



# Clinical Trial Report For Naturamore French Vanilla 50% Protein

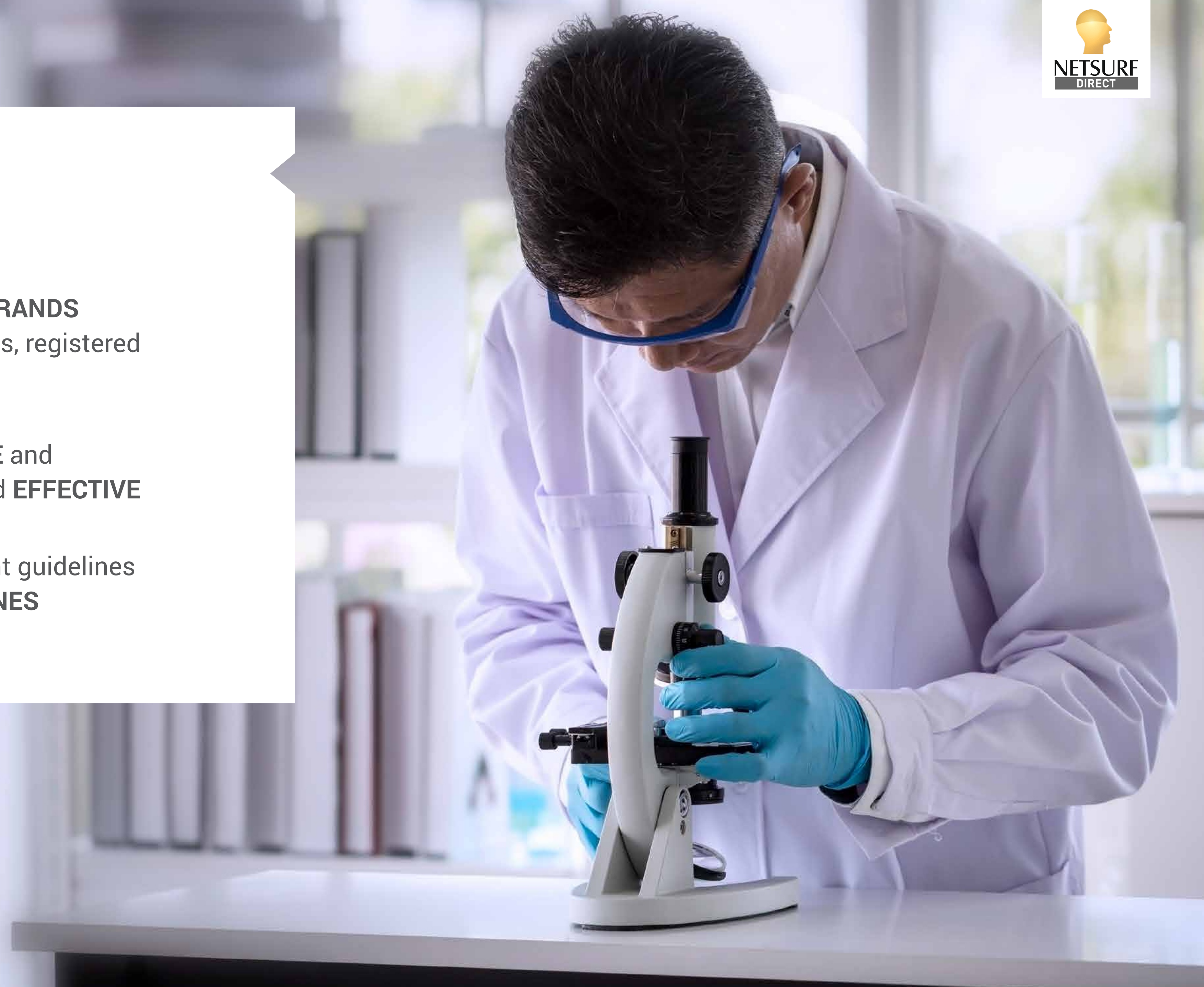
CTRI/2019/10/021716 [Registered on: 18/10/2019]





