

ISO 8284:2024-12 (E)

Traditional Chinese medicine - Simplified accelerated stress simulation methods

Contents

Page

Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Simplified accelerated stress simulation methods.....	2
4.1 General.....	2
4.2 Different types of accelerated stress simulation.....	3
4.2.1 Types of accelerated stress.....	3
4.2.2 Accelerated gas stress simulation.....	3
4.2.3 Accelerated chemical stress simulation.....	3
4.2.4 Accelerated storage stress simulation.....	4
5 Application methods for accelerated gas stress simulations.....	4
5.1 General.....	4
5.2 Stability-relevant reactions.....	4
5.2.1 General.....	4
5.2.2 Oxidation with gaseous reactants.....	4
5.2.3 Reduction with gaseous reactants.....	5
5.2.4 Other gaseous reactants.....	5
5.3 Reagents.....	5
5.4 Apparatus.....	5
5.5 General stress simulation setup.....	7
5.6 General implementation.....	7
5.7 Analysis.....	8
5.8 Oxidative gas stress simulation.....	8
5.8.1 Oxygen as gas stress factor.....	8
5.8.2 Sulfur dioxide as gas stress factor.....	8
5.8.3 Nitrogen oxide as gas stress factor.....	9
5.9 Reductive gas stress simulation.....	9
5.9.1 Carbon monoxide as gas stress factor.....	9
5.9.2 Hydrogen as gas stress factor.....	9
5.10 Other gas stress simulation by use of carbon dioxide as gas stress factor.....	9
6 Application methods for accelerated chemical stress simulations.....	10
6.1 General.....	10
6.2 Types of accelerated chemical stress simulations.....	10
6.2.1 Catalytic stress simulation.....	10
6.2.2 Redox and pH stress simulation.....	10
6.3 Accelerated catalytic stress simulation.....	10
6.3.1 General.....	10
6.3.2 Pre-simulation with a catalytic heavy metal mixture.....	11
6.3.3 Identification of a specific stability-influencing catalytic reaction.....	13
6.4 Accelerated redox and pH stress simulation.....	14
6.4.1 General.....	14
6.4.2 Reagents.....	14
6.4.3 Apparatus.....	14
6.4.4 Execution.....	15
6.4.5 Sample preparation and analysis.....	15
6.4.6 Accuracy criterion for accelerated Redox pH stress simulation (validation).....	16

7	Application methods for accelerated storage stress simulations	16
7.1	General	16
7.2	Types of accelerated storage stress simulation	16
7.2.1	Temperature stress simulation	16
7.2.2	Humidity stress simulation	16
7.2.3	Combined humidity and temperature stress simulation	17
7.3	Accelerated temperature stress tests	17
7.3.1	Reagents	17
7.3.2	Apparatus	17
7.3.3	Execution	17
7.3.4	Analysis	18
7.3.5	Accuracy criterion for accelerated temperature stress simulation (validation)	18
7.4	Accelerated humidity stress simulation	18
7.4.1	Reagents	18
7.4.2	Apparatus	19
7.4.3	Execution	19
7.4.4	Analysis	20
7.4.5	Accuracy criterion for accelerated humidity stress simulation (validation)	20
7.5	Accelerated humidity and temperature stress tests	20
	Annex A (informative) Accuracy criterion for accelerated gas stress simulation (validation)	21
	Bibliography	23