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Optimized Manufacturing Strategy for Personalized Tumor Neoantigen Peptide Vaccines

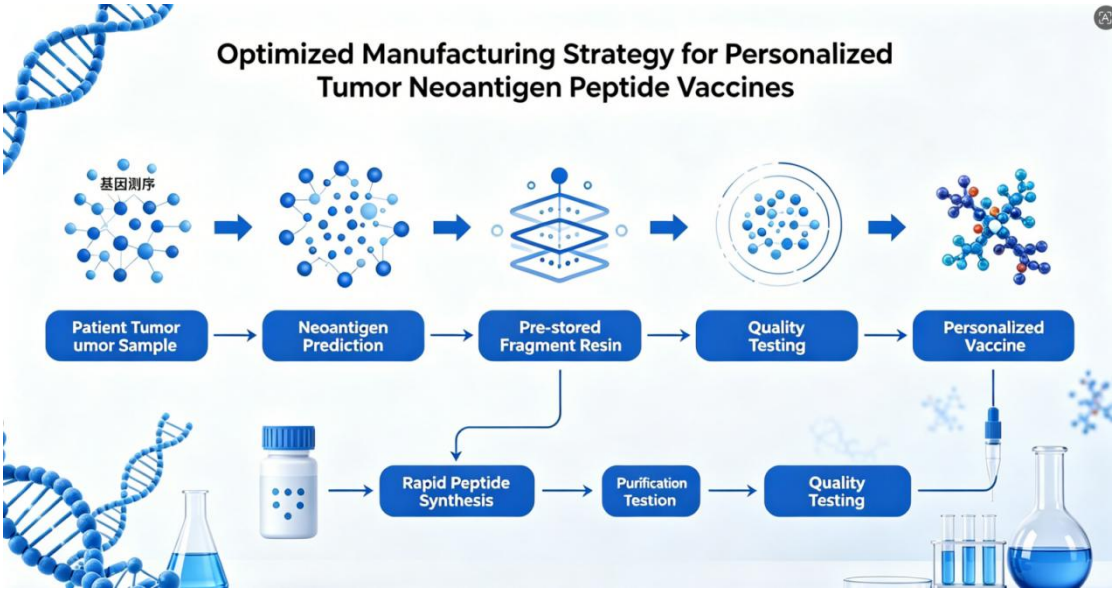
1.Research Background

Tumor neoantigen peptide vaccines realize precise anti-tumor immunotherapy by activating specific immune response against cancer cells. Since neoantigens are individualized for every patient, traditional preparation methods face prominent bottlenecks: customized synthesis cycle up to two months, poor crude peptide purity and complicated purification, which severely delay clinical medication and restrict vaccine popularization. To solve these industrial pain points, researchers develop an innovative pre-stored fragment resin preparation route to shorten production cycle and improve product quality.

2.Research Purpose and Significance

The study aims to optimize the whole production process of neoantigen peptides by prefabricating and reserving universal Link-NitraTh peptide resin. The improved technology shortens production lead time, raises crude peptide purity, reduces purification difficulty, and meets strict clinical quality specifications including over95% HPLC purity, low

endotoxin and residual trifluoroacetate. The optimized process lays standardized production foundation for personalized neoantigen vaccine industrialization and accelerates its clinical transformation.



3.Research Content

The core innovation is pre-synthesis and cold storage of shared Link-NitraTh intermediate resin. Researchers first optimize the synthesis parameters of this common peptide segment: increase amino acid feed ratio, adopt high-temperature and double condensation for difficult-coupled arginine, lifting crude purity from 9.12% to 33.54%. After reserving qualified intermediate resin, only personalized antigen fragment needs to be extended on standby resin once clinical sequences are confirmed. Actual verification shows 12 kinds of 38-amino-acid neoantigen peptides can be fully manufactured within 23 working days, covering synthesis, cleavage, HPLC purification, acetate conversion, freeze-drying and full quality inspection. Finished products meet clinical standards: purity > 95%,

endotoxin < 10 EU/mg, TFA residue < 1%, single batch yield above 20 mg, and product qualification rate superior to outsourced raw materials.

4.Conclusion & Outlook

The pre-stored fragment resin technique greatly cuts neoantigen vaccine production period from two months to around one month with obviously upgraded crude purity and simplified purification workflow, effectively resolving the long-cycle and low-yield drawbacks of traditional personalized peptide production. In the future, the team will further refine synthesis parameters, expand applicable neoantigen sequence types, upgrade standardized manufacturing specifications, and push this mature preparation process into large-scale industrial production to facilitate wider clinical application of individualized tumor immunization vaccines.