# 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

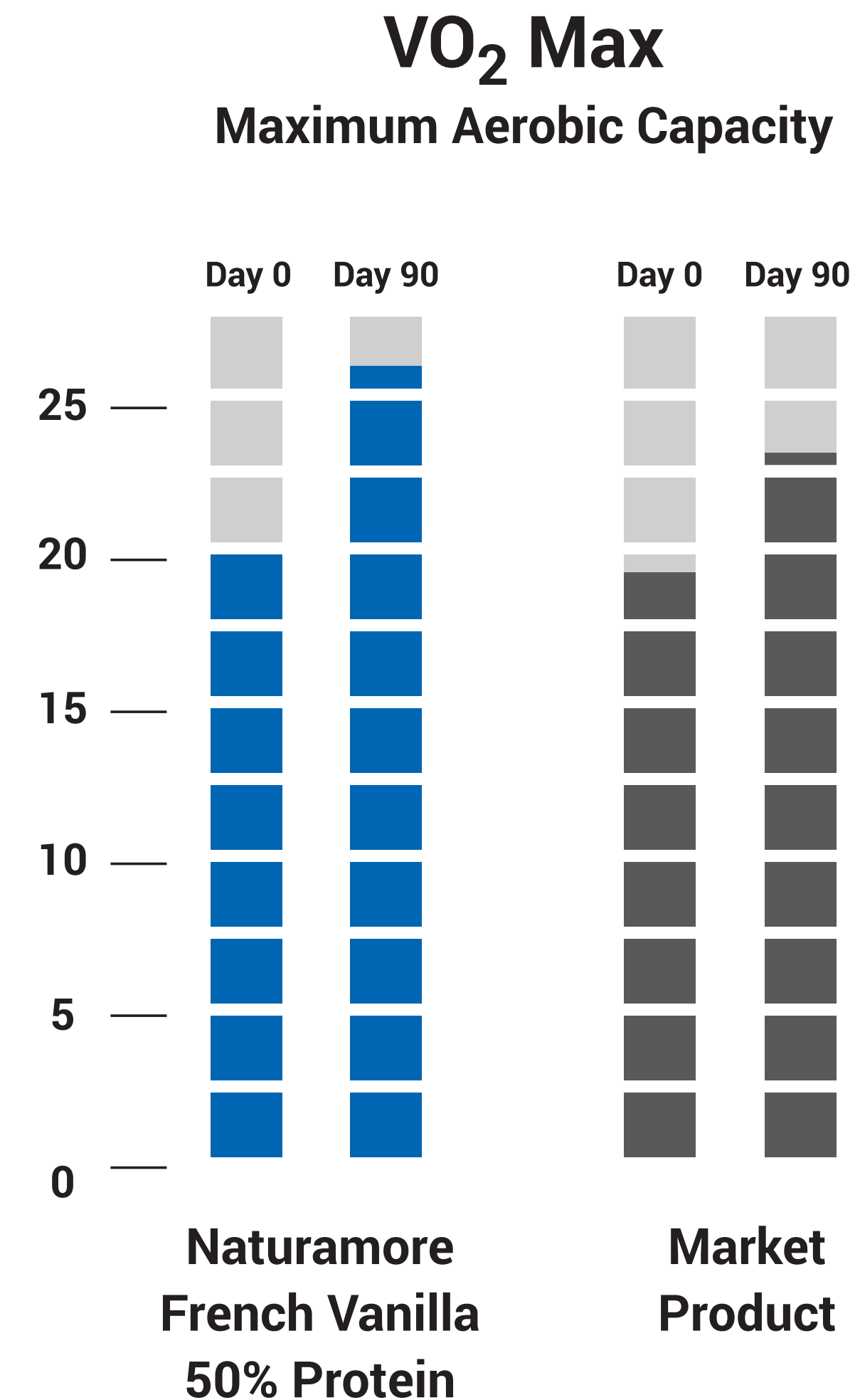




# Endurance testing

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*



