

**Summary of Quality Differences**

This form must be completed and submitted to each Non-EU agency proposed in the EOI Request

| **Summary of Quality Differences**  Modules and numbering reflect the ICH Common Technical Document.  Modules where there are no differences between the products filed with the EU CP/DCP (delete as appropriate) and the non-EU agency should be reported as “No differences”. Where minor differences exist for a listed module, a brief summary of the details should be described. | | | |
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| **Module** | **Details in application to be filed with the EU CP/DCP (delete as appropriate)** | **Details in application to be filed with the non-EU agency** | **Discussion of noted differences** |
| ***3.2.S Drug Substance*** | | | |
| 3.2.S.1 General Information |  |  |  |
| 3.2.S.2 Manufacture |  |  |  |
| 3.2.S.3 Characterisation |  |  |  |
| 3.2.S.4 Control of the Drug Substance |  |  |  |
| 3.2.S.5 Reference Standard or Materials |  |  |  |
| 3.2.S.6 Container Closure System |  |  |  |
| 3.2.S.7 Stability |  |  |  |
| ***3.2.P Drug Product*** | | | |
| 3.2.P.1 Description and Composition of the Drug Product |  |  |  |
| 3.2.P.2 Pharmaceutical Development |  |  |  |
| 3.2.P.3 Manufacture |  |  |  |
| 3.2.P.4 Control of Excipients |  |  |  |
| 3.2.P.5 Control of Drug Product |  |  |  |
| 3.2.P.6 Reference Standard or Materials |  |  |  |
| 3.2.P.7 Container Closure System |  |  |  |
| 3.2.P.8 Stability |  |  |  |