

CLAIMS

What is claimed is:

1. A hepatitis B therapeutic vaccine based on inactivated whole recombinant Hansenula polymorpha cells expressing HBsAg, wherein the hepatitis B therapeutic vaccine uses the inactivated whole recombinant Hansenula polymorpha cells as an adjuvant, the intracellular expression level of HBsAg in the recombinant Hansenula polymorpha cells is 6-10 μg HBsAg per 10^8 cells; and each HBsAg has 19 HBsAg-specific CTL epitopes, and the DNA sequence expressed by the recombinant Hansenula polymorpha cell is shown as SEQ ID NO: 1.
2. The hepatitis B therapeutic vaccine according to claim 1, wherein the HBsAg expressed by the recombinant Hansenula polymorpha cells comprises SEQ ID NO: 2.
3. The hepatitis B therapeutic vaccine according to claim 1, wherein the HBsAg expressed by the recombinant Hansenula polymorpha cells is a virus-like particle structure, which is formed by inserting HBsAg into Hansenula polymorpha lipid, and wherein 9 to 12 among the 14 cysteic acids of the HBsAg form disulfide bonds.
4. The hepatitis B therapeutic vaccine according to claim 1, wherein the host Hansenula polymorpha cell line of the recombinant Hansenula polymorpha cells is HU-11, and the accession number is CGMCC No. 1218, and the disrupted DNA sequence of the orphanin-5-phosphate decarboxylase gene of the host Hansenula polymorpha is shown in SEQ ID NO: 3.
5. The hepatitis B therapeutic vaccine according to claim 1, further comprising HBsAg stock solution or aluminum adjuvant HBsAg.
6. A recombinant Hansenula polymorpha, wherein the recombinant Hansenula polymorpha comprises the nucleotide sequence of SEQ ID NO: 1, and the nucleotide sequence of SEQ ID NO: 1 is integrated into the genome of the recombinant Hansenula polymorpha.

7. The hepatitis B therapeutic vaccine according to claim 2, wherein the dosage form of the hepatitis B therapeutic vaccine is selected from pre-filled injection solution, injection solution, or lyophilized powder injection.

8. The hepatitis B therapeutic vaccine according to claim 1, wherein the dosage form of the hepatitis B therapeutic vaccine is selected from pre-filled injection solution, injection solution, or lyophilized powder injection.

9. The hepatitis B therapeutic vaccine according to claim 2, wherein the dosage form of the hepatitis B therapeutic vaccine is selected from pre-filled injection solution, injection solution, or lyophilized powder injection.

10. The hepatitis B therapeutic vaccine according to claim 3, wherein the dosage form of the hepatitis B therapeutic vaccine is selected from pre-filled injection solution, injection solution, or lyophilized powder injection.