ISO 10993-11:2017-09 (E)

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 General considerations 3
4.1 General 3
4.2 Selection of animal species 3
4.3 Animal status 3
4.4 Animal care and husbandry 3
4.5 Size and number of groups 4
4.5.1 Size of groups 4
4.5.2 Number of groups 4
4.5.3 Treatment controls 4
4.6 Route of exposure 5
4.7 Sample preparation 5
4.8 Dosing 5
4.8.1 Test sample administration 5
4.8.2 Dosage volumes 5
4.8.3 Dosage frequency 6
4.9 Body weight and food/water consumption 6
4.10 Clinical observations 6
4.11 Clinical pathology 6
4.12 Anatomic pathology 7
4.13 Study designs 7
4.14 Quality of investigation 7

5 Acute systemic toxicity 7
5.1 General 7
5.2 Study design 8
5.2.1 Preparations 8
5.2.2 Experimental animals 8
5.2.3 Test conditions 8
5.2.4 Body weights 9
5.2.5 Clinical observations 9
5.2.6 Pathology 9
5.3 Evaluation criteria 10
5.3.1 General 10
5.3.2 Evaluation of results 10
5.4 Final report 10

6 Repeated exposure systemic toxicity (subacute, subchronic and chronic systemic toxicity) 12
6.1 General 12
6.2 Study design 12
6.2.1 Preparations 12
6.2.2 Experimental animals 12

6.2.3 Test conditions 13
6.2.4 Body weights 13
6.2.5 Clinical observations 13
6.2.6 Pathology 13
6.3 Evaluation criteria 14
6.3.1 General 14
6.3.2 Evaluation of results 14

6.4 Final report 15

Annex A (informative) Routes of administration 16

Annex B (informative) Dosage volumes 18

Annex C (informative) Common clinical signs and observations 19

Annex D (informative) Suggested haematology, clinical chemistry and urinalysis measurements20
Annex E (informative) Suggested organ list for histopathological evaluation 22

Annex F (informative) Organ list for limited histopathology for medical devices subjected to systemic toxicity testing 24

Annex G (informative) Information on material-mediated pyrogens 25

Annex H (informative) Subchronic rat -- Dual routes of parenteral administration 26

Bibliography 28