

**TABLE 2** Residual Moisture Content and Predicted Loss of Factor VIII Activity from Accelerated Degradation Testing of Formulation Options for Lyophilized Human Plasma

Formulation	Residual moisture (% wt/wt) with CV (%) in parentheses ( $n = 6$ )	Mean % loss per year at $-20^{\circ}\text{C}$ (and 95% upper confidence limit)	Mean % loss per year at $20^{\circ}\text{C}$ (and 95% upper confidence limit)
Plasma FD	0.47 (5.8)	0.75 (1.00)	36.4 (38.7)
Plasma FD & SD	0.15 (9.9)	0.12 (0.30)	20.7 (27.8)
Plasma + Hepes FD	0.38 (15.4)	0.80 (0.09)	22.0 (22.4)
Plasma + Hepes FD & SD	0.10 (5)	0.07 (0.14)	16.3 (20.4)
Plasma + glycine FD	0.37 (15.9)	0.03 (0.04)	8.8 (9.7)
Plasma + glycine/Hepes FD & SD	0.13 (16.5)	0.13 (0.26)	10.33 (12.9)
Plasma + glycine/Hepes FD	0.61 (14.5)	0.03 (0.08)	6.3 (8.3)
Plasma + glycine/Hepes FD & SD	0.90 (10.3)	0.06 (0.06)	7.54 (7.6)

*Abbreviations:* FD, freeze-dried only; FD & SD, freeze-dried and secondary desiccated; CV, coefficient of variation.

*Source:* From Ref. 11.

**FIGURE 8** Flame sealing of ampoules on Bausch & Strobel filling line.