

Methods for Preparing Complex Multivalent Immunogenic Conjugates

Technology Summary

FDA researchers developed novel methods for preparing multivalent immunogenic conjugates, including vaccines. The multivalent immunogenic conjugates are synthesized by using hydrazide chemistry to conjugate mixtures of more than one polysaccharide (at a desired ratio) to at least one carrier protein. The hydrazide-based chemistry is highly efficient at conjugating the polysaccharides to the carrier protein(s), resulting in vaccines that are highly effective in inducing antibodies in mice against each polysaccharide component. The conjugation method also does not require complicated purification procedures such as chromatography and/or ammonium sulfate precipitation,

The patent applications claim the preparation of multivalent conjugate vaccines using simultaneous conjugation reactions in a single reaction mixture or batch that includes at least two immunogenic-distinct polysaccharides. This single-batch simultaneous reaction eliminates the need for multiple parallel synthesis processes for each polysaccharide vaccine conjugate component as used in conventional methods for making multivalent conjugate vaccines.

Potential Commercial Applications

- Cost effective
- Improve efficiency of conjugate vaccine manufacture

Competitive Advantages

- Streamlines preparation of combined conjugate vaccines
- Can also be applied to conjugation of mixtures of other reagents (peptides, therapeutic agents) to carrier proteins to make therapeutics and reagents

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Publications:

Pinto VB, Burden R, Wagner A, Moran EE, Lee CH. The development of an experimental multiple serogroups vaccine for *Neisseria meningitidis*. *PLoS One*. 2013;8(11):e79304. PMID: [24244473](https://pubmed.ncbi.nlm.nih.gov/24244473/)

Intellectual Property:

United States Patent No. [8,173,135](#) issued 05.08.2012,

United States Patent No. [8,557,250](#) issued 10.15.2013,

United States Patent No. [9,175,033](#) issued 11.03.2015, Related international patent applications filed

Product Area: Combined conjugate vaccines, combined conjugate therapeutics, combined conjugate biomedical reagents

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