

# ISO 23419:2021-12 (E)

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

---

<b>Contents</b>	<b>Page</b>
Foreword.....	iv
Introduction.....	v
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 General requirements of manufacturing procedures.....</b>	<b>3</b>
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
<b>5 General requirement of quality assurance.....</b>	<b>8</b>
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
<b>6 Requirements of safety tests.....</b>	<b>10</b>
6.1 Pesticide residues.....	10
6.2 Heavy metals.....	10
6.3 Aflatoxins.....	10
6.4 Microorganism.....	10
<b>Annex A (informative) Production, quality and selection of crude drugs.....</b>	<b>11</b>
<b>Annex B (informative) Particle size distribution.....</b>	<b>12</b>
<b>Annex C (informative) Equivalency evaluation.....</b>	<b>13</b>
<b>Annex D (informative) Determination of the content of methanol-soluble extractives.....</b>	<b>15</b>
<b>Bibliography.....</b>	<b>17</b>