

NATIONAL MEDICAL PRODUCTS NEWSLETTER



中国药品国际交流中心

Special Provision on Supervision and Administration of Manufacturing of Traditional Chinese Medicines

Chapter I General Provisions

Article 1 In order to promote the inheritance, innovation, and development of traditional Chinese medicine, strengthen the supervision and administration of manufacturing of traditional Chinese medicines (TCMs), regulate production activities for TCMs, and improve the quality of TCMs, the *Special Provision on Supervision and Administration of Manufacturing of Traditional Chinese Medicines* (hereinafter referred to as the Provision) is established in accordance with the *Drug Administration Law of the People's Republic of China*, the *Law of the People's Republic of China on Traditional Chinese Medicine*, the *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China*, the *Measures for the Administration of Drug Registration*, the *Measures for the Supervision and Administration of Drug Manufacturing*, and other relevant laws, regulations, and rules.

Article 2 The Provision shall apply to the manufacturing, supervision, and administration of traditional Chinese medicinal (TCM) prepared slices, TCM dispensing granules, Chinese proprietary medicines, TCM crude drugs under approval administration, and TCM extracts under filing management.

Article 3 The marketing authorization holder (hereinafter referred to as the MAH) and TCM manufacturer shall adhere to the principles and characteristics of traditional Chinese medicine, strictly manufacture in accordance with laws and regulations, and ensure that the entire TCM production process continuously complies with statutory requirements.

Article 4 Drug regulatory authorities shall strengthen supervision and administration over TCM manufacturing, supervise MAHs and TCM manufacturers in fulfilling their primary responsibilities for quality and safety, and ensure the safety, efficacy, and quality control of TCMs.

Article 5 The MAHs and TCM manufacturers shall be encouraged to extend their quality management systems to cover the entire

production process of TCM crude drugs, ensure the quality of TCM crude drugs, accelerate the construction of high-level digital workshops, smart factories, and green factories, improve the quality control level of TCM manufacturing, and promote the digital and intelligent transformation of TCM manufacturing.

Article 6 Drug regulatory authorities shall strengthen research on TCM regulatory science, promote interdisciplinary and interdepartmental collaborative efforts, accelerate the research and application of new regulatory tools, methods, and standards for TCMs by leveraging the resources of higher education institutions and research institutes, improve the manufacturing regulatory system in line with the characteristics of TCMs, and facilitate high-quality development of the TCM industry.

Article 7 Industry associations in the field of traditional Chinese medicine shall strengthen industry self-discipline, guide and urge the MAHs and TCM manufacturers to comply with industry rules consciously, enhance integrity building, regulate product promotion, promote fair competition, and jointly foster a sound industry order in the TCM industry.

Chapter II Essential Requirements

Article 8 The manufacturing of prepared slices shall not exceed the scope of processing approved by the drug manufacturing license, and the prepared slices purchased from outside sources shall not be directly repackaged or placed on the market after merely changing their packaging or labels. Manufacturers of prepared slices shall label their products clearly, accurately, and in a standardized manner in accordance with the *Provision for Labels of TCM Prepared Slices*.

Where toxic drugs for medical use are used for the manufacturing of TCM prepared slices, manufacturers shall comply with the relevant laws, regulations, and provisions concerning toxic crude drugs for medical use and toxic prepared pieces.

Article 9 An application for expanding the

中药生产监督管理专门规定

第一章 总 则

第一条 为促进中医药传承创新发展，加强中药生产监督管理，规范中药生产活动，提升中药质量，根据《中华人民共和国药品管理法》《中华人民共和国中医药法》《中华人民共和国药品管理法实施条例》《药品注册管理办法》《药品生产监督管理办法》等有关法律、法规和规章，制定本规定。

第二条 中药饮片、中药配方颗粒、中成药、实施审批管理的中药材、实施备案管理的中药提取物等的生产及监督管理适用本规定。

第三条 药品上市许可持有人（以下称持有人）、中药生产企业应当遵循中医药规律和特点，严格依法依规生产，保证中药生产全过程持续符合法定要求。

第四条 药品监督管理部门应当加强中药生产监督管理，监督持有人和中药生产企业落实质量安全主体责任，保障中药安全、有效和质量可控。

第五条 鼓励持有人、中药生产企业将质量管理体系延伸到中药材生产全过程，保障中药材质量，加快建设高水平数字化车间和智能工厂、绿色工厂，提升中药生产质量控制水平，促进中药生产数智化转型。

第六条 药品监督管理部门应当加强中药监管科学研究，推进多学科、多部门联合攻关，依托高等院校、科研机构等加快推进中药监管新工具、新方法、新标准研究和应用，健全符合中药特点的生产监管体系，促进中药产业高质量发展。

第七条 中医药行业社会组织应当加强行业自律，引导和督促持有人、中药生产企业自觉遵守行业规则，强化诚信建设，规范产品宣传，促进公平竞争，共同营造良好的中药行业秩序。

第二章 基本要求

第八条 生产中药饮片不得超出药品生产许可批准的炮制范围，不得外购中药饮片直接分包装或者改换包装标签后上市。中药饮片生产企业应当按照中药饮片标签管理规定清晰、准确、规范地标注。

中药饮片生产企业以医疗用毒性药品中药材生产中药饮片的，还应当符合医疗用毒性药品、毒性饮片相关法律法规和管理规定。

第九条 申请增加中药配方颗粒生产范围的，应当为已取得中药饮片和颗粒剂生产范围的药品生产企业，具备中药炮制、提取、分离、浓缩、干燥、制粒等完整的生产能力，以及生产、销售品种数量相适应的生产规模，具有全过程追溯及风险管理能力。

manufacturing scope to include TCM dispensing granules shall be made by a drug manufacturer that has been approved to manufacture TCM prepared slices and granules, and that possesses complete manufacturing capabilities for processing of TCM prepared slices, extraction, separation, concentration, drying, and granulation, as well as the manufacturing capability commensurate with the number of products manufactured and marketed, and has the capability of whole-process traceability and risk management.

