

# ISO 19617:2018 (E)

## Traditional Chinese medicine — General requirements for the manufacturing process of natural products

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Assurance of manufacturing process
4.1	Premises
4.1.1	General
4.1.2	Storage areas
4.1.3	Production areas
4.1.4	Sanitation
4.2	Documentation
4.2.1	General
4.2.2	Crude drugs
4.2.3	Finished traditional Chinese medicinal products
4.2.4	Crude drug preparations
4.2.5	Processing instructions
4.3	Personnel
4.3.1	General
4.3.2	Crude drug control manager
4.3.2.1	General
4.3.2.2	Competence of crude drug control manager
4.3.2.3	Duties of crude drug control manager
4.3.3	Training
4.3.4	Personnel hygiene
4.4	Change control
4.5	Deviation control
4.6	Self-inspections
Annex A	(normative) Manufacturing control
A.1	General
A.2	General considerations
A.3	Mixing of batches and blending
Annex B	(normative) Quality control
B.1	General
B.2	Sampling
B.3	Testing
B.3.1	Classification
B.3.2	Identification tests
B.3.3	Quantitative determination