



DE-STRESS

Clinical Study Report



Clinical Trials

Assessment of stress in human subjects in response to treatment with Naturamore De-Stress formulation developed by Netsurf, India in comparison with subjects treated with a placebo formulation in twenty four male human subjects in a double blinded balanced randomized efficacy study in a parallel design.



Clinical Trials

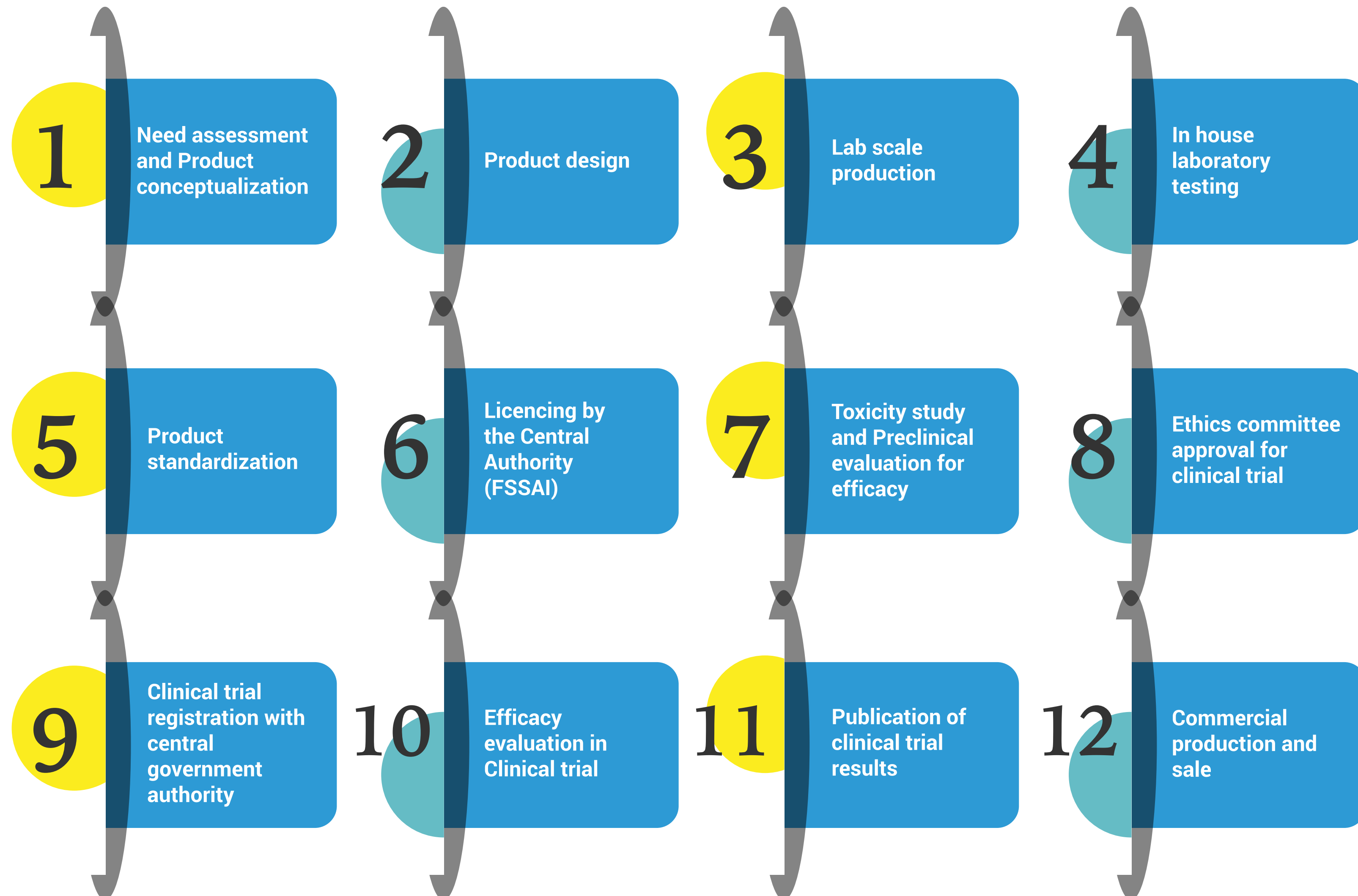
24 healthy male volunteers with a stressful lifestyle were clinically tested for the efficacy of Naturamore De-Stress tablets with a dose of 1 tablet per day for two months against a placebo in a randomized double blind trial.

