

TABLE 9.3 (Continued)

Composition of Approved Biological Products

Product	Composition
<p>Insulin lispro (rDNA origin) is Lys(B28), Pro(B29) human insulin analog, created when the amino acids at positions 28 and 29 on the insulin B-chain are reversed. It has the empirical formula C₂₅₇H₃₈₃N₆₅O₇₇S₆ and a MW of 5808, both identical to that of human insulin.</p>	<p>Each milliliter contains insulin lispro 100 units, 16 mg of glycerin, 1.88 mg of dibasic sodium phosphate, 3.15 mg of m-cresol, zinc oxide content adjusted to provide 0.0197 mg of zinc ion, trace amounts of phenol, and water for injection. Insulin lispro has a pH of 7.0–7.8. Hydrochloric acid 10% and/or sodium hydroxide 10% may be added to adjust pH.</p>
<p>Interferon alpha-2a contains 165 amino acids, and it has an approximate MW of 19,000 Da.</p>	<p>Each milliliter contains 3 MIU of interferon alpha-2a, recombinant, 7.21 mg of sodium chloride, 0.2 mg of polysorbate 80, 10 mg of benzyl alcohol as a preservative, and 0.77 mg of ammonium acetate.</p>
<p>Interferon alpha-2b has a MW of 19,271 Da.</p>	<p>Each milliliter contains 3, 5, 18, 25, or 50 MIU and also contains 20 mg of glycine, 2.3 mg of sodium phosphate dibasic, 0.55 mg of sodium phosphate monobasic, and 1.0 mg of human albumin after reconstitution. The solution formulation contains besides the active drug, 7.5 mg of sodium chloride, 1.8 mg of sodium phosphate dibasic, 1.3 mg of sodium phosphate monobasic, 0.1 mg of edetate disodium, 0.1 mg of polysorbate 80, and 1.5 mg of m-cresol as a preservative. The multidose preparations also contain 1.5 mg of cresol as preservative.</p>
<p>Interferon alfacon1 has a 166-amino acid sequence and differs from interferon alpha-2b at 20/166 amino acids (88% homology), and comparison with interferon-beta shows identity over 30% of the amino acid positions and has a MW of 19,434 Da.</p>	<p>Each vial and prefilled syringe contain 0.03 mg/mL of interferon alpha con-1, 5.9 mg/mL of sodium chloride, and 3.8 mg/mL of sodium phosphate in water for injection, USP.</p>
<p>Interferon beta-1a is a 166-amino acid glycoprotein with a MW of approximately 22,500 Da.</p>	<p>Each 0.5 mL contains either 44 mcg or 22 mcg of interferon beta-1a, 4 or 2 mg of albumin (human) USP, 27.3 mg of mannitol USP, 0.4 mg of sodium acetate, and water for injection, USP.</p>
<p>Interferon beta-1a is a 166-amino acid glycoprotein with a predicted MW of approximately 22,500 Da.</p>	<p>Each 1.0 mL (1.0 cc) of reconstituted solution contains 30 mcg of interferon beta-1a, 15 mg of albumin (human), USP, 5.8 mg of sodium chloride, USP, 5.7 mg of dibasic sodium phosphate, USP, and 1.2 mg of monobasic sodium phosphate, USP, at a pH of approximately 7.3.</p>

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