

3.2.S.1. General Information [{Drug Substance Name}, {Manufacturer}]

3. GENERAL PROPERTIES [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

A list should be provided of physicochemical and other relevant properties of the drug substance, including biological activity for Biotech.

Reference ICH guidances Q6A and Q6B.

The list is normally easiest compiled in a table in a section 3.2.S.3.1. that might look something like this:

Property	Result	Section Reference
Appearance (color, physical form)	Off-white yellow powder	3.2.S.3.1.2
Melting range	30 –31-deg C	3.2.S.3.1.3
Solution pH	6.3 to 6.4	3.2.S.3.1.2
		Etc.

Following is a sample list of some topics to consider in this section (obviously dependent on product nature):

- Appearance (color, physical form)
- Melting range
- Optical rotation
- Organic solubility (synthesis solvents)
- Aqueous solubility
- Solution pH
- Partition coefficient
- Dissociation constants
- Solid-state forms (polymorphs, solvates, hydrates)