

0.99 (Shi et al., 2022). At the process-evaluation level, wall-breaking technology must be assessed not only by breaking rate but also by nutrient release, since broken powders showed much higher intestinal bioaccessibility of polysaccharides and triterpenes than unbroken powders, and sporoderm-removed powders contained higher active-constituent levels and stronger antitumor activity than ordinary wall-broken powders (Qi et al., 2024).

4.3 Safety evaluation and quality standard system construction

The safety evaluation system for *G. lucidum* spore powder should cover authenticity, contaminant limits, and toxicological evidence rather than relying only on active-component content. Market studies show that product consistency is often poor: in a U.S. survey, only 5 of 19 products (26.3%) matched their label ingredients, indicating that identity auditing and adulterant screening are essential parts of quality control (Wu et al., 2017). Heavy metals remain a concrete concern in commercial Lingzhi products, with about one-third of tested samples exceeding allowable limits for arsenic and more than half exceeding limits for cadmium, while organochlorine pesticides were less problematic in the tested subset. These findings support setting mandatory limits for Pb, As, Hg, Cd, pesticide residues, and microbial contamination, together with strengthened GAP and GMP management across cultivation, harvesting, and processing.

The quality standard system should therefore integrate pharmacopoeial indicators, local or industry standards, and safety validation by toxicology. Existing standards already provide a regulatory basis, including the industry standard GH/T 1133-2017 for wall-broken *Ganoderma* spores and local food safety standards in Guizhou and Zhejiang (Li et al., 2026). Toxicological evidence is reassuring but still needs product-specific confirmation: a 26-week repeated-dose study found no significant systemic toxicity for sporoderm-removed spores in rats and established a NOAEL of 4.0 g/kg, about 20 times the human equivalent dose (Xia et al., 2023). Broader mushroom-powder toxicology also found no acute toxicity, no subchronic oral toxicity up to 2 000 mg/kg bw/day, and no genotoxic potential in tested *G. lucidum* powder preparations (Chrysostomou et al., 2024). However, safety reviews still note that high doses of spore extract should be used cautiously because some evidence raised concern about increased CA72-4 despite no clear organ toxicity, so the final standard system should include routine toxicology review, batch traceability, and post-market monitoring in addition to compositional release tests (Thuy et al., 2023).

5 Standardization and Industrial Application of *Ganoderma lucidum* Spore Powder Production

5.1 Whole-process standardized production model of “strain-cultivation-collection-processing”

A whole-process standardized production model for *Ganoderma lucidum* spore powder should begin with elite strain selection and then connect strain, substrate, cultivation environment, collection, and processing into one closed technical chain. High-spore-yield strains are a core upstream variable, because most existing cultivars were originally bred for fruiting bodies rather than spores, while the mutant strain UV119 achieved 19.27% higher basidiospore yield than its parent and 20.56% higher yield than “Longzhi No.1,” with stronger resistance to undesired microorganisms (Tang et al., 2023). Standardization at the cultivation stage then requires procedural control of culture material preparation, sterilization, inoculation, mycelial growth, land or bag management, and fruiting management, because complete workflow designs for spore production patents already define sequential operations from strain selection through inoculation and field management to spore collection. These workflow designs also show that collection is not an isolated terminal step but part of the cultivation system itself, with sleeve barrels, filter-cloth wrapping, film laying, packaging, drying, sieving, and storage all treated as standardized downstream operations that influence purity, recovery, and marketable quality.

A mature whole-process model therefore needs to align production standards with regulatory standards so that each link has measurable control points. The Chinese Pharmacopoeia already specifies identification, content determination, and microbial limits for *Ganoderma* spore powder, with minimum limits of 0.90% polysaccharides and 0.50% triterpenes and sterols, while GB/T 29344-2023 provides technical specifications for harvesting and processing and NY/T standards provide methods for wall-breaking rate, ganoderic acid, and total triterpenoid determination. International standardization is also advancing, because ISO 21315:2018 established the first