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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Tianjin Tianyao Pharmaceuticals Co., Ltd
Corporate address of manufacturer	No. 221, Huanghai Road, Tianjin Economic –Technological Development Area, Tianjin 300457, China Wu Sheng / GM, 862266321558
Contact person	Mr. Sheng Wu, wusheng@tipc.com.cn , Tel: 00 86 22 66 32 1558
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	No. 19 Xin Ye 9th street, Tianjin 300462 China GPS coordinates: Latitude (N): 39º05.915´, Longitude (E): 117º32.314´ DUNS number: 654534197
Synthetic Unit /Block/Workshop	• Block # 28 for chemical synthesis • Block # 15, Room 12# for clean area
Manufacturing license number	Certificate number JIN20150001 from Tianjin Medical Products Administration Valid from September 9, 2025 to September 8, 2030
Inspection details	
Dates of inspection	22 – 24 April 2026
Type of inspection	Routine inspection
Inspection record Number	INSP-API-2025-0049
Introduction	
Brief description of the manufacturing activities	The main production site of Tianjin Tianyao Pharmaceuticals in Tianjin is a large-scale, integrated pharmaceutical manufacturing complex focusing on steroid-based and other APIs. The site manufactures several intermediates and APIs including Hydrocortisone Acetate, Dexamethasone Acetate, Fluocinonide, Triamcinolone Acetonide Acetate, Dexamethasone Sodium Phosphate, Hydrocortisone, Halcinonide, Triamcinolone acetonide, Betamethasone, Flunarizine Hydrocloride, Triamcinolone, Hydrocortisone Butyrate, Methylprednisolone hemisuccinate, Bucinnazine hydrocloride, Cinnarizine, Clioquinol, Methylprednisolone, Dexamethasone, Clobetasol Propionate, Beclometasone Dipropionate, Adapalene, Fluticasone Propionate, Mometasone Furoate, Mometasone Furoate Monohydrate, Prednisone Acetate, Prednisone, Prednisolone, Spironolactone, Threonine, Leucine, Glycine, Lysine Hydrochloride, Phenylalanine, Alanine, Lycine acetate, Methionine, Arginine, Histidine Hydrochloride, Valine, Isoleucine, Serine, Aspartic Acid, Glutamic Acid, Tryptophan, Cysteine Hydrochloride,

	Tyrosine, N-Acetyl-L-Tryptophan, Acetyltyrosine, Cysteine, Arginine hydrochloride, Cystine, Sodium lactate solution, Dipotassium hydrogen phosphate, potassium dihydrogen phosphate, Methylcobalamin, Budesonide, Methylprednisolone Acetate, Celecoxib, Fluocinonide acetonide. There are no toxic substances handled at the site. The site is equipped with cleanroom facilities for final purification and packaging of APIs. All finished APIs are stored at dedicated warehouses with temperatures of NMT 25 °C and 65% RH.
General information about the company and site	Tianjin Tianyao Pharmaceuticals Co., Ltd. is a Chinese pharmaceutical company headquartered in Tianjin, with a history dating back to 1939. It is the first company in China to produce corticosteroid APIs. The company has been publicly listed on the Shanghai Stock Exchange since 2001. The company focuses primarily on the research, development, manufacturing and sales of active pharmaceutical ingredients (APIs), with a specialization in corticosteroids (such as dexamethasone and prednisone). The area of the whole site is 455 000 m^2 and that of the buildings 169 000 m^2.
Inspection History	The site has been regularly inspected by local authorities (NMPA and provincial MPA) Below is the list of major regulatory inspections of Tianjin Tianyao Pharmaceuticals Co., Ltd.

Date	Inspecting Authority	Outcome
November 2025	NMPA, China	GMP compliant
December 2024	FDA, USA	VAI
October 2024	ANVISA, Brazil	GMP compliant
April 2021	MOH, Russia	GMP compliant

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following GMP subjects were covered during the inspection: 1. Quality system 2. Production system 3. Facilities and equipment system 4. Laboratory control system 5. Materials system 6. Packaging and labelling system The following areas were visited and inspected: 1. Production suite (block # 28 for chemical synthesis, and block # 15 [Room 12] for clean area). 2. QC laboratory (second floor of building 22). 3. Warehouse facilities for raw and starting materials, intermediates and finished APIs as well as the solvent farm. 4. Utilities.
Restrictions	NA
Out of scope	Products, processes and facilities that are not related to the scope of the WHO prequalification programme (PQP).

