3.2.S.3. Characterization [{Drug Substance Name}, {Manufacturer]]

1. ELUCIDATION OF STRUCTURE AND OTHER CHARACTERISTICS [{DRUG SUBSTANCE NAME}, {MANUFACTURER]]

For NCE:

Confirmation of structure based on, for example, synthetic route and spectral analyses should be provided. Information such as the potential for isomerism, the identification of stereochemistry, or the potential for forming polymorphs should also be included. Examples may include ^{1}H NMR, ^{13}C NMR, IR, MS, UV, elemental analysis, and other tests.

Details and data on other characteristic of the drug substance should also be included here including details on particle size distribution, isomerism potential, stereochemistry, and solid-state forms. This discussion should include information on their potential for formation and specifications for these may be required (use the Q6A Decision Tree).

Reference ICH guidance Q6A.

For Biotech:

For desired product and product-related substances, details should be provided on primary, secondary and higher-order structure; posttranslational forms (eg, glycoforms); biological activity, purity, and immunochemical properties, when relevant.

Reference ICH guidance Q6B.