Chapter 8

Conclusion
8. CONCLUSION

The present study conducted during the years 2000-2004 has comprehensively evaluated the new recombinant hepatitis B vaccine Genevac B in healthy adults, adolescents and in babies born to HBsAg positive mothers in Chennai in comparison with the other commercial vaccines. The salient conclusions that could be drawn from the study are as follows:

8.1 The Genevac B vaccine was well tolerated by all the 222 volunteers who received the three doses of the vaccines and no serious side effects were observed. The seroconversion and seroprotection rates were 100% and 95% respectively. The GMT of anti-HBs obtained in this study were similar to those reported with both Engerix B and Shanvac B vaccinees. The results of the study further showed that recombinant Hepatitis B vaccine (Genevac B) manufactured by Serum Institute of India Ltd. using *Hansenulla polymorpha* (yeast) as a host system is safe and is immunogenic like those using saccharomyces cerevisiae as expression system. In conclusion, the accelerated administration schedule of Genevac B was well-tolerated and provided comparable seroprotection levels of immunogenicity and safety with international acceptable standards.

8.2 The Genevac B vaccine when given in a lower doses of 10μg to adolescents also brought about 100% seroconversion and seroprotection rates like those with 20μg dosage schedule. The GMT of anti-HBs obtained from this study with two different doses of Genevac-B proved that significant immunogenicity was triggered in all the volunteers even with a lower dose indicating the economy of the vaccine Genevac B for adolescents.
8.3 In babies born to Hepatitis B positive mothers, Genevac B was well tolerated by all children who received the three doses of the vaccines in the study. The seroconversion and seroprotection rates were 100% by Genevac B with GMT of anti-HBs obtained from this study showing no significant difference when compared with both Engerix B and Shanvac B vaccinees. This study has proved that the Genevac B is successful in eliciting significant level of anti-HBs also in babies born to HBsAg positive mother comparable to the other available vaccines.

8.4 Follow up analysis of vaccinees involved in Genevac B clinical trials revealed a good protective immune response of antibody titer $\geq 10$ mIU/ml in almost all the vaccinees (adults, adolescents and in infants) followed up to three years. Thus it could be furnished that the Genevac B vaccine induces high persistence of antibody response in vaccinees and boosters may be required only after 5 years.

8.5 The cytokine analysis of vaccinees involved in Genevac B clinical trials in adults, adolescents and infants had shown a series of cytokine marker responses for IL-12, TNF-$\alpha$ in high responders, intermediate and non-responders. The comparison of the cytokine profile obtained in our study has revealed that the quantitative response of cytokines observed in our study were directly propotional to the antibody response to the hepatitis B vaccine. Thus from this study it is also proved that apart from the humoral (anti-HBs) response, Genevac B also produces cytokines suggesting that the vaccine has induced also cell mediated immune response in the vaccinees.