Stress related blood parameters and subjective parameters were evaluated for two months.

The results were evaluated statistically.



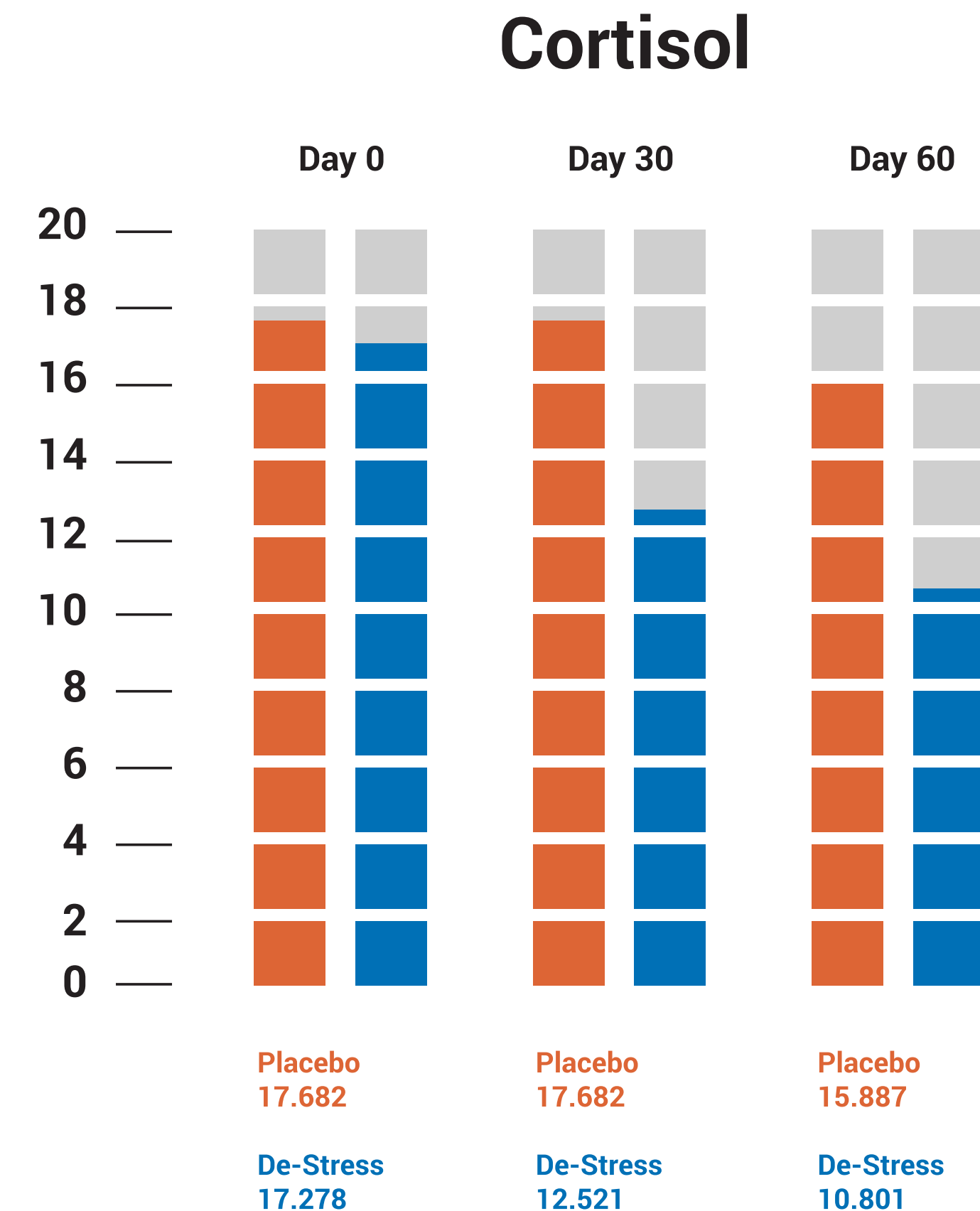
Process flow of the Naturamore Product Development



Cortisol levels ($\mu\text{g/dl}$)

