

GelSite[®] Vaccine Delivery Platform

Ology Bioservices, Inc. (formerly Nanotherapeutics, Inc.) acquired the assets of DelSite Technologies, Inc. (Formerly Carrington Laboratories, Inc) in 2009. DelSite had developed a novel delivery technology useful for vaccines and biological therapeutics.

Chemistry GelSite polymer is a chemically and functionally distinct high molecular weight anionic polysaccharide (sodium polygalacturonate, CAS RN 119758-46-2) extracted from *Aloe vera* L., a succulent plant widely cultivated in the tropical and subtropical regions. It belongs to the pectin class of the plant polysaccharides. However, it possesses distinctive chemical and functional properties that distinguish it from all known pectins or pectic substances and other natural or synthetic polymers. It is characterized by a high galacturonic acid (Gal UA) content of >90%, an exceptionally low DM (degree of methylation) of <10%, and a high molecular weight of > 400 kDa (weight average). A combination of these chemical properties has never before been described for a pectic substance and is the key for its unique *in-situ* gelation function.

Function GelSite polymer is uniquely capable of *in-situ* gelation, i.e., changing from a liquid to a gel upon contact with bodily fluids at multiple administration sites, including subcutaneous and intramuscular injection sites and surfaces of the eye, nasal cavity, oral cavity, and wounds. This *in-situ* gelling is mediated through ionic cross-linking by divalent calcium ions present in body fluids. Gelation can occur at a very low GelSite polymer concentration and in the presence of high concentrations of other excipients or thickeners.

Manufacturing A cGMP manufacturing process for GelSite polymer has been developed.

Regulatory FDA Drug Master File #18741 is held by Ology Bioservices.

Technology platforms

Three delivery platform technologies based on GelSite polymer have been developed:

- **GelVac[™]** powder for nasal delivery of vaccines and protein/peptide therapeutics
- Injectable formulation for protein/peptide therapeutics
- Depot adjuvant for immunoenhancing and antigen sparing

Ology Bioservices is also seeking licensees and/or partners for GelVac formulated Norovirus VLP Vaccine, and a GelVac-derived typhoid vaccine (Gelsite-OAc[™]).

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