WHO APIs (including WHO API or APIMF numbers) covered by the inspection	• Dexamethasone (sodium phosphate) for WHO prequalified FPPs including CV004 and HA734

Part 2	Summary of the findings and comments

1. Quality System

Principles, quality manual (QM) and quality policy (QP)

An overall pharmaceutical quality system (PQS) was established at the site, apart from an overarching quality management system of the corporate company. A quality policy was available and focused on continuous improvement and customer focus towards people's access to high quality, safe and effective medical products.

Quality unit (QU)

A quality unit which was independent of production and comprised quality assurance (QA) and quality control (QC) departments oversaw quality related responsibilities including deviation management, change control, OOS & OOT, CAPA, complaints, recalls, annual product quality review, documentation control, oversight of validation activities, product release, supplier qualification, internal audit and data integrity.

The quality unit was led by the Qualified Person or an authorized delegate, with responsibility for overall product quality, including batch release.

Personnel

The site employed a total of 870 employees. Pre-employment medical examinations were conducted for all new employees, and staff underwent annual medical check-ups. Employees working in clean areas were subject to an additional health monitoring program.

Operators in chemical areas wore clean caps, protective clothing, and safety shoes. Personnel working in clean areas wore appropriate cleanroom garments, including face masks, hair caps, dedicated shoes (or overshoes), and other suitable protective attire.

Training

The training procedure, established by the Human Resources Department, governed various training activities, including general, job-specific, initial, and on-the-job training. A structured training program was implemented and subject to regular review and updates.

Training activities covered key areas such as quality management, production management, materials management, documentation and record control, validation and qualification, complaints handling, recall procedures, and laboratory control. Two types of training were conducted: in-house and external. The effectiveness of training was evaluated through questionnaires and practical assessments.

Management review (MR)

The SOP for management review "annual review of quality system" was in place. The MR was required to be performed before March each year for the review of data of the previous year. The scope of the review included organizational structure, quality management, supplier management, release control, OOS, deviations, non-conformance, change control, risk management, CAPA, internal audit and validation management. The MR was required to be attended by the General Manager, along with the heads of relevant departments, including production, quality, human resources, supply chain, etc.

The last MR was performed on 20/2/2026 as per the respective MR report. The meeting was led by the General Manager while being organized and coordinated by the quality director. The MR included follow up on recommendations of previous MR.

Product quality review (PQR)

The SOP for annual product review was in place. The SOP provided for preparation of the PQR on annual (rolling) basis, even when no production occurred. The review covered a wide range of subjects including raw and packaging materials; review of intermediates and finished APIs; review of deviation, OOS, OOT, investigations along with CAPA; review of changes; review of stability studies; review of complaints, recalls, and returns; review of equipment, utilities and environmental monitoring; review of post-marketing commitments; review of technical agreements and service suppliers; and review of self-inspection.

The PQR reports and data of 2024 and 2025 were reviewed.

Quality risk management (QRM)

The SOP for QRM was in place. The procedure provided for guidance on QRM in compliance with ICH Q9/R2. Several risk management tools were referenced in the procedure including PHA, FMEA, and HACCP. A risk register was established and the following risk assessments were spot-checked:

- QRM of sharing clean area #12 between Dexamethasone (Sodium Phosphate) and Prednisolone.
- QRM for nitrosamine impurities.
- QRM for elemental impurities.

Deviations

The SOP for deviations management provided for handling deviations including initiation and recording, classification (critical, major, minor and incident), investigation, and CAPA. Deviations were required to be logged in a logbook (one logbook for critical, major and minor deviations; and another logbook for incidents). The deviation logbooks covering 2025 and 2026 were reviewed. No deviations were related to Dexamethasone (sodium phosphate) were reported during this period. The logbooks covered all non-Quality Control deviations. The latter were logged in a different standalone logbook. The latter logbook was also checked and several deviations were spot-checked.

Deviations were reviewed on an annual basis. The deviation 2025 annual report was presented. The report comprehensively analysed all deviations raised in 2025 for all products and workshops including trending and comparison with 2024 deviations.

Internal audit (self-inspection)

This subject was not inspected due to time limitation.

