### 9.10.3 Carbohydrate Structure

For glycoproteins, the carbohydrate content (neutral sugars, amino sugars, and sialic acids) is determined. In addition, the structure of the carbohydrate chains, the oligosaccharide pattern (antennary profile), and the glycosylation site(s) of the polypeptide chain are analyzed, to the extent possible.

### 9.10.4 Physicochemical Properties

#### *9.10.4.1 Molecular Weight or Size*

Molecular weight (or size) is determined using SEC, SDS-PAGE (under reducing and/or nonreducing conditions), MS, and other appropriate techniques.

#### *9.10.4.2 Isoform Pattern*

This is determined by IEF or other appropriate techniques.

#### *9.10.4.3 Extinction Coefficient (or Molar Absorptivity)*

In many cases, it will be desirable to determine the extinction coefficient (or molar absorptivity) for the desired product at a particular UV/VIS wavelength (e.g., 280 nm). The extinction coefficient is determined using UV/VIS spectrophotometry on a solution of the product having a known protein content, as determined by techniques such as amino acid compositional analysis and nitrogen determination. If UV absorption is used to measure the protein content, the extinction coefficient for the particular product should be used.

#### *9.10.4.4 Electrophoretic Patterns*

Electrophoretic patterns and data on identity, homogeneity, and purity can be obtained by PAGE, IEF, SDS-PAGE, Western blot, capillary electrophoresis, or other suitable procedures.

#### *9.10.4.5 Liquid Chromatographic Patterns*

Chromatographic patterns and data on the identity, homogeneity, and purity can be obtained by SEC, RPLC, IEX-LC, affinity chromatography, or other suitable procedures.

## 9.11 Spectroscopic Profiles

The UV and VIS absorption spectra are determined, as appropriate. The HOS of the product is examined using procedures such as CD, NMR, and other suitable techniques, as appropriate.