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Recombinant Hepatitis B Dry Vaccine Formulation and In Vitro and In Vivo Potency Testing

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Abstract: Hepatitis B vaccines are available in the market in the form of liquid suspensions that is heat sensitive. The study was conducted to produce the hepatitis B vaccine formula which can be managed out of the cold chain.

Utilization of the drying instrument indicates that liquid vaccine formula can be dried and monitored to produce quality vaccines powder. Drying techniques used include: spray drying, freeze drying and vacuum drying. Vaccine formulas were prepared as much as 6 samples with codes F-A through F-F, which reflects the composition of fillers and drying techniques. The powder vaccine was characterized by physical, chemical and antigenic potential as well as an accelerated stability. Vaccine immunogenicity carried out by an ELISA test using a Kit Anti-HBs-Elisa.

The drying technique affecting the decrease of pH and the potential of antigenic vaccine. The combination of trehalose and mannitol did not provide a significant difference to the pH and the relative potency of dried vaccine. The vaccine which was dried by freeze-drying with the composition of trehalose-mannitol (7:3) showed the relative potency in vitro at 97,78% and in vivo at 35,6%.

A dry Hepatitis B Vaccine F-B has an opportunity to be managed out of the cold chain system.

Keywords : Hepatitis B Surface Antigen (HBsAg); in vitro; in vivo; relative potency; vaccine.

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