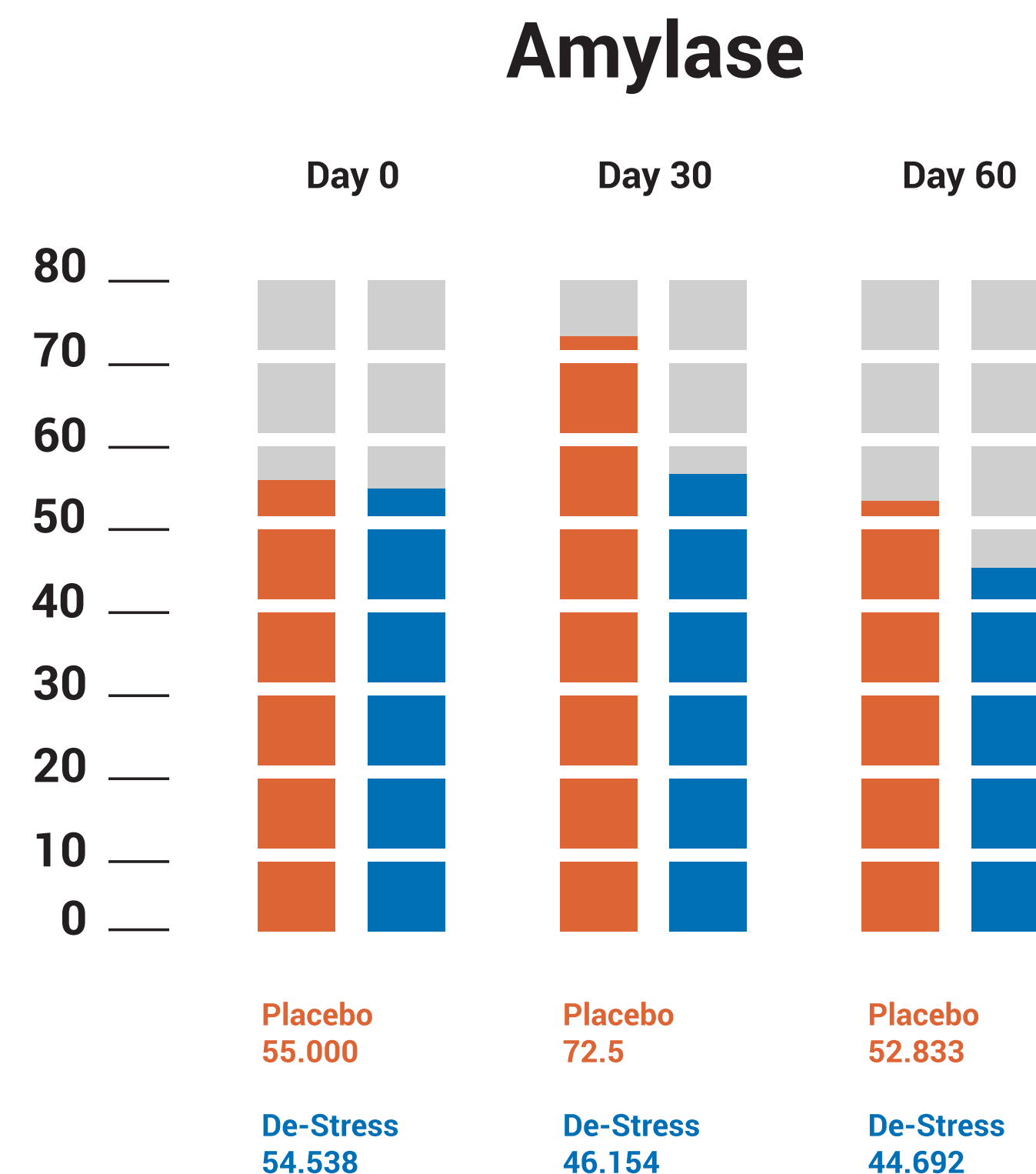
Cortisol is a primary stress hormone. Continuously raised cortisol levels exert severe adverse effects on the body including high blood pressure, high blood sugar, palpitation, sleep disturbances, etc.

At 30 days of treatment, there was a reduction of 27.5% in the level of cortisol in saliva as compared to baseline whereas at 60 days of treatment, the cortisol levels reduced by 37.49% of the baseline value.