CAPA management

The SOP for CAPA management was in place. The procedure provided for the application of CAPA for deviations, OOS, complaints, recalls, inspections, and other inputs (e.g., management review). The SOP guided CAPA initiation, implementation and effectiveness verification.

CAPA management was subject to annual review. The 2025 CAPA review report was checked.

Change control

The SOP for change control was established and guided change initiation, change review, change evaluation, change classification (critical, major and minor), change implementation and change annual review. A logbook was established for changes across the site. The 2025 and 2026 logbooks for changes were reviewed and the several changes related to Dexamethasone (sodium phosphate) were spot-checked.

The annual review report for change control in 2025 was checked. The review included a full list of changes in 2025 along with statistical evaluation in comparison with 2024 data.

Complaints

The SOP for complaints management guided the management of customer complaints including receipt, classification, processing/review and closure. A logbook was established for received complaints. Several complaints were spot-checked.

Recalls

The SOP for recall management guided the management of product recall including recall initiation, classification (level 1 recall related to serious health hazards, level 2 recall related to temporary or reversible health hazards and level 3 recall related to non-critical or major reasons), recall decision (by the Qualified Person), recall implementation including notification to regulatory authorities (by RA department) and recall closure including reconciliation as well as mock recall in case of absence of regulatory (normal) recall.

The last mock recall was executed in April 2026 concerning one API for overseas market.

Outsourcing and contracting out of manufacturing activities

No manufacturing activities (neither production nor quality control) were outsourced or contracted out. A system was in place though for contract manufacturing as per the established procedure.

Data integrity

A data integrity risk assessment (DIRA) was in place. The risk assessment using FMEA estimated some risk factors/elements with medium and high risk ranking. A risk control was introduced for a number of risk events to render the associated risks low.

A couple of SOPs guided audit trail of QC data including the SOP for Audit trail and the SOP for laboratory data review. The audit trail was mandatory to be performed for each tested batch and on a

monthly basis. Both audit trails were performed according to established templates which were subject to QA oversight.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

2. Production System

Production activities
The batch production and analytical records of a couple of batches were spot-checked..

Validation policy
The SOP for validation master plan (VMP) was in place. A VMP for 2026 was established including workshop 105 comprising blocks 28 and 15 related to Dexamethasone Sodium Phosphate.

Validation documentation
Validation activities were well documented as per validation protocols and reports. Several validation related documentation were spot-checked in connection with the inspection of process validation, cleaning validation, hold time studies, and equipment qualification including performance qualification.

Process Validation
Protocol of Process Validation of Dexamethasone Sodium Phosphate and report were reviewed. Production process consistency was evident by the revalidation exercise. The manufacturing process did not change; however, the mentioned revalidation was executed based on the policy for revalidation (every 5 years).

Periodic review of validated systems
Validated systems were subject to regular review or rolling basis, or when revalidation was necessary (e.g., in case of changes). Manufacturing consistency, as represented by process capability and other statistical process controls (SPC) were verified as part of the annual product quality review. Production process was revalidated every 5 years.

Holding time studies
Intermediate storage time validation protocol and report of Dexamethasone Sodium Phosphate were spot-checked.

Cleaning Validation (CV)
Cleaning validation protocols and reports were available for different equipment used for production activities. Dirty equipment holding time (DEHT) and clean equipment holding time (CEHT) were covered during the aforementioned CV.

A policy for revalidation once every 5 years, at the latest unless initiated by major changes, was in place.

Reprocessing and reworking
The SOP for reprocessing and reworking was in place. Reprocessing and reworking were not allowed for some markets while being allowed for others based on the authorizations by the respective authorities.

Recovery of materials and solvents
As per the manufacturing instructions and master batch records of Dexamethasone (Sodium Phosphate), no solvent recovery was allowed during the production process.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

3. Facilities and Equipment System

Design and layout
Documented layouts of the site were available. The site comprised several buildings and workshops; two production buildings were covered by this inspection being relevant to the inspection scope and at which production operations of Dexamethasone Sodium Phosphate took place.

1. Building no. 28 (Chemical area) which comprised of two floors;
    a. First floors for centrifuges.
    b. Second floor for reactors.
2. Building no. 15 including
    a. Chemical area for the final steps before the final crystallization.
    b. Clean area no. (12); grade D clean area used for final crystallization, drying, and packaging of the API.