A manufacturer of TCM dispensing granules shall carry out by itself the processing of qualified prepared slices used for the manufacturing of TCM dispensing granules, and their descriptions and specifications shall comply with the specifications and requirements for the manufacturing of the corresponding products.

Article 10 Where TCM extracts subject to filing management are manufactured and used, the TCM extract manufacturers and the MAHs of Chinese proprietary medicines shall respectively carry out manufacturing and use filings in accordance with relevant requirements. For TCM extracts made by MAHs themselves and used only for the manufacturing of Chinese proprietary medicines within MAHs' own enterprises, filing is not required for manufacturing or use. For a single TCM extract for Chinese proprietary medicines, the MAHs may file for more than one supplier of the TCM extract. Prior to changing a supplier that has already been filed for manufacturing, the MAHs shall conduct a study validation and quality comparison. On-site inspection shall be conducted when necessary.

Article 11 The MAHs shall organize manufacturing in accordance with the production process recognized by the drug regulatory authority. The MAHs may procure prepared slices with characteristics and specifications meeting manufacturing requirements from manufacturers or distributors of prepared slices; alternatively, the MAHs may also procure TCM crude drugs and then pre-process them for the manufacturing of Chinese proprietary medicines, including collection processed (cut while fresh) TCM crude drugs from compliant manufacturers of TCM crude drugs. The standards and processes for pre-processing or collection processing of TCM crude drugs shall comply with national drug standards for the corresponding prepared slices or Chinese proprietary medicines, or the

provincial-level processing specifications for prepared slices.

For the manufacturing of compound preparations derived from ancient classic formulas, TCM manufacturers shall possess complete manufacturing capabilities for the processing of prepared slices, extraction, concentration, drying, and formulation.

Article 12 For drugs that have completed drug re-registration but have not undergone commercial-scale manufacturing during the re-registration period, the MAHs shall complete all relevant procedures strictly in accordance with the requirements of the National Medical Products Administration (NMPA) on domestic drug re-registration application procedures before resuming manufacturing.

Before resuming manufacturing of TCM injections, the MAHs shall complete post-marketing studies and evaluations as required and submit supplementary applications.

Article 13 Where the MAHs contract the manufacturing of Chinese proprietary medicines, the MAHs shall strictly perform their primary responsibilities in accordance with laws and regulations. Both the MAHs and contract manufacturers shall, in accordance with the requirements of the NMPA on the administration of contract manufacturing and contracted manufacturing of drugs, carry out tasks such as audit, research, evaluation, and reporting, and ensure the effective alignment of their quality management systems.

For contract manufacturing of TCM injections, the production heads, persons in charge of quality, and qualified persons of both the MAHs and the contract manufacturers shall have at least three years of practical experience in the manufacturing and quality management of TCM injections. The product shall have records of continuous manufacturing and marketing in the past five years without serious adverse reactions or failing sampling inspection, and the contract manufacturer shall have records of continuous manufacturing of TCM injections in the past three years.

For contract manufacturing of Chinese proprietary medicines that have not undergone commercial-scale manufacturing during the re-registration period, the MAHs shall complete the manufacturing resumption process as stipulated in Article 12 of the Provision and may proceed with contract manufacturing only after ensuring product quality stability.

Article 14 The MAHs and TCM manufacturers

中药配方颗粒生产企业应当自行炮制用于中药配方颗粒生产的合格中药饮片，其性状、规格应当符合相应品种生产的规定和要求。

第十条 生产、使用实施备案管理中中药提取物的，中药提取物生产企业和中成药持有人应当按照要求分别进行生产备案、使用备案。持有人自行提取且仅用于本企业中成药生产的，无需进行生产及使用备案。中成药持有人可以对一种中药提取物的多家供应商进行使用备案，生产过程中变更已经使用备案的供应商前，应当开展研究验证和质量对比，必要时进行现场审核。

第十一条 持有人应当按照药品监督管理部门核准的生产工艺组织生产。持有人可以从中药饮片生产经营企业采购性状、规格符合生产需求的中药饮片用于中成药生产；也可以采购中药材经过前处理后用于中成药生产，包括从符合要求的中药材生产企业采购产地加工（趁鲜切制）中药材。中药材的前处理或者产地加工标准和工艺，应当符合相应中药饮片、中成药的国家药品标准或者省级中药饮片炮制规范要求。

生产古代经典名方中药复方制剂的，中药生产企业应当具备中药饮片炮制、提取、浓缩、干燥、制剂等完整的生产能力。

第十二条 对已通过药品再注册但药品再注册周期内未开展商业化规模生产的，持有人恢复生产前应当严格按照国家药监局关于境内生产药品再注册申报程序等规定完成相关工作。

中药注射剂恢复生产前，持有人还应当按照要求完成上市后研究和评价，并提出补充申请。

第十三条 持有人委托生产中成药的，应当严格依法依规履行主体责任。持有人和受托生产企业均应当按照国家药监局对药品委托和受托生产管理的要求，完成审核、研究、评估和报告等工作，保证双方质量管理体系有效衔接。

委托生产中成药注射剂的，持有人和受托生产企业的生产负责人、质量负责人、质量受权人均应当具备中药注射剂三年及以上生产和质量管理的实践经验；产品应当具有近五年连续生产销售记录，且未发生过严重不良反应和抽检不合格的情况；受托生产企业应当具备中药注射剂近三年连续生产的记录。

委托生产药品再注册周期内未开展商业化规模生产中成药的，持有人应当按照本规定第十二条要求完成恢复生产，确保质量稳定后，方可委托生产。

第十四条 持有人、中药生产企业应当建立并实施药品追溯制度，通过信息化手段实施中药产品追溯，及时准确记录、保存追溯数据，完善中成药生产经营全过程信息化追溯体系。中药饮片、中药配方颗粒生产企业应当分步骤、分品种逐步建立健全生产经营信息化追溯制度。持有人、中药生产企业应当探索中药生产经营信息化追溯与中药材生产信息化追溯的有效衔接。受托生产企业应当配合持有人实施药品追溯制度。

shall establish and implement a drug traceability system, carry out TCM product traceability through information-based means, promptly and accurately record and preserve traceability data, and improve the information-based traceability system for the whole process of manufacturing and distribution of Chinese proprietary medicines. Manufacturers of prepared slices and TCM dispensing granules shall gradually establish and improve information-based traceability systems for manufacturing and distribution, step by step and product by product. The MAHs and TCM manufacturers shall explore effective integration between information-based traceability of TCM manufacturing and distribution and information-based traceability of TCM crude drug manufacturing. The contract manufacturers shall cooperate with the MAHs to implement the drug traceability system.