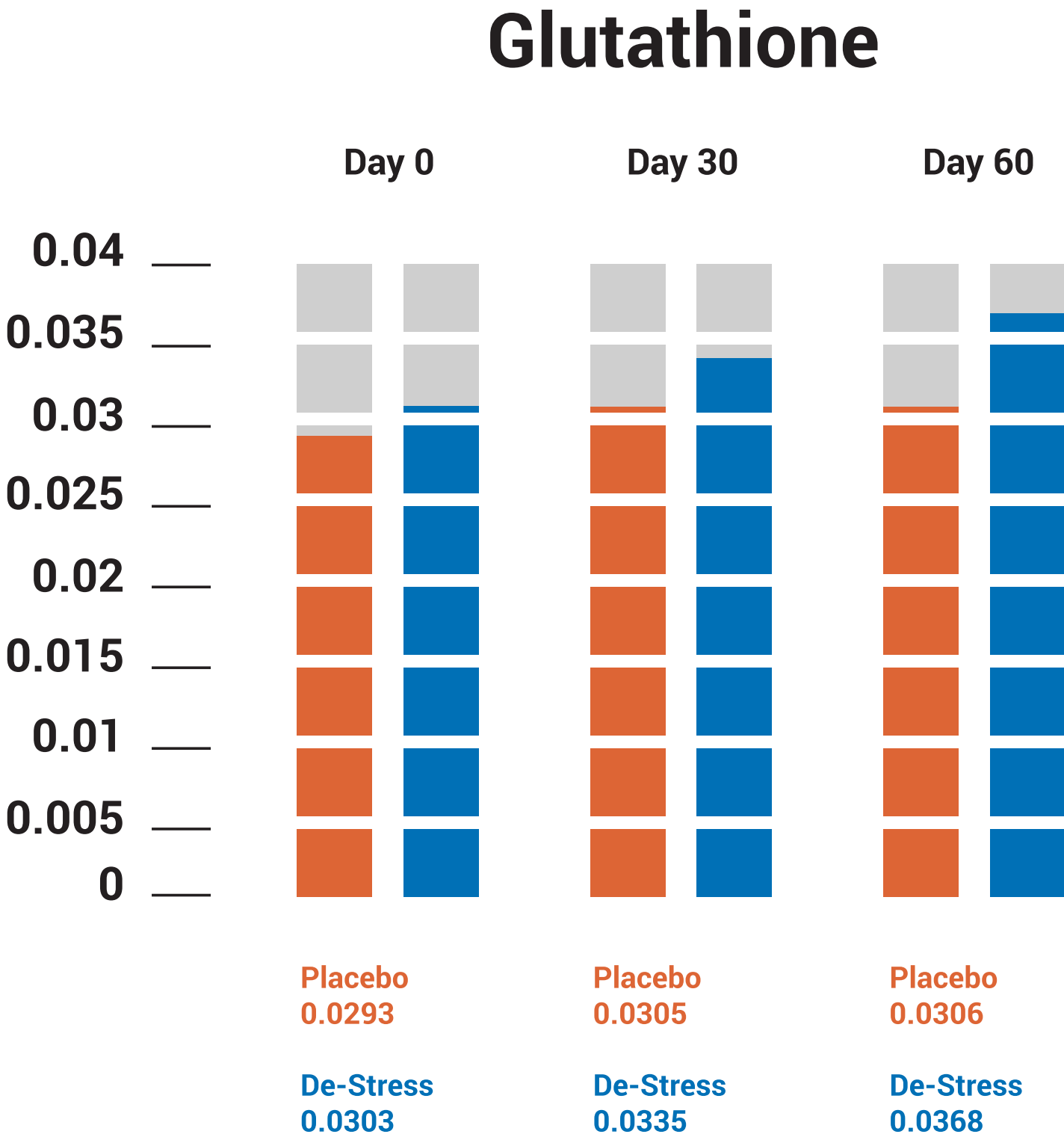
Amylase levels (IU/L)

At 30 days treatment, there was 15.37% reduction and at 60 days treatment, there was 18.05% reduction as compared to the baseline Amylase values.



