

### 3.2.P.3.2 Batch Formula

The batch formula for FLP is presented in [Table 1](#) for the minimum and maximum batch sizes. The batch size is specified by the volume of the Formulated bulk (FB) available for manufacture.

Table 1: Quantitative Ingredient Statement for FLP for Minimum (40 L) and Maximum (192 L) Batch Sizes

Ingredient	Reference	Minimum Batch Size (g)	Maximum Batch Size (g)
Siltuximab		2,000	9,600
L-Histidine	USP/ Ph. Eur./JP	7.6	36.5
L-Histidine Monohydrochloride Monohydrate	Ph. Eur./JP	73	350.4
Sucrose	NF/ Ph. Eur./JP	3,400	16,320
Polysorbate 80	NF/ Ph. Eur./JP	16	76.8
Water for Injection, qs.	USP/ Ph. Eur.	40,000 <sup>a</sup>	192,000 <sup>b</sup>

<sup>a</sup> Corresponds to theoretical batch size of 4,557 vials respectively at target fill weight of 8.778 g/vial.

<sup>b</sup> Corresponds to theoretical batch size of 21,872 vials respectively at target fill weight of 8.778 g/vial.