

## 14 CLINICAL STUDIES

### 14.4 Hypercholesterolemia

The effects of SBI on lipid indices was evaluated in a randomized, double-blind, parallel-group, placebo-controlled study. Fifty-two (52) adult subjects (aged 25-70 years) with hypercholesterolemia (5.44 – 6.99 mmol/L) who were not receiving cholesterol-lowering medication were administered either 5 g SBI or control (hydrolyzed gelatin) for 6 weeks. Mean ( $\pm$  SD) total cholesterol at baseline was 6.33 $\pm$ 0.1 mmol/L for SBI and 6.16 $\pm$ 0.1 mmol/L for placebo. Mean ( $\pm$  SD) LDL cholesterol at baseline was 4.12 $\pm$ 0.6 mmol/L for SBI and 3.95 $\pm$ 0.5 mmol/L for placebo. After 6 weeks of treatment, the SBI group had a significantly lower total cholesterol (5.97 $\pm$ 0.7 mmol/L;  $p < 0.05$ ) and LDL cholesterol (3.84 $\pm$ 0.6 mmol/L;  $p < 0.05$ ) from that in the placebo group. No significant changes in the placebo group or in any other lipid indices or markers associated with hepatorenal or cardiovascular function were observed. The consumption of SBI appeared to positively modulate the primary lipid indices.