

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