3.2.S.4.2 Analytical procedures (name, manufacturer)

ICH Q2, WHO Technical Report Series No. 943, Annex 3

3.2.S.4.3 Validation of analytical procedures (name, manufacturer)

ICH Q2

3.2.S.4.4 Batch analyses (name, manufacturer)

ICH Q3A, ICH Q3C, ICH Q6A

3.2.S.4.5 Justification of specification (name, manufacturer)

ICH Q3A, ICH Q3C, ICH Q6A, officially recognized pharmacopoeia

3.2.S.5 Reference standards and materials (name, manufacturer)

ICH Q6A, WHO Technical Report Series No. 943, Annex 3

3.2.S.6 Container closure system (name, manufacturer)

WHO Technical Report Series No. 902, Annex 9, 2002, officially recognized pharmacopoeia

3.2.S.7 Stability (name, manufacturer)

3.2.S.7.1 Stability summary and conclusion (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, WHO Technical Report Series No. 953, Annex 2

3.2.S.7.2 Post-approval stability protocol and stability commitment (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, WHO Technical Report Series No. 953, Annex 2

3.2.S.7.3 Stability data (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, ICH Q2, WHO Technical Report Series No. 953, Annex 2

3.2.P Drug Product (Finished Pharmaceutical Product [FPP])

3.2.P.1 Description and composition of the FPP (name, dosage form)

ICH Q6A

3.2.P.2 Pharmaceutical development (name, dosage form)

ICH Q6A, ICH Q8, ICH Q9, ICH Q10

3.2.P.2.1 Components of the FPP (name, dosage form)

3.2.P.2.1.1 Active pharmaceutical ingredient (name, dosage form)

3.2.P.2.1.2 Excipients (name, dosage form)

3.2.P.2.2 Finished pharmaceutical product (name, dosage form)

3.2.P.2.2.1 Formulation development (name, dosage form)

WHO Technical Report Series No. 970, 2012

3.2.P.2.2.2 Overages (name, dosage form)

3.2.P.2.2.3 Physicochemical and biological properties (name, dosage form)

3.2.P.2.3 Manufacturing process development (name, dosage form)

ICH Q8

3.2.P.2.4 Container closure system (name, dosage form)

3.2.P.2.5 Microbiological attributes (name, dosage form)

WHO Technical Report Series No. 970, 2012

3.2.P.2.6 Compatibility (name, dosage form)

3.2.P.3 Manufacture (name, dosage form)

3.2.P.3.1 Manufacturer(s) (name, dosage form)

WHO Technical Report Series No. 970, 2012

3.2.P.3.2 Batch formula (name, dosage form)

3.2.P.3.3 Description of manufacturing process and process controls (name, dosage form)

ICH Q8, ICH Q9, ICH Q10

3.2.P.3.4 Controls of critical steps and intermediates (name, dosage form)

ICH Q2, ICH Q6A, ICH Q8, ICH Q9, WHO Technical Report Series No. 929, Annex 5

3.2.P.3.5 Process validation and/or evaluation (name, dosage form)

ICH Q8, ICH Q9, ICH Q10, WHO Technical Report Series No. 961, Annex 3

3.2.P.4 Control of excipients (name, dosage form)

3.2.P.4.1 Specifications (name, dosage form)

ICH Q6A

3.2.P.4.2 Analytical procedures (name, dosage form)

ICH Q2

3.2.P.4.3 Validation of analytical procedures (name, dosage form)

ICH Q2

3.2.P.4.4 Justification of specifications (name, dosage form)

3.2.P.4.5 Excipients of human or animal origin (name, dosage form)

ICH Q5A, ICH Q5D, ICH Q6B, WHO Technical Report Series No. 908, Annex 1

3.2.P.4.6 Novel excipients (name, dosage form)

3.2.P.5 Control of FPP (name, dosage form)

3.2.P.5.1 Specification(s) (name, dosage form)

ICH Q3B, ICH Q3C, ICH Q6A

3.2.P.5.2 Analytical procedures (name, dosage form)

ICH Q2

3.2.P.5.3 Validation of analytical procedures (name, dosage form)

ICH Q2, ICH Q2B, ICH Q6B

3.2.P.5.4 Batch analyses (name, dosage form)

ICH Q3B, ICH Q3C, ICH Q6A

3.2.P.5.5 Characterization of impurities (name, dosage form)

ICH Q3B, ICH Q3C, ICH Q6A

3.2.P.5.6 Justification of specification(s) (name, dosage form)

ICH Q6A

3.2.P.6 Reference standards or materials (name, dosage form)

ICH Q6A, WHO Technical Report Series No. 943, Annex 3

3.2.P.7 Container closure system (name, dosage form)

WHO Technical Report Series No. 902, Annex 9, 2002