Questions and answers regarding to S Part (Drug Substance Part) of CTD file.

S.N	Question	EDA Answer
1	**What are the requirements in case of CEP submission?** (*Certificate of suitability which sourced from EDQM to approve the comply the API in accordance to Ph.Eur monograph*)	At least, current CEP certificate and relevant sections in respective to the additional information over Ph.Eur monograph and control of Drug substance sections (specifications & Batch Analysis).
2	**What is the required solubility profile as a general property?**	Different solubility in organic and aqueous solvents.
3	**What are the elucidation techniques required?**	At least five techniques; IR, H^1 NMR, C^{13} NMR, Elemental analysis and Mass spectroscopy.
3	**Is the IR spectroscopy enough to confirm elucidation of structure?**	Yes, in case of using Pharmacopeial standards against the API manufactured (IR spectra of both are similar).
4	**Is the polymorph data required?**	Yes, if the API have a different polymorph and have an impact on stability and performance attributes.
5	**Is the particle size test required?**	Yes, If the particle size is critical and has an effect on Quality attributes.
6	**Is the risk assessment for elemental impurities required?**	It is preferred to be submitted from supplier to be considered in the risk assessment of the finished product.
7	**Is the risk assessment for mutagenic impurities required?**	Yes, a screening of all materials and reagents during synthesis should be submitted according to ICH M7.
8	**Is the risk assessment for benzene required?**	It is required in case of the possibility of being present as a contaminant in other materials used in the synthesis.