Article 15 The MAHs and TCM manufacturers shall establish a pharmacovigilance system and consistently improve it, thereby strengthening the monitoring of adverse reactions, proactively conducting post-marketing studies and evaluations, and analyzing the characteristics of TCM formulas (such as the effects of processing and compatibility), and, taking into account clinical use, patient conditions, and other factors, promptly conducting comprehensive assessments of identified safety risk signals and taking effective risk control measures. The contract manufacturers shall cooperate with the MAHs in conducting pharmacovigilance activities.

Article 16 The MAHs and TCM manufacturers are encouraged to strengthen technological integration and manufacturing innovation. The MAHs and TCM manufacturers shall comprehensively apply modern science and technology, accelerate the development of manufacturing automation, digitalization, and intelligentization, and establish video-based visual monitoring capabilities in key processes such as manufacturing and inspection in an orderly manner. They are also encouraged to explore the application of online inspection and monitoring, gradually adopt information systems for real-time recording to replace traditional paper-based records, and continuously promote the transformation and upgrading of TCM manufacturing.

Chapter III Quality Management

Article 17 The internal departments of MAHs

and TCM manufacturers responsible for manufacturing and quality control shall be staffed with professionals who are familiar with the properties of TCMs, and who possess the capability to identify the authenticity and quality of TCM crude drugs and prepared slices, as well as quality control capabilities. Professionals responsible for the procurement and acceptance, maintenance, storage, and processing of TCM crude drugs and prepared slices shall meet the requirements for their respective positions. Professionals involved in the processing of toxic crude drugs and other work with special requirements shall possess the necessary professional knowledge and skills and be familiar with occupational protection requirements.

The MAHs and TCM manufacturers shall designate a department or specific personnel to be responsible for training management. The training content shall align with the requirements of TCM manufacturing, emphasize traditional authentication techniques and processing techniques, and include periodic assessment of the practical competence of professionals.

Article 18 The MAHs and TCM manufacturers shall, based on the characteristics of TCMs and product attributes, apply technologies such as characteristic chromatograms, fingerprint chromatograms, and multi-component assay to conduct quality control studies of TCM crude drugs, prepared slices, intermediates, and finished products. They shall establish internal quality standards consistent with manufacturing practices, continuously update drug registration standards, and participate in the update of national drug standards and provincial-level TCM standards.

Article 19 The MAHs and TCM manufacturers shall conduct drug stability studies according to relevant requirements. When necessary, additional stability items shall be added. Based on product characteristics and historical data of stability studies, reasonable fluctuation ranges and principles for determining abnormal trends shall be recognized. When abnormal trends are identified, risk assessment shall be conducted in a timely manner, and effective control measures shall be taken.

Article 20 The MAHs and TCM manufacturers may, through quality review and risk assessment, study and establish effective quality control methods, and adopt partial testing results of bulk products for the quality evaluation of finished products. The relative

第十五条 持有人、中药生产企业应当建立和完善药物警戒体系, 加强不良反应监测, 主动开展上市后研究和评价, 并分析中药处方特点(如炮制、配伍等), 结合临床使用、患者机体等因素, 对发现的安全性风险信号及时开展综合研判, 采取有效风险控制措施。受托生产企业应当配合持有人开展药物警戒工作。

第十六条 鼓励持有人、中药生产企业加强技术集成和生产创新, 综合运用现代科学技术, 加快生产自动化、数字化、智能化建设, 有序建立生产、检验等关键环节的可视化视频监控能力, 探索应用在线检验和监测, 逐步采用信息化系统实时记录替代传统纸质记录, 持续推进中药生产改造升级。

第三章 质量管理

第十七条 持有人、中药生产企业内部负责生产、质量等管理机构应当配备熟悉中药药性, 具有中药材和中药饮片真伪优劣鉴别能力及质量控制能力的专业人员。负责中药材和中药饮片采购及验收、养护、仓储保管、炮制等专业人员应当符合相应岗位职责要求。涉及毒性中药材炮制等有特殊要求的专业人员应当具有满足需要的专业知识和技能并熟知劳动保护要求。

持有人、中药生产企业应当指定部门或者专人负责培训管理工作, 培训内容应当与中药生产要求相适应, 注重开展传统鉴别技术与炮制技术培训, 定期对专业人员的实际能力进行确认。

第十八条 持有人、中药生产企业应当根据中药特点及产品特性, 应用特征图谱、指纹图谱、多组份含量测定等技术, 开展中药材、中药饮片、中间产品及成品的质量控制研究, 建立符合生产实际的内控质量标准, 持续提高药品注册标准, 参与提高国家药品标准、省级中药标准。

第十九条 持有人、中药生产企业应当按照要求开展药品稳定性考察, 必要时增加稳定性考察项目。应当根据产品特性和稳定性考察历史数据, 制定合理的波动范围和异常趋势判定原则。发现异常趋势的, 应当及时开展风险研判, 并采取有效控制措施。

第二十条 持有人、中药生产企业可以通过质量审核和风险评估, 研究建立有效的质量控制方法, 引用待包装产品的部分检验结果进行成品的质量评价; 中药饮片炮制加工、中药材前处理等工序不会对中药材及中药产品部分项目检验结果产生不利影响的, 可以引用该中药材相应项目的检验结果进行产品质量评价。

同一集团内执行统一质量管理体系的持有人或者中药生产企业使用同一批号原料、辅料或者包装材料的, 经质量审核和风险评估后, 可以共享检验结果。

引用或者共享的检验结果应当在检验报告中注明数据来源。

中药注射剂不能引用或者共享检验结果。

第二十一条 持有人、中药生产企业应当

dtesting items and their results for TCM crude drugs may be adopted for final product quality evaluation if the processing of TCM crude drugs or prepared slices does not affect the quality of TCM crude drugs and final products. Within the same group implementing a unified quality management system, the MAHs or TCM manufacturers that use the same batch of raw materials, excipients, or packaging materials may share test results upon quality audit and risk assessment.

