2.3.P.3 Manufacture

The manufacturing, release and stability testing facility of KN035 DP is as follows:

AlphaMab Co.,Ltd

Bldg. C23, Biobay

218 XingHu Street, Suzhou Industrial Park

SuZhou, Jiang Su，PR China, 215125

Tel：0512-65951826 Fax：0512-65951825

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2.3.P.3.3 Description of Manufacturing Process and Process Controls

The DP manufacturing process is an aseptic fill process in a cGMP environment. The DP manufacturing process includes buffer exchange, product concentration and formulation, sterile filtration, filling, stoppering, and sealing procedure. The process flowchart with appropriate in process controls are presented in Figure 2.5.

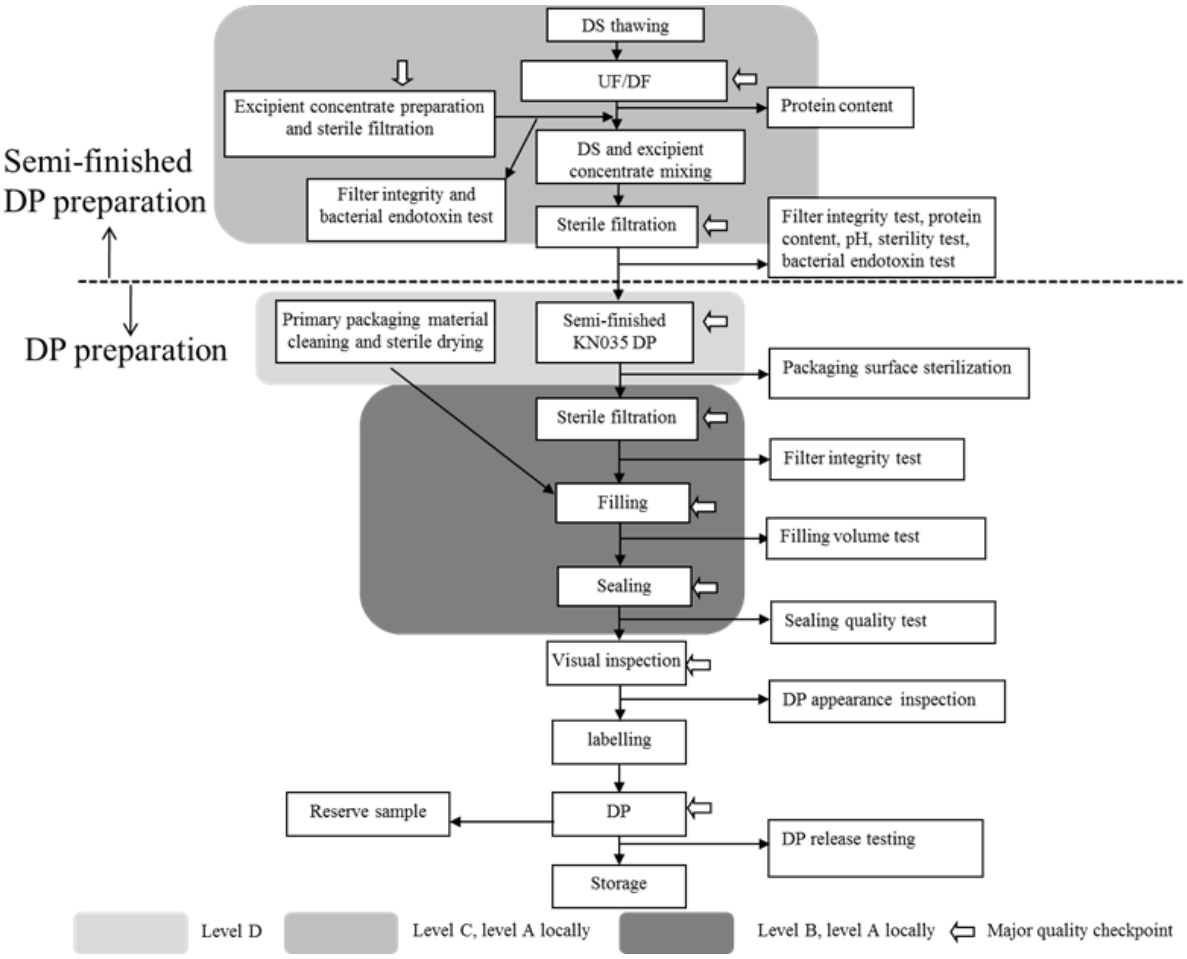

Figure 2.5 DP manufacturing flow chart

2.3.P.3.4 Controls of Critical Steps and Intermediates

Table 2.12 In-process control of DP manufacturing

Step	Test Item	Specifications
UF/DF	Protein concentration	200- 220 mg/mL
1st sterile filtration (post filtration test)	Filter Integrity*	≥3200 mbar
	Endotoxin	0.5 EU/mg
	Sterility	Sterile
	Protein concentration	180 -220 mg/mL
	pH	6.4±0.1
2nd sterile filtration (post filtration test)	Filter integrity	≥ 3200 mbar
Filling	Filling volume	1.5 mL

* Filter integrity was measured by bubble point test.