In general, the facilities were located, designed, and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Adequate space was provided for the orderly placement of equipment and materials. Entrance to production workshops was via a change room cascade and PAL (personal air lock), gowning procedure photos were displayed. Final steps were performed in grade D clean rooms. Premises visited were seen clean and properly maintained.

The production, quality control and storage premises can be summarized as follows:

Block #	Function and/or Activities
# 28	Chemical area for fluorination, iodination, replacement, hydrolysis, and esterification
# 25	Clean area (class D) for crystallization, drying and packaging
# 23	Storage area of solid raw materials including key starting material, and API
# 53	Storage area of packaging materials (primary, secondary packaging materials, labels)
# 35	Storage area of Solvents in tank
# 29	Storage area of solvents in drums
# 44/ 45	Storage of API (Equipped with WMS system)
# 22	Physico-chemical and microbiological quality control laboratory (on the 2nd floor)

Cleaning and sanitation
The facilities were cleaned and maintained in accordance with the written procedure and records were maintained. The procedure "Workshop Clean Area Management" was applied to Grade D clean areas of each production workshop and it outlined the cleaning and the disinfection activities in those areas.

Utilities

HVAC system

The production environment for the Dexamethasone Sodium Phosphate purification process was designed to fulfil requirements of cleanliness class D. Terminal HEPA filters were installed in the ceilings of the cleanrooms and they were changed every three years. Monitoring of humidity, temperatures and relevant pressure differences between rooms was ensured in the cleanroom area. The performance requalification for HVAC system was performed every three years. The frequency of testing activities was every three years except for the installed filter leakage test which was performed on an annual basis. The performance qualification protocol titled "Protocol of PQ on Air Cleaning System of 12# Cleaning Area", its relevant report were reviewed and the results were found within the predetermined acceptance criteria for the performed tests.

Purified water (PW) system

Purified water was prepared by RO/electro-deionization (EDI) and provisions were made for in-line measurement for total organic carbon (TOC), conductivity, flow and temperature. Operation, monitoring, and system sanitization were generally discussed and logbooks for monitoring and sanitization of the water system were checked. Sampling and testing were performed according to a defined schedule. The offline testing of conductivity and TOC for PW samples were carried out in a separate room located within the water system building.

Nitrogen

No nitrogen generation system was available at the site. Liquid nitrogen was supplied by a qualified supplier. The nitrogen distribution system was requalified on an annual basis and the testing activities included particulate count testing, oil content and water content. The nitrogen gas used in contact with the product was supplied through microbial filters installed at the user point.

Equipment qualification

The process equipment was qualified and the requalification frequency was generally 5 years, or in the case of a major change. The equipment requalification for the Fluidized bed drier for Dexamethasone sodium phosphate and its relevant report approved were reviewed and found acceptable.

The process equipment was regularly maintained in accordance with the annual and monthly maintenance schedules. The preventive maintenance plan was presented and found acceptable.

Calibration and measurement verification

Production and analytical equipment, including balances, sensors, and other measuring devices, contained a unique identifier, along with calibration dates. Calibration labels were available on the equipment with clear indication of the date of the last and the due date for subsequent calibration activities. Balances were verified daily (when in use).

Computerized systems

GMP-related computerized systems were validated. The depth and scope of validation was based on the diversity, complexity and criticality of the computerized application. Written procedures were available for the operation and maintenance of computerized systems. The warehouse management system (WMS) was used for management of quarantined and released finished API. The following documents were spot checked and the access and privilege list was discussed;

1. User Requirements Specification
2. WMS system account list
3. WMS Validation PQ Protocol
4. WMS Validation PQ Report

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

4. Laboratory Control System

General controls

The quality control laboratory being a part of the quality unit was independent from the production department. Laboratory facilities were also independent from the production facilities and, in general, adequate in terms of design, space and equipment.

The laboratory was responsible for physical, chemical, microbiological, and stability testing of incoming raw and starting materials; intermediates; finished APIs; packaging and labelling materials; purified water and other utilities along with environmental monitoring; and stability programme.

The quality control premises were located on the second floor of block 22 with a total of 90 employees. It was equipped with around 40 HPLC, 10 GC, IR, XRD and other instruments. The chemical quality of purified water, including offline testing for TOC and conductivity was tested in a room allocated nearby the water generation system.