The data sources of the adopted or shared test results shall be clearly indicated in the testing report.

Test results shall not be adopted nor shared for TCM injections.

Article 21 The MAHs and TCM manufacturers shall complete testing of all items in accordance with the standards for marketing clearance, or adopt or share test results that meet the standards.

For testing items that involve equipment with high costs and low frequency of use, the MAHs and TCM manufacturers may contract qualified third-party testing institutions to conduct the testing. When contracting for testing, the MAHs and TCM manufacturers shall strictly comply with the relevant requirements of *Good Manufacturing Practices for drugs* (GMP), strengthen the review of qualifications and capabilities of the contracted testing institutions, sign contract testing agreements, take responsibility for the testing results of the contracted institutions, and report to the provincial-level drug regulatory authority at the place where they are located before carrying out the contracted testing.

Within the same group implementing a unified quality management system, the MAHs or TCM manufacturers may share testing equipment with high costs and low frequency of use, with implementation by reference to the contracted testing approach.

Article 22 The MAHs and TCM manufacturers shall conduct periodic quality reviews of the entire TCM production process, with emphasis on the impact of fluctuations in the quality of TCM crude drugs on extraction yield, the content of active ingredients or marker components, and other factors, assess the effectiveness of internal quality standards in controlling the quality of raw materials, excipients, and finished products, promptly carry out study validation, improve and enhance the level of quality control, and ensure stable and reliable processes.

Chapter IV Material Management

Article 23 MAHs and TCM manufacturers shall conduct quality evaluations on the procured TCM crude drugs to ensure that they meet the requirements for medication use, with accurate origin of TCM crude drugs, clear source, definite place of origin, and standardized processing and storage. Where the drug approval documents require a fixed origin of TCM crude drugs, the origin of TCM crude drugs shall be fixed. Using wild TCM crude drugs or imported TCM crude drugs, effective measures shall be taken to ensure a fixed origin of crude drugs, stable quality, and effective control of the risk of contamination by exogenous hazardous substances. For the manufacturing of TCM injections, raw materials shall comply with the requirements of *Good Agricultural Practice for TCM Crude Drugs* (GAP for TCM Crude Drugs). For the manufacturing of TCM dispensing granules, raw materials are recommended to comply with the requirements of *Good Agricultural Practice for TCM Crude Drugs* (GAP for TCM Crude Drugs).

When using Dao-di TCM crude drugs, TCM crude drugs that comply with the requirements of GAP for TCM crude drugs, or TCM crude drugs directly procured from TCM crude drug manufacturers at the place of origin, the MAHs or TCM manufacturers may, upon review during quality audit, refer to materials such as the origin identification and quality testing results of the TCM crude drugs, and the source of the referenced materials shall be indicated.

Article 24 MAHs and TCM manufacturers shall procure collection-processed (cut while fresh) TCM crude drugs from manufacturers at the place of origin with a mature quality management system. The procured TCM crude drugs (cut while fresh) shall be the products listed by the provincial-level drug regulatory authority at the place of origin. MAHs and TCM manufacturers shall guide and urge TCM crude drug manufacturers at the place of origin to establish a complete traceability system for TCM crude drugs.

Article 25 MAHs and TCM manufacturers shall strengthen the audit of raw material suppliers. During procurement and use, quality evaluation shall be conducted regularly based on the results of annual reviews, and on-site inspections shall be conducted regularly for suppliers of major raw materials; when necessary, on-site inspections shall be conducted on the cultivation and breeding, harvesting and processing, storage, and

对上市放行的产品按照相应药品标准完成全部项目的检验，可以引用或者共享符合要求的检验结果。

相关检验项目涉及成本高昂且使用频次较少等设备的，持有人、中药生产企业可以委托具有资质的第三方检验机构检验。持有人、中药生产企业委托检验的，应当严格按照药品生产质量管理规范相关要求，对受托检验机构的资质和能力加强审核，签订委托检验协议，对受托检验机构的检验结果负责，并在委托检验开展前向所在地省级药品监督管理部门报告。

同一集团内执行统一质量管理体系的持有人或者中药生产企业可以共用成本高昂且使用频次较少的检验设备，并参照委托检验方式实施。

第二十二條 持有人、中药生产企业应当对中药生产全过程定期进行质量回顾，重点关注中药材质量波动对提取收率、活性成份或者指标成份的含量等影响，研判内控质量标准对原料、辅料及成品的质量控制情况，及时开展研究验证，改进提升质量控制水平，保证工艺稳定可靠。

第四章 物料管理

第二十三條 持有人、中药生产企业应当对所采购的中药材开展质量评估，保证符合药用要求，做到基原准确、来源清楚、产地明确、加工和仓储规范；药品批准证明文件要求固定基原的，应当固定基原；使用野生中药材、进口中药材的，应当采取有效措施保证基原固定、质量稳定，有效控制外源性有害物质污染风险。中药注射剂生产所用中药材，原则上应当符合中药材生产质量管理规范（中药材GAP）要求；中药配方颗粒生产应当优先使用符合中药材GAP要求的中药材。

使用道地中药材、使用符合中药材GAP要求的中药材或者直接产地中药材生产企业采购中药材的，持有人或者中药生产企业质量评估时，经审核可以引用该中药材基原鉴定、质量检验结果等资料，引用的资料应当注明来源。

第二十四條 持有人、中药生产企业应当从具备健全质量管理体系的产地中药材生产企业采购产地加工（趁鲜切制）中药材，采购的趁鲜切制中药材应当是产地省级药品监督管理部门公布的品种。持有人、中药生产企业应当指导和督促产地中药材生产企业建立完整的中药材追溯体系。

第二十五條 持有人、中药生产企业应当加强对原料供应商的审核。采购和使用过程中应当根据年度回顾情况定期开展质量评估，对主要原料的供应商应当定期开展现场审核，必要时对中药材种植养殖、采收加工、仓储运输等进行现场审核。持有人、中药生产企业应当建立完整的供应商审核档案。

第二十六條 持有人、中药生产企业应当对采购的中药材按照来源、供应商、药材规格等进行分类，划分批次并编制批号。对同一供应商和基原、同一种种植养殖基地、生长周期相

transportation of TCM crude drugs. MAHs and TCM manufacturers shall establish complete audit files for suppliers.