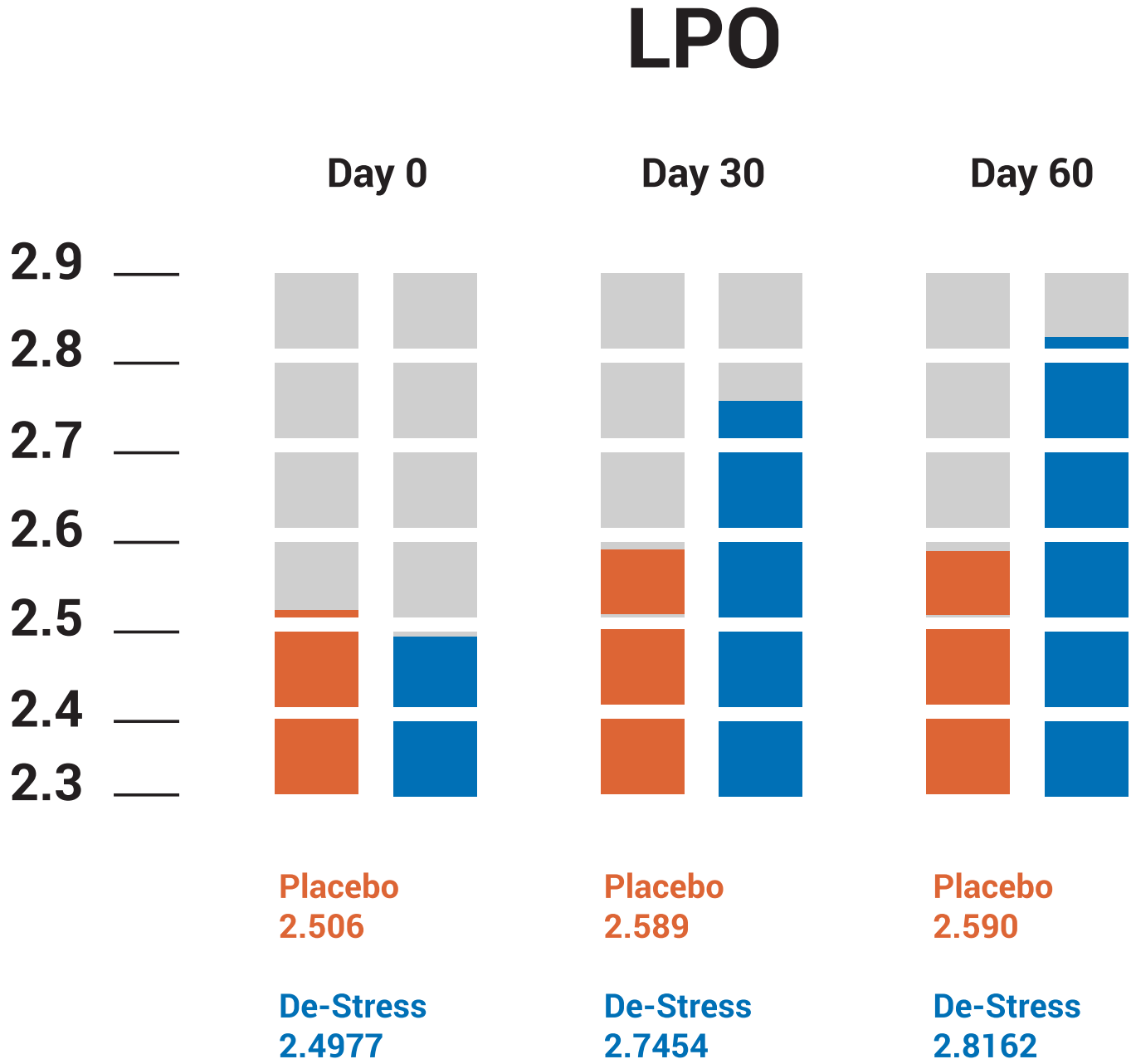
Glutathione (U/ml)

The blood levels of glutathione showed significant increase at both 30 days and 60 days of treatment. The increase was 10.55% at 30 days treatment and 21.22% at 60 days of treatment as compared to the baseline.



