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1. DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

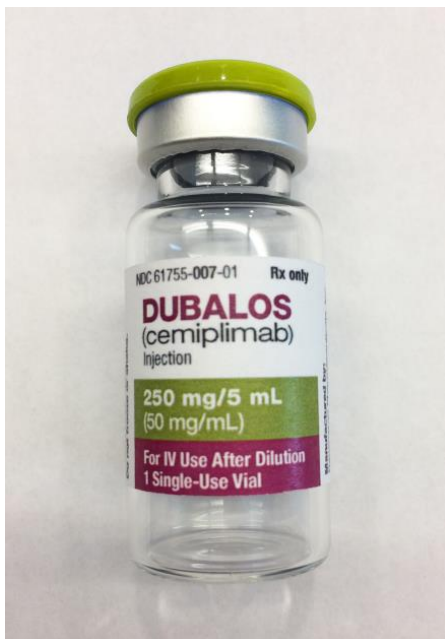
Cemiplimab solution for infusion (50 mg/mL) is a clear to slightly opalescent, colorless to pale yellow, aqueous buffered, sterile solution that may contain trace amounts of translucent to white proteinaceous particles.

There are two drug product (DP) forms: a 250 mg vial and a 350 mg vial of cemiplimab, both for infusion. Both DP forms are manufactured by filling 50 mg/mL cemiplimab into an identical single-use 10 mL glass vial, but are filled to a different target volume. The nominal composition of the cemiplimab solution for infusion for both presentations are identical and presented in [Table 1](#). A detailed description of the formulation components is provided in Module P.2.1 Components of the Drug Product.

Cemiplimab is provided in a 10 mL glass vial with a 20 mm finish made of clear Type 1 glass, equipped with a 20 mm gray chlorobutyl elastomeric liquid stopper with a B2-40 coating, FluroTec[®] film on the plug of the stopper, and a 20 mm seal cap with a flip-off button. The 250 mg vial has a light green flip-off button and the 350 mg vial has a violet flip-off button. Photographs of each DP presentation are provided in [Figure 1](#). The details of the container closure system are provided in Module P.2.4 Container Closure System and Module P.7 Container Closure System.

Cemiplimab is a sterile drug product manufactured using aseptic processing. The final finished product is not subjected to terminal sterilization.

Figure 1: Cemiplimab Drug Product Presentations (10 mL Vial)



250 mg cemiplimab presentation



350 mg cemiplimab presentation

10 mL vial, containing 50 mg/mL cemiplimab solution for injection. The label affixed to these vials is a mock-up of the actual label that would be affixed to the commercial product.

P.1 Description and Composition of the Drug Product
 ASEAN Index II.C.P.1
 Solution for Intravenous Use, Infusion – 50 mg/mL

cemiplimab

Table 1: Nominal Composition of Cemiplimab Solution for Injection

Component	Function	Reference to Quality Standard	Drug Product Nominal Composition	Content per Vial			
				5.5 mL Minimum Fill Volume	5.0 mL Withdrawable	7.44 mL Minimum Fill Volume	7.0 mL Withdrawable
Cemiplimab	Active pharmaceutical ingredient	Manufacturer's specification	50 mg/mL	275 mg	250 mg	372 mg	350 mg
L-Histidine	Buffer	USP, Ph. Eur., JP	4.8 mM	4.1 mg	3.7 mg	5.6 mg	5.2 mg
L-Histidine Monohydrochloride Monohydrate ^a	Buffer	Ph. Eur., JP	5.2 mM	6.0 mg	5.5 mg	8.1 mg	7.6 mg
Sucrose	Stabilizer	NF, Ph. Eur., JP	5% (w/v)	275 mg	250 mg	372 mg	350 mg
L-Proline	Stabilizer	USP, Ph. Eur., JP	1.5% (w/v)	82.5 mg	75 mg	112 mg	105 mg
Polysorbate 80	Stabilizer	NF, Ph. Eur., JP	0.2% (w/v)	11 mg	10 mg	15 mg	14 mg
Water for Injection	Solvent	USP, Ph. Eur.	QS	QS	QS	QS	QS

^a Named L-histidine hydrochloride hydrate in JP.

JP, Japanese Pharmacopeia; NF, National Formulary; Ph. Eur., European Pharmacopeia; QS, quantity sufficient; USP, United States Pharmacopeia