Article 26 MAHs and TCM manufacturers shall categorize the procured TCM crude drugs based on their source, supplier, and crude drug specifications, divide them into batches, and assign batch numbers. TCM crude drugs from the same supplier and origin of crude drugs, the same cultivation and breeding base, with the same growth cycle, and with consistent ecological environment and conditions, harvesting time, and processing methods at the place of origin, as well as with uniform quality, may be recognized as the same batch.

Article 27 MAHs and TCM manufacturers shall establish and effectively implement acceptance management procedures to ensure that raw materials, excipients, and packaging materials are accepted and stored in the warehouse only after being confirmed to comply with the standards and medicinally-used requirements. The acceptance management procedure shall incorporate traditional experience-based identification methods.

MAHs and TCM manufacturers shall test by batch on each procurement of raw materials, excipients, and packaging materials. For TCM crude drugs complying with the requirements of GAP purchased in batches under the same batch number, after the first procurement passes full-item testing, partial-item testing may be conducted for subsequent procurements based on quality risk assessment. MAHs and TCM manufacturers shall also check whether the content of the labels and marks on the raw material packages is complete and complies with the relevant regulations. For TCM crude drugs and prepared slices subject to special mark requirements, such as toxic drugs for medical use and narcotic drugs, they shall also check whether their package labels are printed with the special marks in compliance with the relevant regulations.

Article 28 MAHs and TCM manufacturers shall define maintenance measures and storage periods for various raw materials according to their characteristics, specify the re-test period or shelf life, and transport, store, and maintain the raw materials according to relevant requirements.

Article 29 MAHs or TCM manufacturers shall review and evaluate the origin of TCM crude drugs, place of origin, harvesting and processing of the imported TCM crude drugs, and the

qualification of the import enterprise when using imported TCM crude drugs for TCM manufacturing. Materials such as copies of the original certification documents, testing reports of the imported TCM crude drugs, and copies of the customs clearance documents for the imported drugs shall be included in the supplier review files.

Article 30 MAHs or TCM manufacturers shall prepare special facilities and equipment according to relevant requirements. Strict management systems, operating procedures, dedicated storage, detailed records and product traceability shall be applied to prevent their illegal use for use of TCM raw materials managed as toxic drugs for medical use, narcotic drugs, etc., and for the manufacturing of Ephedra Herba dispensing granules, the source, processing, transportation, storage, procurement, acceptance, and manufacturing of such TCM raw materials shall comply with the laws and regulations.

Article 31 MAHs or TCM manufacturers where TCM crude drugs of wild fauna, flora or fossils are used, the relevant laws and regulations of the state on the protection of wild animals, plants, and fossils shall be complied with, and the legality and compliance of the source and processing shall be ensured. Special ledgers shall be established with consistency between the accounts and the actual inventory shall be maintained.

Chapter V In-process Control

Article 32 MAHs and TCM manufacturers shall establish manufacturing instructions in accordance with the GMP and its annexes. The instructions shall comply with the national drug standards, drug registration standards, or provincial-level TCM standards and the production process recognized by the drug regulatory authority. MAHs and TCM manufacturers shall specify key process parameters, determine a reasonable yield range, and prevent contamination, cross-contamination, mix-ups, and errors.

For the manufacturing of TCM injections, the process parameters and quality control requirements for the entire production process shall also be specified and detailed.

Article 33 MAHs and TCM manufacturers shall carry out process validation in accordance with the requirements, which may be conducted in stages according to the extraction process and the preparation process. The process validation of prepared slices shall also integrate the judgment standards of traditional attributes.

同, 且生态环境及条件、采收时间、产地加工方法基本一致, 以及质量基本均一的中药材, 可以划分为同一批次。

第二十七条 持有人、中药生产企业应当制定并有效实施验收管理规程, 确保原料、辅料及包装材料符合相应标准和药用要求后方可验收入库。验收管理规程应当结合传统经验鉴别方法。

持有人、中药生产企业应当对每次采购的原料、辅料及包装材料按照批次进行检验。分次采购同一批号符合中药材GAP要求中药材的, 首次采购全项检验合格后, 可以基于质量风险评估, 对后续采购的中药材采取部分项目检验。

持有人、中药生产企业还应当检查原料包装标签标识内容是否齐全并符合规定。对医疗用毒性药品、麻醉药品等有专用标识要求的中药材、中药饮片, 还应当检查其包装标签是否印有符合规定的专用标识。

第二十八条 持有人、中药生产企业应当根据每种原料的特性, 确定养护措施、贮存期限, 明确复验期或者保质期, 按照要求运输、贮存、养护原料。

第二十九条 使用进口中药材生产中药的, 应当对进口中药材的基原、产地、采收及加工、进口单位资质等进行审核评估, 将其产地证明文件、进口药材检验报告复印件和进口药品通关单复印件等资料纳入供应商审核档案。

第三十条 使用按照医疗用毒性药品、麻醉药品等管理的中药原料及生产麻黄配方颗粒的, 应当确保中药原料的来源、加工、运输、贮存、采购、验收及中药生产等符合法律法规规定, 按照要求配备专用设施、设备, 建立严格的管理制度、操作规程, 设置专库存放、细化记录台账、完善产品追溯, 防止流入非法渠道。

第三十一条 使用野生动植物及古生物化石类中药材的, 应当符合国家关于野生动植物保护及古生物化石保护等有关法律法规规定, 确保来源和加工等合法合规, 建立专用台账, 做到账物相符。

