

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Abbreviated terms
5	General and resource requirements
6	Selection of processing methods
7	Processing method implementation
7.1	Targets for method implementation
7.2	Processing method implementation
8	Initial validation of a processing method
8.1	General
8.2	Validation plan
8.3	Assays for properties of interest
8.4	Validation execution
8.4.1	General
8.4.2	Validation site
8.4.3	In-house or outsourced testing
8.5	Targets for processing method validation
8.5.1	General
8.5.2	Fitness for purpose
8.5.3	Reproducibility
8.5.4	Robustness
8.5.5	Homogeneity
8.5.6	Stability
8.6	Review and approval of validation report
9	Further validation
10	Method verification
11	Ongoing monitoring of a processing method
11.1	General
11.2	Frequency of the monitoring
11.3	Planning
11.4	Procedure of the systematic monitoring
11.5	Procedure of the periodic monitoring
11.6	External quality assessments (EQA)/Interlaboratory exercises
12	Record keeping and archiving
Annex A	(informative) Processing and testing methods
Annex B	(informative) Examples of validation plans