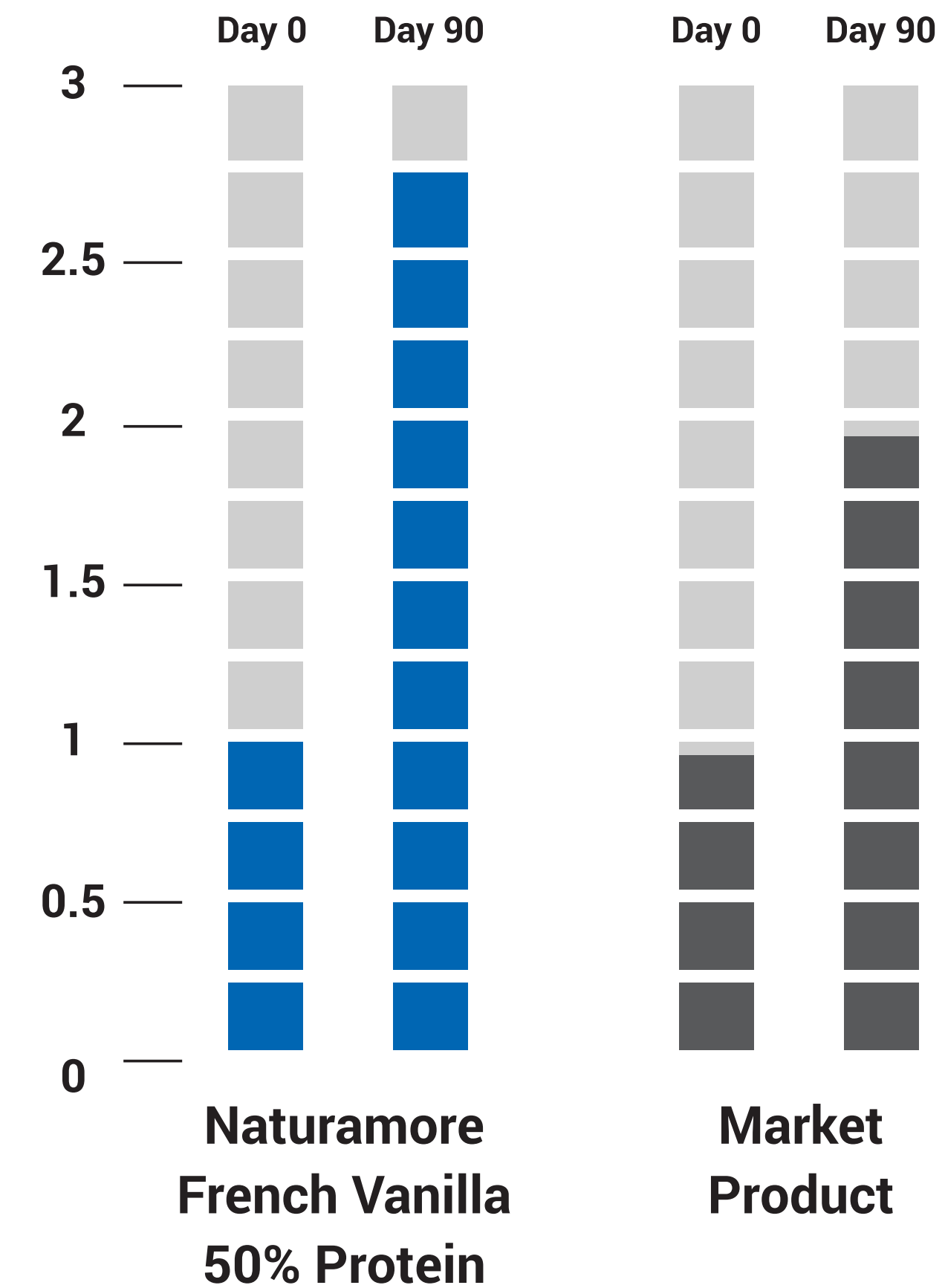


# Mood & Behaviour Testing

It is to check your overall mood during the day, energy levels and enthusiasm to work.