第五章 生产过程控制

第三十二条 持有人、中药生产企业应当根据药品生产质量管理规范及其附录的规定制定生产工艺规程。生产工艺规程应当符合相应国家药品标准、药品注册标准或者省级中药标准及药品监督管理部门核准的生产工艺, 明确关键工艺参数, 确定合理的收率范围, 防止污染、交叉污染及混淆、差错等。

生产中药注射剂的, 还应当明确和细化生产全过程工艺参数及质量控制要求。

第三十三条 持有人、中药生产企业应当按照规定开展工艺验证, 可以按照提取工艺和制剂工艺分阶段验证。中药饮片的工艺验证还应当结合传统属性判断标准。

工艺再验证涉及多个相同生产线的, 经风险评估可以选取其中一个代表性生产线进行验证, 验证过程应当涵盖实际生产情形。

第三十四条 中成药应当严格按照国家药

Where process re-validation involves multiple identical manufacturing lines, one representative manufacturing line may be selected for validation after risk assessment, and the validation process shall reflect actual manufacturing conditions.

Article 34 Chinese proprietary medicines shall be manufactured strictly in accordance with the composition and quantity of the ingredients in the formulas as specified in the national drug standards, drug registration standards, and the drug production process recognized by the drug regulatory authorities. Before feeding, TCM crude drugs and prepared slices shall be subjected to purification treatment as required; if directly fed after washing, the feeding amount shall be calculated according to the drying conversion rate to ensure the feeding amount is in compliance with specified ingredients in formulas.

Article 35 MAHs and TCM manufacturers may, with reference to the *Technical Guidelines for the Study of TCM Homogenization*, conduct research and demonstration based on product characteristics, drug standards, production processes, manufacturing data, and validation data, establish operating procedures, and charge after conducting homogenization treatment of raw materials.

Raw materials subjected to homogenization treatment shall be manufactured in compliance with standards and meet quality requirements. Homogenization operations shall have complete records to ensure authenticity, integrity, and traceability.

Article 36 Measures shall be taken in each stage of the TCM production process to reduce microbial load, and strict in-process control and appropriate sterilization methods shall be applied to ensure that the microbial limits meet the requirements.

Where the national drug standards for Chinese proprietary medicines, drug registration standards, or drug production processes approved by the drug regulatory authority do not explicitly specify sterilization processes, but such sterilization processes have already been practically applied in the manufacturing of Chinese proprietary medicines, and, in accordance with the Provision on Post-marketing Changes of Drugs, are not subject to re-submission, the MAHs shall improve research and validation, specify them in the production process procedures, and report through the annual drug report.

Article 37 Where deviations exist in the yield of TCM extract, the MAHs shall, on the basis

of stable origin of crude drugs, place of origin, TCM crude drugs, and prepared slices, optimize the extraction process parameters of TCMs, define the yield ranges of the extract and finished products, specify them in the production process procedures, and report through the annual drug report. If the yield exceeds the defined ranges, the MAHs shall promptly conduct a deviation investigation, carry out risk assessment on product quality, conduct research and validation with reference to the relevant technical guidelines for registration or post-marketing change management of TCMs, and perform filing, submit supplementary applications, or registration applications in accordance with the regulation.

Article 38 MAHs and TCM manufacturers may establish pretreatment and extraction workshops at different locations, or share pretreatment and extraction workshops with drug manufacturers within the same group that implement a unified quality management system, after signing a quality agreement. The above provision shall not apply to drug manufacturers engaged in the contract manufacturing of Chinese proprietary medicines. MAHs and TCM manufacturers shall implement unified management of off-site or shared workshops, establish feasible manufacturing and quality management measures, establish strict quality control standards, and manage the entire production process of pretreatment and extraction in such off-site or shared workshops to ensure compliance with the drug standards and the production process approved or filed by the drug regulatory authority.

Article 39 The solvents used for TCM extraction and their quantities shall comply with the national drug standards for Chinese proprietary medicines, drug registration standards, and the production process approved by the drug regulatory authority. Where the solvent quantity is not explicitly specified, it shall, in principle, be calculated according to the weight ratio of the charging quantity. Where TCM extraction solvents need to be recycled for use, quality studies shall be conducted on the recycled solvents, risks such as cross-contamination and residues of medicinal substances shall be assessed, the number of recycling times shall be determined, operating procedures and quality standards for solvent recycling shall be established, and the recycled solvents shall be ensured to meet the requirements for reuse. In principle, the recycled solvents shall not be used for other products.

Article 40 MAHs and TCM manufacturers shall establish management systems and

品标准、药品注册标准和经药品监督管理部门核准的药品生产工艺规定的处方组成、处方量投料。投料前应当按照要求对中药材、中药饮片进行净制处理；清洗后直接投料的，应当按照折干率计算投料量，保证投料量符合处方要求。

第三十五条 持有人、中药生产企业可以参照中药均一化研究技术指导原则，根据产品特点、药品标准、生产工艺、生产数据、验证资料等开展研究论证，制定操作规程，对原料进行质量均一化处理后投料。

均一化处理的原料应当规范生产且符合质量要求。均一化操作应当有完整记录，保证真实、完整、可追溯。

第三十六条 中药生产过程各环节应当采取降低微生物负载的措施，通过严格的生产过程控制和适宜的灭菌方式等保证微生物限度符合要求。

中成药国家药品标准、药品注册标准或者药品监督管理部门核准的药品生产工艺中未明确规定，但中成药生产中已实际应用的灭菌工艺，且按照药品上市后变更管理规定无需重新申报的，持有人应当完善研究验证，在生产工艺规程中明确，并通过药品年度报告填报。

第三十七条 中药提取浸膏收率存在偏差的，持有人应当在中药材、中药饮片等基原、产地稳定基础上，优化中药提取工艺参数，确定提取浸膏及成品收率范围，在生产工艺规程中明确，并通过药品年度报告填报。超出收率范围的，持有人应当及时开展偏差调查，对产品质量进行风险评估，参照中药注册或者上市后变更管理及其相关技术指导原则开展研究验证，并按照规定进行备案、提出补充申请或者注册申请。

