Formulasi vaksin kering hepatitis B rekombinan serta pengujian potensi secara in vitro dan in vivo = Dried vaccine formulation of recombinant hepatitis B and potential testing in vitro and in vivo

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Abstrak

Vaksinasi merupakan upaya kesehatan preventif terhadap penularan penyakit infeksi, terutama oleh bakteri dan virus. Vaksin hepatitis B yang tersedia di pasar berbentuk suspensi cair yang sensitif terhadap panas. Penelitian dilakukan untuk menghasilkan formula vaksin hepatitis B yang dapat dikelola di luar sistem rantai dingin. Optimisasi pada alat pengering menunjukkan bahwa formula vaksin cair dapat dikeringkan dan dimonitor untuk menghasilkan serbuk vaksin yang berkualitas. Teknik pengeringan yang digunakan meliputi : spray drying, freeze drying dan vacuum drying. Formula vaksin yang disiapkan sebanyak 6 sampel dengan kode A sampai F yang merefleksikan komposisi bahan pengisi dan teknik pengeringan. Serbuk vaksin dikarakterisasi secara fisik, kimia dan potensi antigenik serta dilakukan uji stabilitas dipercepat.
Hasil penelitian menunjukkan bahwa teknik pengeringan berpengaruh terhadap penurunan pH dan potensi antigenik vaksin. Kombinasi trehalosa dan mannitol tidak memberikan perbedaan yang signifikan terhadap pH dan potensi relatif vaksin kering. Vaksin yang dikeringkan secara freeze drying dengan komposisi trehalosa: mannitol 7:3 menunjukkan potensi relatif secara in vitro sebesar 97,78 dan in vivo 35,6 serta berpotensi untuk dikelola di luar sistem rantai dingin.
.....Vaccination is a preventive health measure against the transmission of infectious diseases, especially by bacteria and viruses. 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 system. Optimization 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 A through 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 test.
The results showed that 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 and has an opportunity to be managed out of the cold chain system.