TABLE 9.3 (*Continued*)

Composition of Approved Biological Products

Product	Composition
Insulin glargine (rDNA origin) injection is human insulin analog that differs from human insulin in that the amino acid asparagine at position A21 is replaced by glycine and two arginines are added to the C-terminus of the B-chain. Chemically, it is 21 A-Gly-30 B a-L-Arg-30 B b-L-Arg-human insulin and has the empirical formula C267H404N72O78S6 and a MW of 6063.	Each milliliter contains 100 IU (3.6378 mg) of insulin glargine, 30 mcg of zinc, 2.7 mg of m-cresol, 20 mg of glycerol 85%, and water for injection. The pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide and has a pH of approximately 4.
Imiglucerase is an analog of the human enzyme, (beta)-glucocerebrosidase, a monomeric glycoprotein of 497 amino acids, containing four N-linked glycosylation sites (MW = 60,430).	Each vial contains imiglucerase (212 units), mannitol (170 mg), sodium citrates (70 mg), trisodium citrate (52 mg), disodium hydrogen citrate (18 mg), polysorbate 80 (0.53 mg). Citric acid and/or sodium hydroxide may have been added at the time of manufacture to adjust pH. Haemaccel® (cross-linked gelatin polypeptides) is used as a stabilizing agent.
Infliximab is a chimeric IgG1 k MAb with an approximate MW of 149,100 Da. It is composed of human constant and murine variable regions.	Each single-use vial contains 100 mg of infliximab, 500 mg of sucrose, 0.5 mg of polysorbate 80, 2.2 mg of monobasic sodium phosphate, monohydrate, and 6.1 mg of dibasic sodium phosphate, dihydrate. No preservatives are present.
Insulin aspart (rDNA origin) homologous with regular human insulin with the exception of a single substitution of the amino acid proline by aspartic acid in position B28 with the empirical formula C256H381N65O79S6 and a MW of 5825.8.	Each milliliter contains insulin aspart (B28 asp regular human insulin analog), 100 units/mL, glycerin (16 mg/mL), phenol (1.50 mg/mL), metacresol (1.72 mg/mL), zinc (19.6 μg/mL), disodium hydrogen phosphate dihydrate (1.25 mg/mL), and sodium chloride (0.58 mg/mL). It has a pH of 7.2–7.6. Hydrochloric acid 10% and/or sodium hydroxide 10% may be added to adjust pH.
Insulin glulisine (rDNA origin) differs from human insulin in that the amino acid asparagine at position B3 is replaced by lysine and the lysine in position B29 is replaced by glutamic acid. Chemically, it is 3B-lysine-29B-glutamic acid-human insulin, and has the empirical formula C258H384N64O78S6 and a MW of 5823.	Each milliliter of APIDRA (insulin glulisine injection) contains 100 IU (3.49 mg) of insulin glulisine, 3.15 mg of m-cresol, 6 mg of tromethamine, 5 mg of sodium chloride, 0.01 mg of polysorbate 20, and water for injection.

(*Continued*)