第三十八条 持有人、中药生产企业可以异地设立前处理、提取车间，也可以与同一集团内执行统一质量管理体系的药品生产企业签订质量协议后共用前处理、提取车间。受托生产中成药的药品生产企业除外。

持有人、中药生产企业应当对异地或者共用车间实施统一管理，制定切实可行的生产和质量管理措施，建立严格的质量控制标准，对异地或者共用车间的前处理、提取等生产全过程进行管理，确保符合药品标准和药品监督管理部门核准或者备案的生产工艺要求。

第三十九条 中药提取溶剂及用量应当符合中成药国家药品标准、药品注册标准和药品监督管理部门核准的生产工艺要求。溶剂用量未明确规定的，原则上应当按照投料量重量比例折算。中药提取溶剂需要回收使用的，应当对回收溶剂进行质量研究，评估回收溶剂可能造成的交叉污染、药用物质残留等风险，确定回收次数，制定回收溶剂操作规程、质量标准，确保回收溶剂符合再使用要求。回收的溶剂原则上不能用于其他品种。

第四十条 持有人、中药生产企业应当建立药渣处置管理制度和操作规程，明确管理机构和责任人员，防范提取药渣废料非法利用。药渣废料需要暂存的，应当明确专用区域。鼓

operating procedures for the disposal of medicinal residues, designate management organizations and responsible personnel, and prevent the illegal use of extracted medicinal residue waste. Where temporary storage of medicinal residue waste is required, dedicated areas shall be designated. MAHs and TCM manufacturers are encouraged to carry out comprehensive research and utilize green recycling of TCM resources.

Chapter VI Supervision and Administration

Article 41 Drug regulatory authorities shall be staffed with inspectors who meet the needs of TCM regulation, are familiar with the laws, regulations, and technical requirements for the regulation of the manufacturing of TCM crude drugs, prepared slices, and Chinese proprietary medicines, and shall strengthen training in TCM expertise and inspection skills.

Article 42 Where MAHs and TCM manufacturers establish or share pretreatment and extraction workshops at different locations, approval shall be obtained from the provincial-level drug regulatory authority at the location of the MAH or TCM manufacturer. Where such workshops are established across provinces (autonomous regions or municipalities), prior consent shall also be obtained from the provincial-level drug regulatory authority at the location of the workshop. The address of the workshop shall be specified on the Drug Manufacturing License of the MAH or TCM manufacturer; for shared workshops, the drug manufacturing licenses of both parties shall also specify the attribution and the name of the shared enterprise.

The provincial-level drug regulatory authority at the location of the MAH or TCM manufacturer shall be responsible for the regulation of the production process of the relevant products in such off-site or shared workshops. For the regulation of off-site or shared workshops established across provinces (autonomous regions or municipalities), the provincial-level drug regulatory authority at the location of the MAH or TCM manufacturer may conduct it independently, jointly, or request the provincial-level drug regulatory authority at the location of the workshop to conduct it. The provincial-level drug regulatory authority at the location of the workshop shall be responsible for the routine supervision of the pretreatment and extraction in such off-site or shared workshops.

Article 43 Drug regulatory authorities shall, based on products, dosage forms, management

categories of TCMs, and risk factors such as previous inspections, sampling inspections, adverse reaction monitoring, and complaints and reports, comprehensively take into account whether MAHs and TCM manufacturers proactively implement GAP for TCM crude drugs, carry out intelligent manufacturing transformation, and establish whole-chain traceability. MAHs and TCM manufacturers shall be classified into risk levels, regulatory resources shall be scientifically allocated, and differentiated and precise supervision shall be implemented.

Article 44 Provincial-level drug regulatory authorities shall conduct supervision and inspection of MAHs and TCM manufacturers within their administrative regions, and, when necessary, carry out extended inspections of suppliers of raw materials, excipients, packaging materials, as well as contracted testing institutions. Provincial-level drug regulatory authorities shall adhere to the principles of risk management and whole-process control, focus on the procurement of raw materials such as TCM crude drugs, formula, production processes, charging, and release inspection in light of the actual situation and characteristics of TCM manufacturing, and supervise MAHs and TCM manufacturers to conduct manufacturing in compliance with laws and regulations continuously.

Article 45 Drug regulatory authorities shall, in light of the actual regulatory circumstances within their administrative regions, strengthen sampling inspection of TCM products, and, when necessary, conduct sampling inspection of raw materials, excipients, and packaging materials. According to regulatory needs, inspection results shall be comprehensively analyzed, potential risks shall be assessed, and preventive and control measures shall be taken in accordance with the law.

Article 46 Where drug regulatory authorities find that MAHs or TCM manufacturers have engaged in illegal acts such as adulteration or fraud, or have failed to comply with GMP requirements in aspects such as quality management systems, material management, supplier audits, or in-process control, they shall, in accordance with the law, impose strict penalties; where a suspected crime is involved, the case shall be promptly transferred to the public security authorities.

Article 47 Provincial-level drug regulatory authorities shall strengthen coordination and cooperation, and enhance the sharing of regulatory information, such as inspections,

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第六章 监督管理

第四十一条 药品监督管理部门应当配备符合中药监督管理需要,熟悉中药材、中药饮片、中成药等生产监督管理法律法规、技术要求的检查员,加强中药专业知识和检查技能培训。

第四十二条 持有人、中药生产企业异地设立或者共用前处理、提取车间的,应当经所在地省级药品监督管理部门批准。跨省(区、市)设立的,还应当先经车间所在地省级药品监督管理部门审查同意。持有人、中药生产企业《药品生产许可证》上应当注明车间地址;共用车间的,双方《药品生产许可证》还应当分别注明归属及共用企业名称。

持有人、中药生产企业所在地省级药品监督管理部门负责异地或者共用车间相应品种生产过程的监督管理。对跨省(区、市)设立异地或者共用车间的监督管理,持有人、中药生产企业所在地省级药品监督管理部门可以单独开展,也可以联合或者商请车间所在地省级药品监督管理部门开展。车间所在地省级药品监督管理部门负责异地或者共用车间前处理、提取的日常监管。

