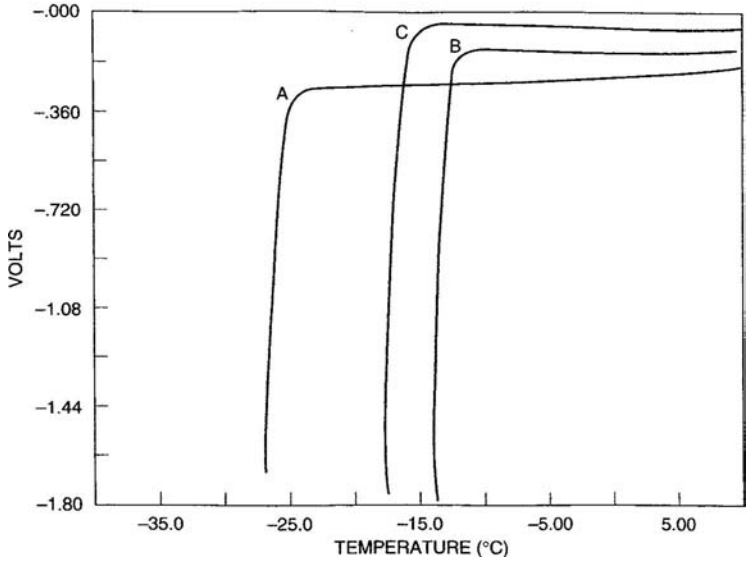

FIGURE 20 Vapor pressure moisture condensation temperature curves for three lots (A, B, and C) of α-interferon.

TABLE 2 Freeze-Dried Cake Residual Moisture Values Compared with Corresponding Vapor Pressure Moisture Values and Whether the Product Met Its Dating Period Stability Requirement

Sample	Residual moisture TG method (%)	Vapor pressure moisture (μg/vial)	Stability
α-Interferon lot A	1.19	2.05	+
α-Interferon lot B	0.98	6.67	+
α-Interferon lot C	1.28	4.76	+
AHF	1.05	0.20	+
Pertussis vaccine lot 8	2.44	9.5	+
Pertussis vaccine lot 9	4.75	26	−
Pertussis vaccine lot 10	2.14	10.2	+

+ indicates product meets dating period requirement; − indicates product does not meet dating period requirement.
Abbreviations: AHF, antihemophilic factor; TG, thermogravimetric.

9, and 10 shown in Figure 21, show condensation temperatures near −6°C and −7°C for lot 8 and lot 10 and a condensation temperature near +4.5°C for lot 9. This corresponds to vapor pressure moisture values of 9.5 and 10.2 μg water/vial for lots 8 and 10, respectively. Lot 9 has a vapor pressure moisture value of 26 μg water/vial, indicating high headspace water vapor and therefore moisture content. This agrees with the higher cake residual moisture value of 4.75% for lot 9 compared to 2.44% and 2.14% of lots 8 and 10, respectively. These are high-moisture values for both cake and headspace for lot 9. Lot 9 failed the product stability requirement. This is illustrative of high-moisture values in a freeze-dried product leading to loss of product potency and therefore stability over