**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. |
| --- |
| **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  |  |  |  |

**Disclaimer**

This document reflects the views of subject matter experts participating in the IPRP Information Sharing Working Group for Generics (IWGG) and should not be construed to represent the official views of any given regulatory authority participating in the IPRP.