*More value is considered better*

## Mood Disorder Questionnaire



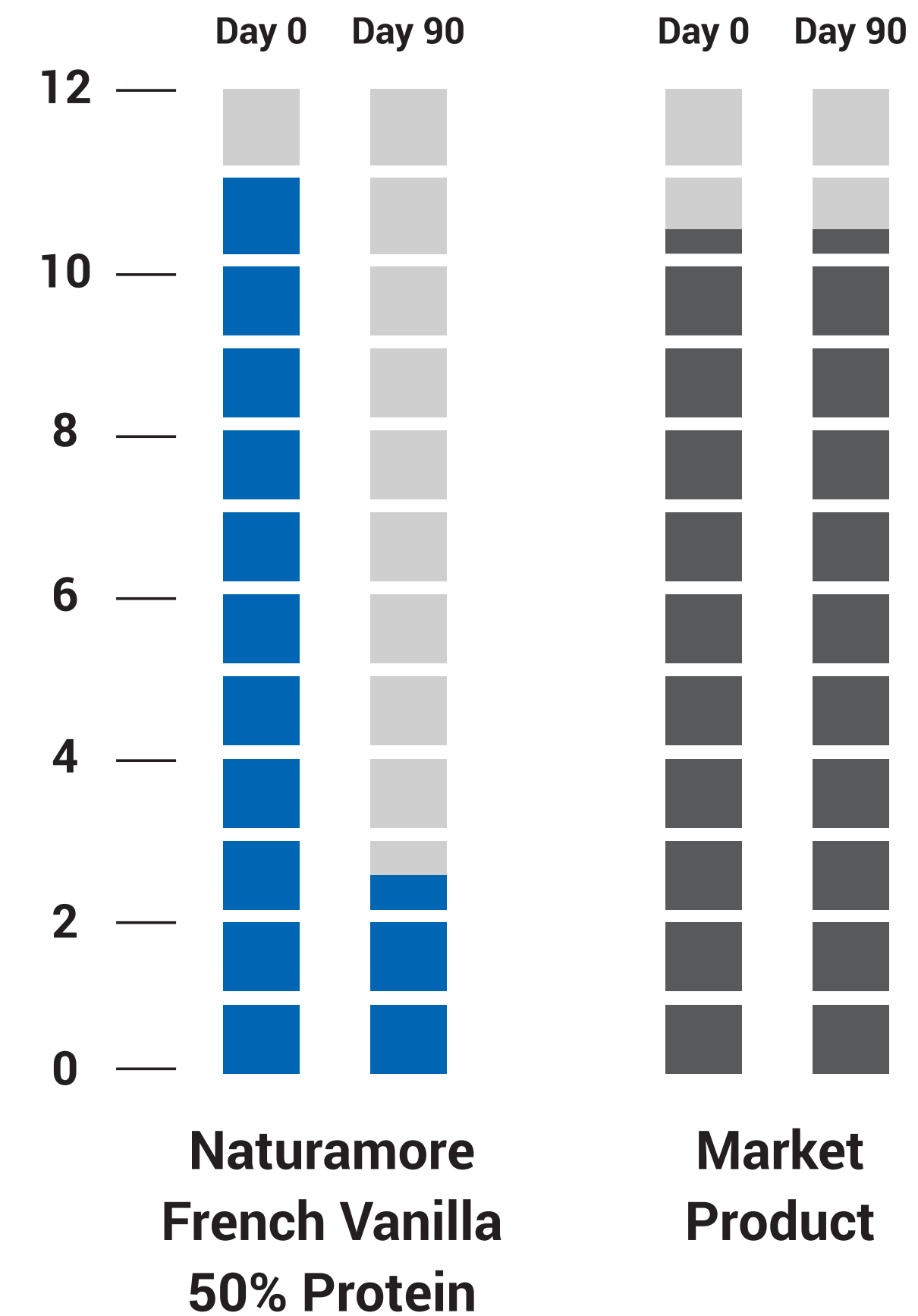


# Sleep Testing

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

