

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

Guidance on Using this template

## **2. IMPURITIES [{DRUG SUBSTANCE NAME}], {MANUFACTURER}]**

Information on impurities should be provided as follows:

- Organic Impurities
- Inorganic impurities
- Residual solvents

These impurities should include starting materials, intermediates, reagents, by-products, degrades, etc. They should include actual observed impurities as well as potential impurities that may not be observed but can be reasonably be expected to be present during the synthesis, side reactions, etc.

Structural characterization should be provided along with a discussion of the route of synthesis and background on how the impurity was identified. Referencing the Batch Analysis section of 3.2.S.4.4. would aid the reviewer in evaluation of the information in this section.

Reference ICH guidances Q3A, Q3C, Q5C, Q6A, and Q6B.