第四十三条 药品监督管理部门应当根据中药品种、剂型、管理类别等,结合既往检查、抽检、不良反应监测、投诉举报等风险情况,综合考虑持有人、中药生产企业主动推进中药材GAP实施、生产智能化改造、全链条追溯等情况,对持有人、中药生产企业划分风险等级,科学配置监管资源,实施差异化、精准化监管。

第四十四条 省级药品监督管理部门对本行政区域内的持有人和中药生产企业开展监督检查,必要时对原料、辅料、包装材料等的供应商,以及受托检验机构等开展延伸检查。

省级药品监督管理部门应当坚持风险管理、全程管控原则,根据中药生产实际和特性,重点关注中药材等原料采购、处方工艺、生产投料、检验放行等环节,监督持有人和中药生产企业持续合法合规生产。

第四十五条 药品监督管理部门应当结合行政区域内监管实际情况,加强中药产品抽样检验,必要时对原料、辅料、包装材料等进行抽样检验。根据监管需要,综合分析检验结果,研判风险隐患,依法采取防控措施。

第四十六条 药品监督管理部门发现持有人、中药生产企业存在掺杂掺伪、弄虚作假等违法行为的,或者在质量管理体系、物料管理、供应商审核、生产过程控制等方面未遵守药品生产质量管理规范的,应当依法严厉查处;涉嫌犯罪的,应当及时移送公安机关。

第四十七条 省级药品监督管理部门应当加强协同配合,强化检查、检验、监测、处罚等监管信息共享。需要对中药材种植养殖基地、中药材生产企业、受托检验机构开展跨省

testing, monitoring, and penalties. Where cross-provincial-level (autonomous region or municipality) extended inspections of TCM crude drug cultivation and breeding bases, TCM crude drug manufacturers, or contracted testing institutions are required, the provincial-level drug regulatory authority at the location of the MAH or TCM manufacturer may request the provincial-level drug regulatory authority at the location of the inspected institution to render assistance in conducting the inspection.

Article 48 Where provincial-level drug regulatory authorities discover that TCM crude drugs, prepared slices, or TCM extracts may involve quality issues related to upstream or downstream products, they shall promptly notify the provincial-level drug regulatory authorities at the locations of the relevant upstream and downstream enterprises, and, when necessary, proactively strengthen communication and coordination with departments at the same level, such as agriculture and rural affairs, market regulation, healthcare security, and Traditional Chinese Medicine administration.

Chapter VII Supplementary Provisions

Article 49 The term "TCM manufacturers" as used in the *Provision* refers to drug manufacturers engaged in the manufacturing of TCMs (including TCM prepared slices, TCM dispensing granules, Chinese proprietary medicines, and TCM crude drugs subject to approval administration) that have legally obtained the *Drug Manufacturing License*. Manufacturers of TCM extracts that have completed filing procedures shall be managed in reference to the requirements applicable to TCM manufacturers under the *Provision*.

Article 50 The term "raw materials" as used in the *Provision* refers to TCM crude drugs used

for the manufacturing of prepared slices, as well as TCM crude drugs, prepared slices, or TCM extracts subject to filing management used for the manufacturing of Chinese proprietary medicines. Raw materials shall comply with medicinal use requirements and the relevant requirements of GMP.

Article 51 The term "TCM crude drugs" as used in the *Provision* refers to medicinal raw materials derived from resources such as medicinal plants, medicinal animals, or minerals, which are used for the manufacturing of prepared slices, TCM dispensing granules, Chinese proprietary medicines, and TCM extracts subject to filing management.

Article 52 The term "TCM crude drug manufacturers" as used in the *Provision* refers to enterprises engaged in the cultivation and breeding, harvesting and collection, and collection processing of TCM crude drugs, including planting and breeding professional cooperatives or associations with the nature of enterprises.

Article 53 The term "TCM extracts subject to filing management" as used in the *Provision* refers to volatile oils, fats and oils, extracts, fluid extracts, dry extracts, active ingredients, active parts, and other components that are specified in the formula of the national drug standards for Chinese proprietary medicines, have separate national drug standards, and are used for the charging and manufacturing of Chinese proprietary medicines.

Article 54 The term "Traditional Chinese Medicine" as used in the *Provision* includes the traditional medicine of ethnic minorities, and the term "Traditional Chinese Medicines" includes the traditional medicines of ethnic minorities.

Article 55 The *Provision* shall come into force as of March 1, 2026.

(区、市)延伸检查的,持有人、中药生产企业所在地省级药品监督管理部门可以商请被检查机构所在地省级药品监督管理部门协助开展。

第四十八条 省级药品监督管理部门发现中药材、中药饮片、中药提取物等可能存在关联上下游产品质量问题的,应当及时通报相关上下游企业所在地省级药品监督管理部门,必要时主动加强与同级农业农村、市场监管、医疗保障、中医药管理等管理部门沟通协作。

第七章 附 则

第四十九条 本规定所称中药生产企业,是指从事中药(含中药饮片、中药配方颗粒、中成药和实施审批管理的中药材等)生产活动,且依法取得《药品生产许可证》的药品生产企业。已备案中药提取物的生产企业参照本规定对中药生产企业的要求进行管理。

第五十条 本规定所称原料,是指中药饮片生产用中药材,以及中成药生产用中药材、中药饮片或者实施备案管理的中药提取物。原料应当符合药用要求、药品生产质量管理规范的有关要求。

第五十一条 本规定所称中药材,是指来源于药用植物、药用动物或者矿物等资源,且用于生产中药饮片、中药配方颗粒、中成药及实施备案管理的中药提取物等的药用原料。

第五十二条 本规定所称中药材生产企业,是指从事中药材种植养殖、采收采集、产地加工等的企业,包括具有企业性质的种植养殖专业合作社或者联合社。

第五十三条 本规定所称实施备案管理的中药提取物,是指中成药国家药品标准的处方项下载明,并具有单独国家药品标准,且用于中成药投料生产的挥发油、油脂、浸膏、流浸膏、干浸膏、有效成份、有效部位等成份。

第五十四条 本规定所称中医药包括民族医药,中药包括民族药。

第五十五条 本规定自2026年3月1日起施行。

- Notes:**
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