The laboratory was equipped with electronic systems to manage HPLC and GC analyses as well as IR spectrophotometry. The users and user types along with privileges matrix of the software application were reviewed.

Documented procedures describing sampling, testing, approval or rejection of materials, intermediates and products were available. Reagents and standard solutions were prepared and labelled following written procedures.

Reference standards

The source of each primary reference standard was documented. Records were maintained of each primary reference standard's storage and use in accordance with the supplier's recommendations including documented regular check for the continued validity of the reference standard material. Secondary reference standards were properly prepared, identified, tested, approved and stored. The suitability of each batch of secondary reference standard was determined prior to first use by comparing it against a primary reference standard. Each batch of secondary reference standards was periodically requalified, on an annual basis, in accordance with a written protocol including prior to retest and/or expiry date.

The SOP for management of reference standards guided the purchase, storage and handling of primary (pharmacopoeial) reference standards. The validity of the primary reference standards was regularly checked, once every two months, with documentation of such checks in a dedicated logbook. The SOP also guided the establishment of secondary (working) reference standards using highly purified routine

commercial API batches along with qualification against primary reference standards. The secondary reference standards were subject to regular requalification, once a year. Prepared secondary reference standards used for quantitative testing were packaged in single use glass vials. Working standard of Dexamethasone (Sodium Phosphate) was spot-checked. A couple of batches were established as working standards namely. The qualification reports of both mentioned batches were spot-checked. The quality of working standards was verified by the end of use (within a maximum of 1 year). Acceptance criterion was set for difference in potency of the beginning and end of use of the working standard.

Testing of intermediates and APIs

The SOP for integration method for chromatographic data was in place. The SOP mandated automatic integration of chromatographic data as per preset parameters. The SOP allowed manual integration of the HPLC chromatographic peaks as well as amendment of the integration parameters, when necessary. In case of change of integration parameters, prior request and approval should be sought from QC supervisor.

The list of aborted HPLC and GC runs in 2025 and 2026 (up to the date of the inspection) was checked. For each of related incidents, a deviation report was raised, followed by an investigation and CAPA, where applicable.

Validation of analytical procedures

The SOP for analytical method validation (AMV) was in place. The SOP provided parameters to be considered during AMV including specificity, accuracy, precision, repeatability, intermediate precision and reproducibility, LOD, LOQ, linearity, range and robustness. Despite the fact that Dexamethasone Sodium Phosphate was tested according to *Ph. Eur.*, the full AMV for assay and related substances testing.

Reports of the AMV of assay test and related substances test for Dexamethasone Sodium Phosphate which were revised in November 2024 and December 2025 respectively due to change in the test method and the same were spot-checked during the inspection. The AMV was updated to improve the system suitability and provide for extension of the solution stability.

Stability monitoring of APIs

The SOP for evaluation of stability test of API was established. The procedure mandated enrolment of at least one batch per year in the ongoing stability testing programme. Usually, the first batch of the year was enrolled in the ongoing stability testing programme. Other batches may also be enrolled within the stability programme based on risk (e.g., considering OOT results, and deviation, etc.).

Product batches subject to stability testing were stored in dedicated stability chambers at a designated room in the quality control laboratory. The chambers were qualified prior to use. Samples of product batches were stored in containers simulating the ones used for finished API packaging.

The test results of the ongoing stability testing of Dexamethasone (sodium phosphate) were spot-checked.

Out-of-specification (OOS)

The SOP for OOS management was established. The procedure included flowchart for OOS management including identification, phase I investigation limited to laboratory investigation, phase II involving full

laboratory (including hypothesis testing as applicable) and production investigation. A logbook was available for OOS test results. In addition, OOS results were subject to annual review. The 2025 and 2026 logbooks were reviewed and several OOS results were spot-checked.

The OOS 2025 annual review was checked. Analysis was made between OOS results of 2025 and 2024 (earlier year).

Expiry and retest dating

The SOP for batch production record management guides the definition of manufacturing date and consequently the expiry and retest date: The manufacturing date was set for the date of charging of the last stage (involving crystallization and drying). The manufacturing date of reprocessed and reworked batches were kept as the date of manufacturing of the original batches, regardless of the concerned production process.

