Module 2.3

2.3.P Drug Product

2.3.P.1 Description and Composition of the Drug Product

KN035 is a liquid for injection that is administrated through subcutaneous injection. The final formulation of drug product is a high protein-concentration liquid which contains 200mg/mL KN035, 20mM sodium acetate, 220mM proline, 0.02% polysorbate20; pH 6.4±0.1. Each vial contains 300mg/1.5mL recombinant humanized PDL-1 single domain antibody.