ISO 23419:2021-12 (E)

Traditional Chinese medicine - General requirements for manufacturing procedures and quality assurance of granules

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 General requirements of manufacturing procedures ... **3**

4.1 General ... 3
4.2 Crushing ... 4
4.3 Extraction ... 4
4.4 Liquid-solid separation ... 5
4.5 Concentration and drying ... 5
4.6 Granulation ... 6
4.6.1 General ... 6
4.6.2 Dry granulation ... 6
4.6.3 Semi-dry granulation ... 7
4.6.4 Wet granulation ... 7
4.7 Compaction ... 8
4.8 Packaging and labelling ... 8

5 General requirement of quality assurance ... **8**

5.1 General ... 8
5.2 Equivalency evaluation ... 9
5.3 Identification ... 9
5.4 Assay ... 9
5.5 Particle size and particle size distribution ... 9
5.6 Dissolution or disintegration test ... 9
5.7 Determination of water or moisture content ... 9
5.8 Uniformity of dosage units ... 10

6 Requirements of safety tests ... **10**

6.1 Pesticide residues ... 10
6.2 Heavy metals ... 10
6.3 Aflatoxins ... 10
6.4 Microorganism ... 10

Annex A (informative) **Production, quality and selection of crude drugs** ... **11**

Annex B (informative) **Particle size distribution** ... **12**

Annex C (informative) **Equivalency evaluation** ... **13**

Annex D (informative) **Determination of the content of methanol-soluble extractives** ... **15**

Bibliography ... **17**