

3.2.P.3.2 BATCH FORMULA

The batch size is defined in [Table 1](#) by the volume of formulated bulk (FB) available with minimum and maximum batch sizes of 40 L and 140 L, respectively, at 50 mg/mL siltuximab.

Table 1: Quantitative Ingredient Statement for FLP for Minimum (40 L) and Maximum (140 L) Batch Sizes

Ingredient	Reference	Minimum Batch Size (g)	Maximum Batch Size (g)
Siltuximab		2000	7000
L-Histidine	USP/ Ph. Eur./JP	7.6	26.6
L-Histidine Monohydrochloride Monohydrate	Ph. Eur./JP	73	255.5
Sucrose	NF/ Ph. Eur./JP	3400	11900
Polysorbate 80	NF/ Ph. Eur./JP	16	56
Water for Injection, qs.	USP/ Ph. Eur.	40,000 ^a	140,000 ^a

^a Corresponds to theoretical batch size of 17,668 and 60,966 vials respectively at target fill weight of 2.299 g/vial