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ICH Q6A

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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

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ICH Q3B, ICH Q3C, ICH Q6A

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

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

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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

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