

Module 2.3

2.3 Quality Overall Summary

2.3.S Drug Substance

2.3.S.1 General Information

Table 2.1 General properties of KN035

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|---|--|
| Appearance | Clear and colorless to slight red-orange color and slight opalescent |
| Identity | Consists of two identical units of humanized camelid heavy-chain antibody (dAb), and Fc (IgG1) fusion protein. |
| Theoretical molecular weight without glycans | 79543.8Dalton |
| Theoretical extinction coefficient | 1.370 mg.mL ⁻¹ .cm ⁻¹ |
| Theoretical pI | 8.56 |
| Glycosylation | N-glycosylation at position 210 of Fc region(N297 in Kabat numbering) with G2F and G1F as dominant glycans. |
| Charge profile¹ | Contains acidic peaks 1 and 2, K0, K1 and K2 peaks, and other basic peaks |
| Binding property | Binds to the extracellular domain of PDL1 with average affinity of 2.86E-09 (M) by Octet K2 system |
| Blocking activity | Blocking the binding of PD1 to PDLI with an average IC ₅₀ of 468 ng/mL. |

1. K0: no C-terminal lysine; K1: one C-terminal lysine; and K2: two C-terminal lysine.