5. CHARACTERIZATION OF IMPURITIES [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Information on the characterization of impurities should be provided if not previously provided in 3.2.S.3.2, Impurities. The discussion should include potential degradation products, interaction products, leachables, etc.

Reference ICH guidances Q3B, Q5C, Q6A, and Q6B.