## **Clinical Trial Summary**

## Efficacy and Safety of Polyherbal Combination (100% Male): in Male Sexual Health. A Randomized Double-blind, Placebo-controlled Study

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Efficacy and safety of herbal product—100% Male —versus placebo (PL) was evaluated in subjects with reduced male sexual function. Males aged 21-60 were studied for erectile function, libido, endurance and satisfaction in this double-blind, randomized, placebo-controlled, trial. All regimens were standardized to 2 capsules twice daily. Efficacy outcome measures were the international index of erectile function: index for premature ejaculation; erectile dysfunction inventory of treatment satisfaction; subjects' and investigators' global assessment. Safety was assessed through adverse events; hematology; blood chemistry. Of 148 subjects enrolled, 1 was excluded from analysis;

data on the intention-to-treat population of 147 (PL = 36, HLD = 38, HHD = 37, HP = 36) were analyzed. There was a significant (P, 0.01) increase in the total international index of erectile function score (mean 6 SEM) in subjects receiving 100% Male. The incidence of adverse events was similar in all the groups. Laboratory evaluations did not show any clinically significant abnormality in any of the groups. Treatment with 100% Male is well tolerated, and more effective than placebo (P, 0.01), in supporting erectile function, ejaculatory control, and sexual satisfaction.