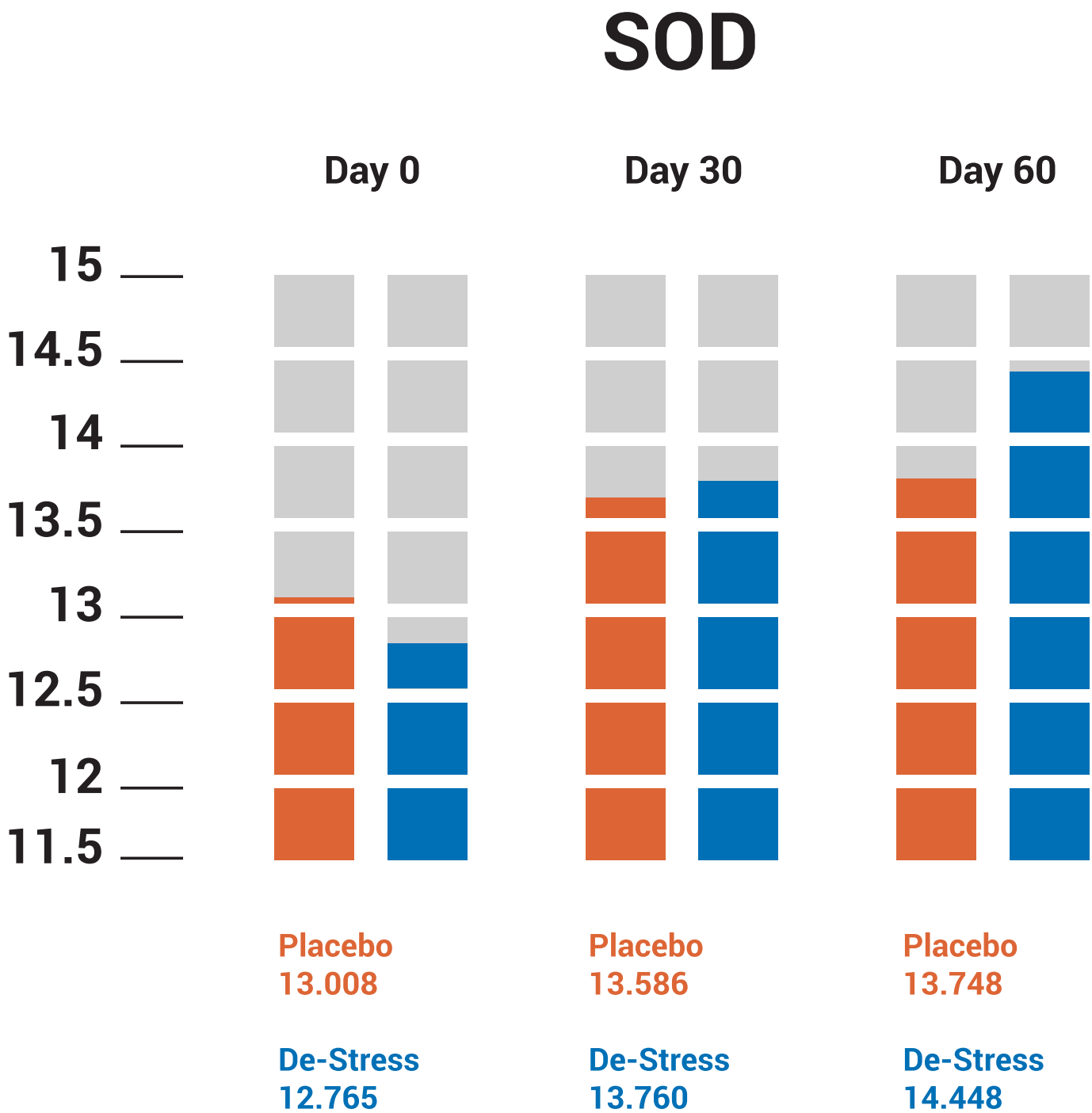
Serum Malondialdehyde LPO (Nmol/ml)

Malondialdehyde Lipid Peroxidase (LPO), there was a significant increase both at 30 days & 60 days of treatment. The increase was 9.92% at 30 days and 12.75% at 60 days of treatment as compared to the baseline.



Serum Super Oxide dismutase SOD (Nmol/ml)

The subject showed significant increase in serum SOD levels at both 30 days and 60 days of treatment. At 30 days of treatment, the increase was 7.79% while at 60 days, the increase was 13.18% as compared to the baseline values.



Other Parameters

Subjects in both the treatment groups in placebo and the investigational product were evaluated for different stress related parameters in routine lifestyle; like bouts of headache, tense muscles of neck and back, general tiredness, worry and fear, feeling of inadequate sleep, irritability, difficulty in getting sleep, boredom, eating disorders, gastrointestinal track related issues, restlessness and urge for urination at night. These symptoms were recorded by the direct response of the subject to a questionnaire before treatment, after 30 days of treatment and then at the end of the treatment. The changes in these parameters were compared with that at the baseline.



Conclusion

- The treatment with the Naturamore De-Stress significantly changed the parameters which reflect reduction in the stress of subjects after treatment.
- The changes in stress markers like reduction in salivary cortisol, increase in glutathione, LPO and SOD are significant findings after the treatment with the Naturamore De-Stress.
- These changes corroborate very well with the subjects evaluation of their own lifestyle changes like improvement in sleep, reduction in the urge to urinate at night, lesser frequency of bouts of headache, reduced irritability and reduce tension in the muscles of neck and back.
- These observations clearly indicate the beneficial effects of the treatment with Naturamore De-stress tablets in alleviating stress in the subjects.

