

3.2.P.4.6. NOVEL EXCIPIENTS (NON-COMPENDIAL)

The two novel lipid excipients used in the BNT162b2 drug product manufacturing are ALC-0159 (2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide) and ALC-0315 ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)). Additional information is provided in [Section 3.2.A.3 Excipients \[ALC-0159\]](#) and [Section 3.2.A.3 Excipients \[ALC-0315\]](#), respectively. Supportive nonclinical and clinical safety data are provided in [Section 2.4.4 Toxicology](#) and [Section 2.5.5 Overview of Safety](#), respectively.