*Less value is considered better*

## Pittsburg Sleep Quality Index



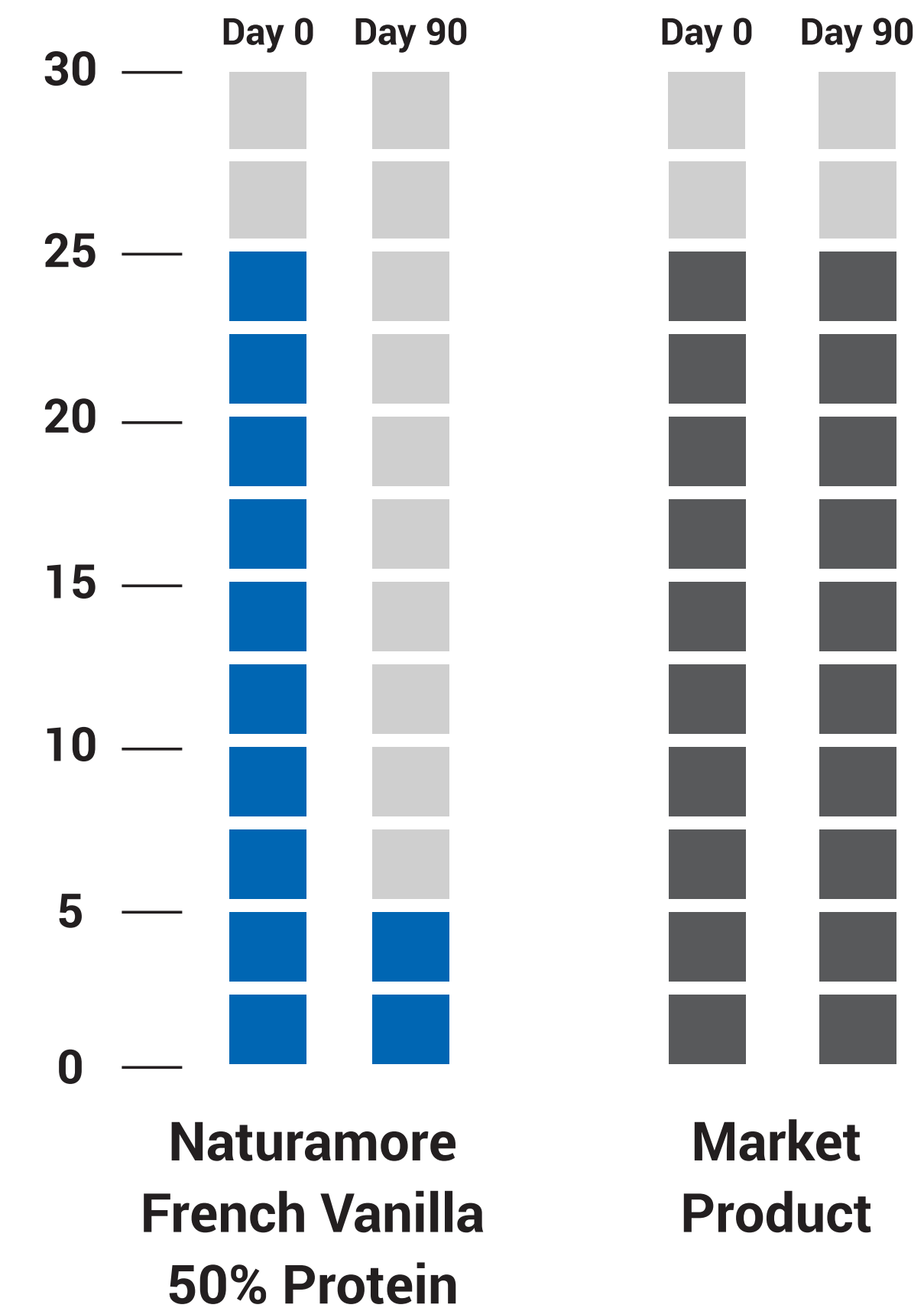


# Perceived Stress Testing

It is to check your feeling of overall mental stress.