Reserve/retention samples

Retention samples were stored in a dedicated area within the quality control laboratory. The room was monitored for temperature and humidity. Retention samples were kept in containers, similar to the finished API containers. The quantities of the retention samples were sufficient to perform any investigational testing if needed. The retention samples of Dexamethasone (Sodium Phosphate) were checked and the proper storage and management of retentions samples was verified.

Materials and batch release

The SOP for release management was implemented. The procedure scope covered all materials and finished API. One qualified person was appointed in charge of finished API release. A list of delegate persons for release of raw and starting materials, intermediates, packaging and labelling materials and finished API was available and authorized by the qualified person. A checklist of batch release was established for release of finished API. A template for release statement was also established as per the procedure based on a checklist for different production and quality control operations as well as deviations, OOS, changes, and validation. The batch release checklists and release statements of Dexamethasone (Sodium Phosphate) CEP of for a couple of batches were spot-checked.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

5. Materials System

General controls

The receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were carried out in accordance with a written procedure. There was system in place for evaluating the suppliers of critical materials and materials were purchased against an agreed specification, from suppliers approved by the quality unit.

Receipt and quarantine

Materials were received in the receiving bay and checked according to the purchase order, including verification of whether the material came from an approved supplier. Each container or grouping of containers of materials were examined visually for correct labelling, damage to containers, broken seals

and evidence of tampering or contamination. Materials were held under quarantine status until they had been sampled, examined, or tested as appropriate, and then released for use.

Sampling and testing of incoming production materials

Sampling of raw materials and packaging materials were conducted at defined locations and the sampling process was carried out according to a written procedure. QC was responsible for sampling, testing and releasing of raw materials, packaging materials and intermediates, while QA was responsible for sampling of Finished API.

Supplier qualifications

Materials were purchased against an agreed specification, from a supplier or suppliers approved by the quality unit and the site has established a material supplier qualification procedure titled “SMP on Supplier Qualification” code no., with the Quality Assurance department responsible for organizing, supervising the evaluation process, and confirming the assessment results. An approved supplier list was updated regularly or whenever there were changes.

The supplier qualification for the starting materials (Methylprednisolone intermediates) was sampled for review. The evaluated record officially established one supplier as the approved manufacturing supplier. The verification confirmed that a comprehensive on-site facility audit was executed by a cross-functional team of site QA and Technical personnel.

Rejects and returns

Rejected materials or finished API and Returned materials were identified and physically segregated in dedicated areas with controlled Access.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

6. Packaging and Labelling System

Packaging materials

A written procedures were established for describing the receipt, identification, quarantine, sampling, examination and/or testing and release and handling of packaging and labelling materials.

Label issuance and control

Access to the label storage area was limited to authorized personnel. Procedures were used to reconcile the quantities of labels issued, used and returned and records were maintained. Printed labels issued for a batch were carefully examined for proper identity and conformity to specifications in the master production record and the results of this examination was documented.

Packaging and labelling operations

Packaging and Labelling operations were carried out in production rooms separated from operations involving other intermediates or APIs. Labels used on outer containers of APIs indicated the name, the batch number of the product and the storage conditions. Packaging and labelling rooms were inspected immediately before use to ensure that all materials not needed for the next packaging operation have been removed and the examination documented in the batch production records.

All the non-compliances observed during the inspection were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

Miscellaneous	
Samples taken	NA
Assessment of the site master file	The SMF (SMF-RA026) was received prior to the commencement of the inspection and it was, in general, found acceptable.
Annexes attached	NA

Part 3	**Final conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, **Tianjin Tianyao Pharmaceuticals Co., Ltd**, located at **No.19 Xin Ye 9th street, Tianjin 300462 China**; was considered to be operating at an acceptable level of the WHO guideline on Good Manufacturing Practices (GMP) for active pharmaceutical ingredients.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	**List of GMP guidelines referenced in the inspection report**

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.

Short name: WHO TRS 1010, Annex 9
https://www.who.int/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
Short name: WHO TRS No. 1033, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1033

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
https://www.who.int/publications/m/item/annex-4-trs-929

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
Short name: WHO TRS No. 957, Annex 1
https://www.who.int/publications/m/item/trs957-annex1

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://www.who.int/publications/m/item/trs957-annex3

8. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8.
Short name: WHO TRS No. 1010, Annex 8
https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4

https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

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