ISO 21756:2026-07 (E)

Traditional Chinese medicine - Salvia miltiorrhiza root and rhizome aqueous extract granules

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements of manufacturing procedures 2

5 Description 2

6 Qualitativeidentification 2
6.1 Thin-Layer chromatographic (TLC) identification 2
6.2 Characteristic chromatogram 2
6.3 Marker compound 2
6.4 Determination of ethanol-soluble extractives 2
6.5 Determination of water or moisture content 2
6.6 Particle size and particle size distribution 2
6.7 Dissolution or disintegration 3
6.8 Uniformity of dosage unit 3

7 Requirements of safety assurance 3
7.1 Heavy metals and harmful elements 3
7.2 Pesticide residues 3
7.3 Microorganism 3

8 Test methods 3
8.1 Thin-Layer chromatographic identification 3
8.2 Determination of characteristic chromatogram 3
8.3 Determination of marker compound content 3
8.4 Determination of ethanol-soluble extractives 3
8.5 Determination of water or moisture content 3
8.6 Determination of particle size and particle size distribution 3
8.7 Dissolution or disintegration test 4
8.8 Estimation of uniformity of dosage unit 4
8.9 Determination of heavy metals and harmful elements content 4
8.10 Determination of pesticide residues content 4
8.11 Microorganism test 4

9 Storage 4

Annex A (informative) Salvia miltiorrhiza root and rhizome aqueous extract granules manufacturing procedures 5

Annex B (informative) Safety requirements in different pharmacopoeias and standards 7

Annex C (informative)Thin-Layerchromatographicidentification 9

Annex D (informative) Determination of characteristic chromatogram 11

Annex E (informative) Determination of marker compound content 13

Annex F (informative) Determination of ethanol-soluble extractives 15

Bibliography 16