

TABLE 9.3 (Continued)
Composition of Approved Biological Products

Product	Composition
Galactosidase alpha is an enzyme, which is a homodimeric glycoprotein with a MW of approximately 100 kDa.	Each vial contains 37 mg of alpha-galactosidase beta as well as 222 mg of mannitol, 20.4 mg of sodium phosphate monobasic monohydrate, and 59.2 mg of sodium phosphate dibasic heptahydrate. Following reconstitution as directed, 35 mg of agalactosidase beta (7 mL) may be extracted from each vial.
Gemtuzumab ozogamicin is a humanized IgG4, kappa antibody conjugated with a cytotoxic antitumor or antibiotic, calicheamicin via a bifunctional linker. It has a MW of 151–153 kDa.	Each vial contains 5 mg of drug conjugate (protein equivalent) in a 20 mL amber vial. The inactive ingredients are: dextran 40, sucrose, sodium chloride, monobasic and dibasic sodium phosphate. Light-sensitive.
Glucagon (rDNA origin) has the empirical formula of C153H225N43O49S, and a MW of 3483. It is a single-chain polypeptide containing 29 amino acid residues and a MW of 3483.	Each vial contains Glucagon as hydrochloride, 1 mg (corresponding to 1 IU). Other ingredient is lactose monohydrate (107 mg).
Hemophilus B conjugate (meningococcal protein conjugate) and Hepatitis B (recombinant) Vaccine is a sterile bivalent vaccine.	Each 0.5 mL contains 7.5 mcg dose conjugated to approximately 125 mcg of outer membrane protein complex, 5 mcg of HBsAg, approximately 225 mcg of aluminum as amorphous aluminum hydroxyphosphate sulfate, and 35 mcg of sodium borate (decahydrate) as a pH stabilizer, in 0.9% sodium chloride. The vaccine contains not more than 0.0004% (w/v) residual formaldehyde.
Hepatitis B (recombinant) vaccine is a noninfectious rDNA hepatitis B vaccine containing purified surface antigen of the virus obtained by culturing genetically engineered <i>Saccharomyces cerevisiae</i> cells, which carry the surface antigen gene of the hepatitis B virus.	Each 0.5 mL of the vaccine consists of 10 mcg of hepatitis B surface antigen adsorbed on 0.25 mg of aluminum as aluminum hydroxide with a trace amount of thimerosal (<0.5 mcg of mercury) from the manufacturing process, sodium chloride (9 mg/mL), and phosphate buffers (disodium phosphate dihydrate, 0.98 mg/mL; sodium dihydrogen phosphate dihydrate, 0.71 mg/mL). Each 1 mL adult dose consists of 20 mcg of hepatitis B surface antigen adsorbed on 0.5 mg of aluminum as aluminum hydroxide. The adult vaccine is formulated without preservatives. The adult formulation contains a trace amount of thimerosal (<1.0 mcg of mercury) from the manufacturing process, sodium chloride (9 mg/mL), and phosphate buffers (disodium phosphate dihydrate, 0.98 mg/mL; sodium dihydrogen phosphate dihydrate, 0.71 mg/mL).

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