

Module 2.3

2.3.P.2 Pharmaceutical Development**2.3.P.2.1 Composition of Drug Product (DP)****Table 2.11 Composition of DP**

Component	Amount (mg) per vial	Concentration (mg/mL)	Function	Grade
KN035	300	200	Active ingredient	In-house standard
Sodium acetate trihydrate	4.08	2.72	Buffer	Ph. Eur., BP, JP, USP
L-Proline	569.85	379.9	Stabilizer	EP, JP, USP
Polysorbate 20	0.3	0.2	Stabilizer	Ph. Eur., JP, NF
Acetic acid, anhydrous	q.s	q.s.	pH adjusting agent	Ph. Eur., JP, USP