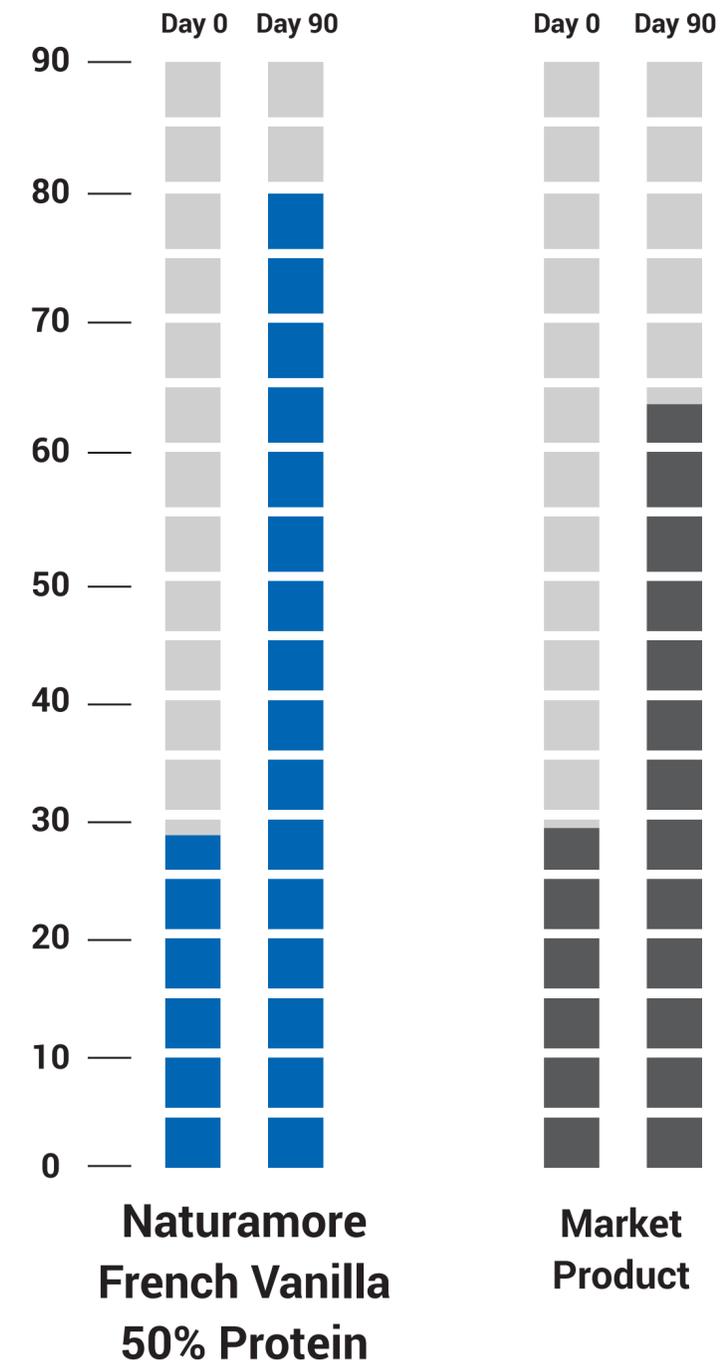


General Health Testing

It is to check status of your wellness using standard General Health Questionnaire-28.

More value is considered better

General Health Questionnaire-28



Other Parameters

- A variety of parameters like appetite, bloating, heartburn, constipation, nausea etc. related to digestive behaviour were **significantly better** in Naturamore group as compared to market product.
- There were **significant reduction in fat %** at day 90, in test group when compared to marketed product treated group.
- There was **significant increase in the skeletal muscle %** at day 90 in test group when compared to marketed product treated group.
- In test group, 43 (86 %) subjects reported **very much overall improvement** as compared to market product 04 (7.84%).
- There was significant ($p < 0.05$) **reduction in Total Cholesterol** in the test product treated group at day 90
- There was **significant decline in HbA1C** level in test treated group compared to marketed product treated groups.



Conclusion

- Naturamore French Vanilla may help **improve cardiovascular performance and overall endurance**
- Naturamore French Vanilla may help **improve mood, behaviour, stress and sleep pattern**
- Naturamore French Vanilla may help **improve digestive parameters and body composition**
- Naturamore French Vanilla is **safe to consume for a long term** in recommended dosage without any adverse events

