

TABLE 9.3 (Continued)

Composition of Approved Biological Products

Product	Composition
Interferon beta-1b is a protein that has 165 amino acids and an approximate MW of 18,500 Da. It does not include the carbohydrate side-chains found in the natural material.	Dextrose and albumin (human), USP (15 mg each/vial) are added as stabilizers. Lyophilized Betaseron is a sterile, white to off-white powder intended for subcutaneous injection after reconstitution with the diluent supplied (sodium chloride, 0.54% solution).
Interferon gamma-1b is a single-chain polypeptide containing 140 amino acids consisting of noncovalent dimers of two identical 16,465 Da monomers.	Each 0.5 mL contains: 100 mcg (two million IU) of interferon gamma-1b formulated in 20 mg of mannitol, 0.36 mg of sodium succinate, 0.05 mg of polysorbate 20, and SWFI.
Interleukin eleven (IL-11) is a thrombopoietic growth factor, has a molecular mass of approximately 19,000 Da, and is nonglycosylated. The polypeptide is 177 amino acids in length.	Each vial contains 5 mg of IL-11 with 2.3 mg of glycine, USP, 1.6 mg of dibasic sodium phosphate heptahydrate, USP, and 0.55 mg of monobasic sodium phosphate monohydrate, USP. When reconstituted with 1 mL of SWFI, USP, the resulting solution has a pH of 7.0 and a concentration of 5 mg/mL.
Laronidase is a glycoprotein with a MW of approximately 83 kDa. The recombinant protein is comprised of 628 amino acids after cleavage of the N-terminus and contains six <i>N</i> -linked oligosaccharide modification sites. Two oligosaccharide chains terminate in mannose-6-phosphate sugars.	Must be diluted prior to administration in 0.9% sodium chloride injection, USP containing 0.1% of albumin (human). The solution in each vial contains a nominal laronidase concentration of 0.58 mg/mL and a pH of approximately 5.5. The extractable volume of 5.0 mL from each vial provides 2.9 mg of laronidase, 43.9 mg of sodium chloride, 63.5 mg of sodium phosphate monobasic monohydrate, 10.7 mg of sodium phosphate dibasic heptahydrate, and 0.05 mg of polysorbate 80.
Lepirudin (rDNA) is: [Leu1, Thr2]-63-desulfolhirudin, a polypeptide composed of 65 amino acids and has a MW of 6979.5 Da.	Each vial contains 50 mg of lepirudin, 40 mg of mannitol and sodium hydroxide for adjustment of pH to approximately 7.
Muromonab-CD3 is a murine MAb to the CD3 antigen of human T cells. The antibody is a biochemically purified IgG2a with a heavy chain of approximately 50,000 Da and a light chain of approximately 25,000 Da.	Each ampule contains a buffered solution (pH 7.0 + 0.5) of monobasic sodium phosphate (2.25 mg), dibasic sodium phosphate (9.0 mg), sodium chloride (43 mg), and polysorbate 80 (1.0 mg) in water for injection.
Nesiritide is a hBNP with a MW of 3464 g/mol and an empirical formula of C143H244N5O042S4.	Each 1.5 mg vial contains nesiritide (1.58 mg), mannitol (20.0 mg), citric acid monohydrate (2.1 mg), and sodium citrate dihydrate (2.94 mg).

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