3.3 Drug Safety

• Major Results in 2024

- Ongoing validity of the GMP manufacturing permit for Chinese medicine approved by the Ministry of Health and Welfare
- Ongoing validity of the PIC/S GDP distribution filing/approval with TFDA for drug products.
- No incidences of critical violation of laws or regulations regarding good practice for medicinal products
- No product quality-related incidents that required reporting occurred
- There were no instances of drug safety issues in the 2024 reporting period

• Quality and Safety Management Organization and Operational Standards

Microbio have set up a Quality Assurance Center, which consists of the Quality Assurance (QA) and Quality Control (QC) divisions, where professional, experienced and qualified personnel are responsible for monitoring and managing product quality and safety. The center ensures that the quality policy of drugs is f implemented across all stages—incoming receipt and storage of Active Pharmaceutical Ingredients (APIs), manufacturing, finished-product testing, and storage and distribution—to ensure medicinal-product safety. The management regulations of the Longtan Plant are formulated based on international standards such as PIC/S GMP and ISO 9001. The Quality Department is responsible for issuing, reviewing, and managing the quality document system. Ensure product quality and safety by formulating and implementing standardized procedures and forms, and maintain the effective implementation of all controlled documents.

1. **System and instrument verification:** Completed a total of 135 verification operations for pharmaceutical-related production and inspection and analysis equipment (including the validation of equipment computerized systems) according to the "Longtan Plant System and Instrument Validation Standard Operating Procedure". It is to ensure that the instruments and equipment achieve the expected results and implement the manufacturing process and inspection to ensure the safety and efficacy of the products.
2. **Process quality validation:** The Company has implemented the Chemo Young Potion Process Verification Plan (including manufacturing, filling, labeling, and packaging) and completed the manufacturing process of Microbio Chemo Young Solution for Internal Use. The "Standard Operating Procedures for Equipment Cleaning of Longtan Plant" are followed to ensure that after three batches of cleaning, there is no risk of cross-contamination in the equipment that is in direct contact with drugs.
3. **Quality review and tracking:** To ensure the consistency of manufacturing processes and product quality, quality assurance reviews the drug product quality once a year according to the "Longtan Plant Product Quality Review Standard Operating Procedure", and analyzes the trend of the stability of production batches in the previous year. Evaluate factors such as internal change control, deviation, customer complaints and so on, and compile the review and evaluation results into the annual product quality evaluation report to dynamically improve the quality of pharmaceutical operation.
4. **Quality education and training:** According to the "Longtan Plant Education and Training Management Operating Procedures" regulations, the personnel of the Production Department and Quality Assurance Center of the Longtan Plant are required to undergo relevant on-the-job education and training within one month of onboarding for new employees; Relevant education and training shall be arranged for the employees of the Quality Assurance Center at least three times each year. In 2024, we conducted three drug-related education and training sessions for plant personnel. All employees were required to pass the exam with full marks, encouraging employees to continuously study drug-related laws and regulations and operational requirements.
5. **Quality audit and review:** To ensure that drug production, equipment, and environment comply with the Company's and GMP/GDP drug specifications, the Quality Assurance Unit conducts regular and irregular internal audits in accordance with the "Longtan Factory Pharmaceutical GMP/GDP Internal Audit Procedures". In 2024, a total of 9 drug-related internal audits of each department were conducted. For pharmaceutical suppliers (including PIC/S GDP logistics providers), external audits are performed according to the "Supplier Management Procedure". For details, see Section 3.8 Supply Chain Management.
6. **Environmental quality monitoring:** In 2024, the environmental monitoring of the entire Longtan Plant area (including indicators such as temperature, humidity, suspended particles, airborne bacteria, etc.) met the clean room standard to ensure that the drug production and warehousing environment can be maintained at the highest product safety and quality; In addition, the water used for production is monitored according to the "Longtan Plant Production Water Sampling and Inspection Standard Operating Procedures," including the raw water, purified water treatment section, and purified water use section, to ensure that the process water continues to meet the purified water specifications of the Chinese Pharmacopoeia.

Adequate preventive measures are taken to prevent the market circulation of counterfeit or prohibited drugs or pharmaceutical products with altered labeling with a view to ensuring medication use safety. Microbio has the following preventive mechanisms in place:

1. Batch numbers and expiry dates are printed and anti-counterfeit laser hologram label are attached to the external packaging for every batch.
2. A domestic PIC/S GDP logistics provider is engaged for the storage and transportation of drugs, which allows comprehensive tracking and tracing and effectively prevents the emergence of counterfeit or prohibited drugs in the supply chain.
3. Consumers, channel operators, and business units are encouraged to immediately notify the logistics provider or Microbio of suspected counterfeit or prohibited drugs. Upon receipt of such reports, competent quality assurance personnel initiate investigations in a prompt manner.
4. If no instances of drug recall occur in the respective year, the Quality Assurance Center conducts a simulated recall drill to rehearse relevant procedures. Business-related units will also educate the operating procedures to colleagues, and implement education and training to ensure that colleagues are aware of the process of the risk of counterfeit drugs.

No instances of drug recall occurred from 2021 through 2024.

When suspected counterfeit drugs and other situations involving safety concerns occur, the following process is immediately initiated.

1. Suspected Counterfeit or Prohibited Drugs

- Notify the quality assurance personnel within 24 hours
- Stop the sale and distribution of suspected counterfeit or prohibited drugs
- Manage centrally and segregate the drugs in inventory to prevent misuse

2. Initiate an Investigation

- Quality assurance personnel initiate deviation or customer complaint investigation procedures
- Execute inventory packaging identification and sampling analysis tests to identify genuine or counterfeit or banned drugs

3. Suspected Counterfeit or Prohibited Determination

If the determination result is confirmed to be：

- Counterfeit or banned drugs, the recall operation will be initiated immediately. The batch of products will be recalled and it is notified to the central competent authority and the local health bureau
- Not counterfeit or banned drugs, it is also necessary to explain the reasons and the corrective and preventive measures in the closing report to avoid from the repeat recurrence.