

ISO 8934-1:2026-05 (E)

Biotechnology - Cell viability analytical methods - Part 1: General requirements and considerations

Contents

Page

Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Symbols and abbreviated terms.....	9
5 General concepts of cell viability.....	9
5.1 General.....	9
5.2 Cell viability analytical methods.....	10
5.2.1 General.....	10
5.2.2 Count-based cell viability analytical methods.....	11
5.2.3 Non-count-based cell viability analytical methods.....	12
5.3 Cell viability as a measurand.....	12
5.3.1 General.....	12
5.3.2 Measurand charts for cell viability analytical methods.....	13
6 Design of fit for purpose cell viability analytical methods.....	15
6.1 General.....	15
6.2 Intended use.....	15
6.3 Viable state attributes and measurement principles.....	16
6.4 Sample considerations and recommendations.....	18
6.5 Measurement process.....	19
7 Design of a matrix of cell viability analytical methods.....	20
8 Managing sources of variability in a cell viability analytical method.....	20
8.1 General.....	20
8.2 Pre-analytical phase considerations.....	21
8.2.1 General.....	21
8.2.2 Presence of contamination (biological).....	23
8.3 Analytical phase considerations.....	23
8.3.1 General.....	23
8.3.2 Test sample preparation.....	23
8.3.3 Test sample stability.....	24
8.3.4 Analytical reagents.....	24
8.3.5 Environmental conditions.....	25
8.3.6 Instrumentation and data collection.....	26
8.3.7 Data analysis.....	27
8.4 Post-analytical phase considerations.....	30
8.4.1 General.....	30
8.4.2 Measurement uncertainty.....	30
8.4.3 Reporting of cell viability.....	31
8.4.4 Metadata documentation.....	31
8.4.5 Interpretation of cell viability results.....	32
9 Cell viability analytical method qualification, validation, and continued verification.....	33
9.1 General.....	33
9.2 Qualification.....	33
9.2.1 Qualification characteristics.....	33
9.2.2 Accuracy.....	33

9.2.3	Repeatability.....	34
9.2.4	Specificity and Selectivity.....	34
9.2.5	Sensitivity.....	34
9.2.6	Linearity and Proportionality.....	35
9.2.7	Range.....	35
9.3	Validation.....	35
9.3.1	Validation characteristics.....	35
9.3.2	Intermediate precision.....	36
9.3.3	Limit of detection (LoD) and limit of quantitation (LoQ).....	36
9.3.4	Robustness and Ruggedness.....	37
9.4	Continued verification.....	37
9.5	Quality control materials for cell viability measurements.....	37
Annex A (Informative) Examples of cell viability analytical methods and their viable state attributes.....		39
Annex B (Informative) Example measurand chart for the luminescent cell viability analytical method.....		41
Annex C (Informative) Sources of cell stress that can affect the viable state of the cell.....		43
Annex D (Informative) Considerations for viability testing by pre-analytical treatment.....		46
Annex E (Informative) Considerations for cell viability as a quality attribute in the testing and characterization of cellular therapeutic products.....		49
Annex F (Informative) Conceptual process for Cell Viability Analytical Method Development.....		51
Bibliography.....		53