

ISO/TS 23758:2021 (E)

Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products

Contents

	Forewords
1	Scope
2	Normative references
3	Terms and definitions
4	Principle
5	General requirements for the test/kit
6	Reagents
6.1	Standard blank matrix
6.2	Antibiotics
6.3	Standard stock solution
6.4	Working stock solutions
6.5	Spiked sample
7	Apparatus
8	Sample Preparation
8.1	Stock solution preparation
8.2	Working stock solution preparation
8.3	Blank matrix sample selection
8.4	Spiked sample creation
9	Procedure
9.1	Validation
9.1.1	General
9.1.2	Detection capability (CC β)
9.1.2.1	General
9.1.2.2	Compounds involved in the study
9.1.2.3	Determination of concentrations of substances to be involved in the study
9.1.2.4	Number of replicates required
9.1.2.5	Testing requirements
9.1.2.6	Determination of a dose response curve (optional)
9.1.3	Test selectivity/specificity
9.1.3.1	General
9.1.3.2	Substance-specific tests
9.1.3.3	Group-specific tests
9.1.3.4	Rate of positive results not caused by residues of veterinary drugs
9.1.4	Robustness testing
9.1.4.1	General
9.1.4.2	Influences of test protocol (where applicable)
9.1.4.2.1	Influences
9.1.4.2.2	Incubation temperature (optional, conditions are met as per those set by the manufacturer)
9.1.4.2.3	Incubation time (for each incubation step)
9.1.4.2.4	Delay of reading
9.1.4.2.5	Set up time (keeping of extract before testing)
9.1.4.2.6	Volume of milk
9.1.4.2.7	Temperature of milk

- 9.1.4.3 Milk quality/composition influences
 - 9.1.4.3.1 General
 - 9.1.4.3.2 High somatic cell count (SCC)
 - 9.1.4.3.3 High total bacterial count (TBC)
 - 9.1.4.3.4 Low fat content (FC)
 - 9.1.4.3.5 High fat content (FC)
 - 9.1.4.3.6 Low protein content (PC)
 - 9.1.4.3.7 High protein content (PC)
 - 9.1.4.3.8 Low pH
 - 9.1.4.3.9 High pH
 - 9.1.4.3.10 Early lactation milk
 - 9.1.4.3.11 Late lactation milk
- 9.1.4.4 Influences by type of milk or animal species (optional)
 - 9.1.4.4.1 General
 - 9.1.4.4.2 UHT milk
 - 9.1.4.4.3 Sterilized milk
 - 9.1.4.4.4 Thawed milk
 - 9.1.4.4.5 Reconstituted milk
 - 9.1.4.4.6 Other animal species' milk
- 9.1.4.5 Influence of production and age of reagents
 - 9.1.4.5.1 Batch differences
 - 9.1.4.5.2 Age of reagents
- 9.1.4.6 Stability of test kits and reagents
- 9.1.5 Reader and test repeatability
 - 9.1.5.1 Visual reading
 - 9.1.5.2 Repeatability of the reader (instrumental reading)
 - 9.1.5.3 Repeatability of the test
- 9.1.6 Participation in a(n) (inter)national ring trial
- 9.2 Verification testing of a transferred screening method
 - 9.2.1 General
 - 9.2.2 Detection capability
 - 9.2.2.1 General
 - 9.2.2.2 Compounds involved in the study
 - 9.2.2.3 Number of replicates required
 - 9.2.3 Test selectivity/specificity
 - 9.2.4 Robustness testing
 - 9.2.5 Reader and test repeatability
 - 9.2.5.1 Visual reading
 - 9.2.5.2 Repeatability of the reader (instrumental reading)
 - 9.2.5.3 Repeatability of the test
 - 9.2.6 Participation in a(n) (inter)national ring trial
- Annex A (informative) European legislation on veterinary drugs in cow milk
 - A.1 General
 - A.2 Allowed substances
 - A.3 Prohibited substances (MRL cannot be established)
- Annex B (informative) USA legislation on animal drug residues in milk
 - B.1 General
- Annex C (informative) List of problematic compounds in the preparation of stock solutions
- Annex D (informative) Summary of the stability of antibiotics in solution and in matrix