*Less value is considered better*

## Perceived Stress Score



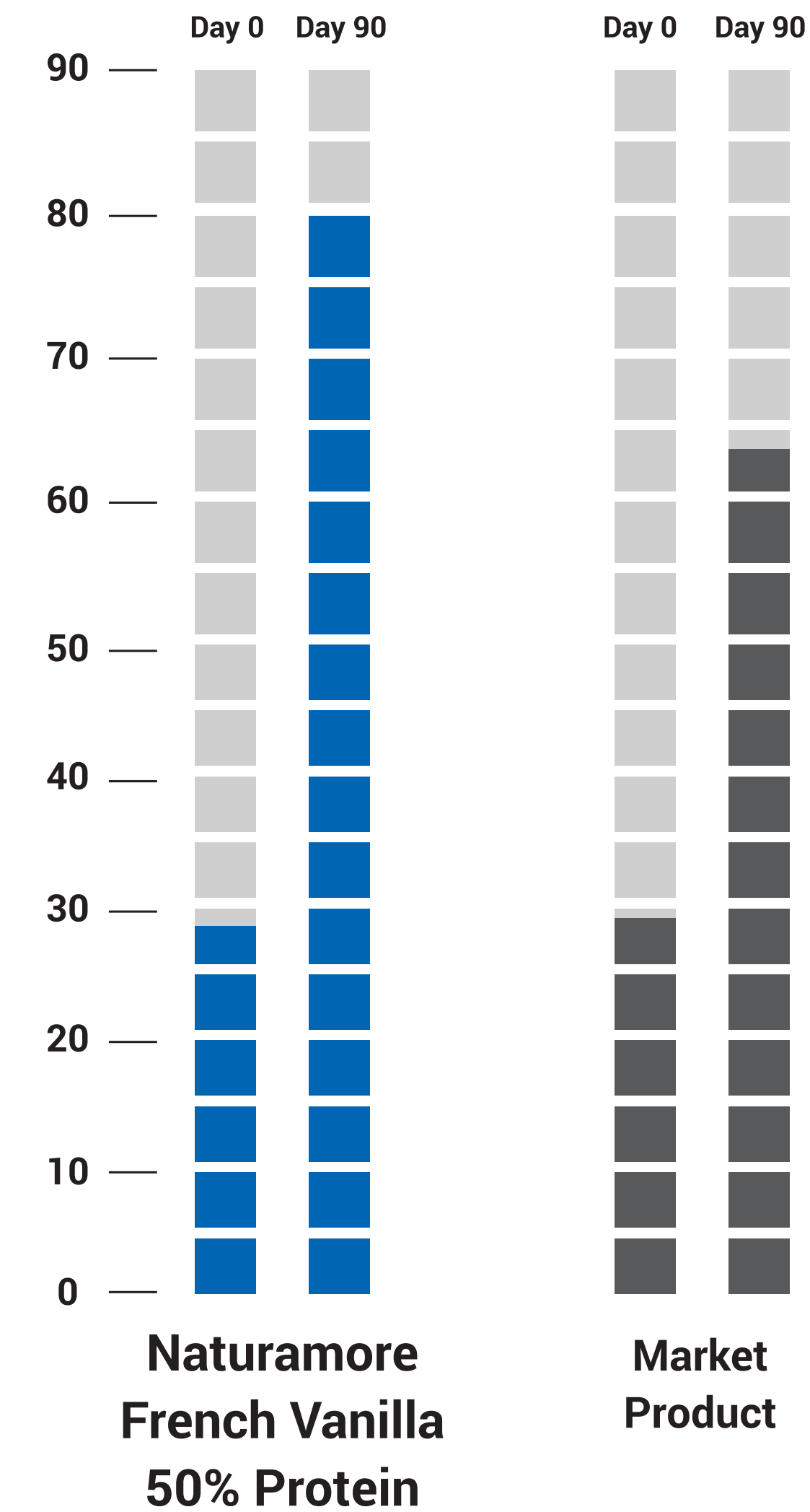


# General Health Testing

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

