

LICENSING AND ENFORCEMENT DIVISION**PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:****Name of company: Sinovac (Dalian) Vaccine Technology Co. Ltd****1.0 General information**

1.1 Name of Inspected company	Sinovac (Dalian) Vaccine Technology Co. Ltd
1.2 Physical address	No.36. 2nd Life Road, DD Port, Economic and Technical Development Zone Dalian, P.R. China
1.3 Corporate address	No. 39, Shangdi Xi Road, Haidian District Beijing, P. R. China
1.4 Summary of the main activities performed	Manufacture of Biologics
1.5 Scope of Inspection	Product- based inspection to verify compliance to cGMP guidelines for the manufacture of Biologics.
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products which have been submitted and those yet to be for registration with the Medicines Control Authority of Zimbabwe (MCAZ).
1.7 Inspectors	Tendai Samkange – Lead Inspector Shamiso C. Shambira- Co-inspector
1.8 Date of Inspection	9 th July– 15 th July, 2025

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

2.0 Abbreviations List

Abbreviation	Expanded Form
AHU	Air Handling Unit
BMR	Batch Manufacturing Record
BPR	Batch Processing Record
CV	Cleaning Validation
EM	Environmental Monitoring
FPP	Finished Pharmaceutical Product
HPLC	High-Performance Liquid Chromatography
HVAC	Heating, Ventilation, and Air Conditioning
MACO	Maximum Allowable Carry Over
MCAZ	Medicines Control Authority of Zimbabwe
PDE	Permitted Daily Exposure
PQ	Performance Qualification
PQR	Product Quality Review
QA	Quality Assurance
SOP	Standard Operating Procedure
TD	Therapeutic Dose
TRS	Technical Report Series
WHO	World Health Organization

3.0 Summary

3.1 Summary about the facility

Sinovac (Dalian) Vaccine Technology Co. Ltd is located at No.36. 2nd Life Road, DD Port, Economic and Technical Development Zone Dalian, P.R. China. The company manufactures biologics.

The Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate audited the block manufacturing Dutasteride. The audit was conducted from the 9th to the 15th of July, 2025. The company has been audited by other regulatory bodies.

3.2 General Information about the Company and the Site

This was a new inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support continued registration of products in Zimbabwe. The site had not been previously audited by MCAZ. The inspection was product-based and focused on the products that were intended for the Zimbabwean market, as provided below:

Product	Strength	Formulation	Registration status/ File No.
---------	----------	-------------	----------------------------------

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

Varicella live vaccine lyophilized powder for solution	0.5ml/vial	Bulk Substance and finished product	QA435
--	------------	-------------------------------------	-------

The inspection was conducted with reference to and in accordance with the WHO Good Manufacturing Practices detailed in the Technical Report Series 986, Annex 2 of 2014, among other relevant current guidelines. The inspection was conducted in an open and cooperative atmosphere.

3.3 Areas inspected (*Not exhaustive*)

- **Quality Management:** Product Quality Review (PQR), Quality Risk Management, Deviation control, finished product and starting material batch release, Contract agreements and Supplier approval.
- **Materials Management:** Receipt, handling, quarantine, sampling, release, reject, temperature (and humidity) monitoring and dispensing.
- **Good Practices in Production:** Production areas, production equipment, documentation and instructions, sanitation cleaning and maintenance, batch records, calibration, contamination control, in process controls.
- **Quality Control:** Review of test procedures and specifications.
- **Utilities:** HVAC, Purified Water,
- **Environmental Monitoring:** EM programme
- **Equipment qualification** and preventive maintenance

3.4 Utilities

- a. Water Purification system
- b. HVAC system

3.5 Documentation reviewed (*Not exhaustive*)

As listed in the final inspection report

3.6 System Summaries

Good Practice in Production

The Strain of Virus used was reviewed. It was approved by the national control authority.

Control of Cell Culture

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

Traceability to the original cell line was demonstrated.

Control of Serum and Other Media

The specifications and their certificates of analysis were reviewed and found to be satisfactory. There was demonstration of adequate testing of media used in culturing. The approved suppliers were indicated.

Package Insert

The package insert of the final product was reviewed. In line with WHO TRS 848, there was inclusion of reconstitution instructions directing clinicians to make use of the provided diluent only. Package inserts were in various languages. Each package insert had a standard colour card which was version controlled. Each printing standard had a validity of two years. There was use of sampling formulae applicable to each consignment of package inserts based on quantity received.

Qualification and Validation

Process Validations – Bulk

The process validation report was submitted for review and found satisfactory.

The validation covered the following stages:

Cell Preparation, Virus Inoculation, Washing and Liquid Change, Preparation of virus harvest and Bulk Preparation. There was adherence to the established cell lifetime. Bulk transportation and thawing were also validated.

Aseptic Process Simulation

The batch manufacturing record of the most recently executed and completely reported aseptic process simulation was reviewed and found satisfactory.

Process Validation of Finished Product

The process validation of the formulation and filling of the final product was reviewed. The validation covered the washing and depyrogenation of vials.

Performance Qualification of the Ultralow refrigerator

The PQ protocol and report for the ultralow temperature refrigerator was submitted for review.

Quality Management System

Product Quality Review

The SMP for Product Annual Quality Review Management regulations was submitted for review. The key pharmaceutical quality system parameters had been considered. All the parameters were in state of control.

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

Vendor Qualification

The SOP for vendor qualification was submitted for review. There was satisfactory qualification of the vendors from questionnaire submission to onsite audits to pre shipment lots evaluation. All the necessary declarations were being submitted as part of the vendor qualification. The approach to ongoing vendor monitoring was reviewed.

Deviations

The SOP for deviations handling was submitted for review. There was provision of categorizing the deviations according to their impact. Timelines for closure of deviations were specified. The logs of deviations and trend reports of deviations were submitted for review.

Complaints

The SOP for complaints handling was submitted for review. The procedure provided for receipt, root cause identification and CAPA provision. The timelines from receipt to closure were specified. The logs of complaints were reviewed. Examples of complaints were reviewed to show the application of the SOP. The approach to handling of complaints was satisfactory.

Quality management review

Annual quality management review report was submitted for review and found satisfactory.

Walk-through inspection

Raw materials Warehouse

The raw materials warehouse was inspected and found satisfactory.

Finished product warehouse-Varicella bulk

The finished product warehouse was inspected and found satisfactory.

Walk-through: Bulk Workshop (Building 2)

The schematic diagram of the cleanroom layout of the Bulk Workshop, was reviewed before the tour of the facility. This was found to be satisfactory.

Walk-Through: Filling Line 2 (Building 3)

The workshop in housing Filling Line 2 was inspected on the second day of the audit. There was filling of the vaccine.

Quality Control Laboratory

The physical and biology laboratories were inspected.

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

Product Stability Monitoring

The stability chambers were inspected.

Analytical Method Validation of the Virus Titre Method

The summary report of the Analytical Method Validation of the Virus Titre Method was reviewed.

Animal House

The animal laboratory was inspected and found satisfactory.

Lot Release

The Standard Management Procedure for Final Product Releasing was reviewed. There was provision for lot releasing by the local regulatory authorities.

Shipment of Temperature and Time Sensitive Products

The Bulk and finished product were considered to be heat labile. Evidence of environmental monitoring of finished vaccine was submitted for review and found to be satisfactory.

Utilities

Pharmaceutical Water System

The approach to PWS generation, storage and distribution was specified. The material of construction for the different stages was acceptable. There was provision of an SOP for sanitization of the system. The records were satisfactory. The annual water trend reports for the online monitored parameters were reviewed and these were satisfactory.

HVAC System

The service area housing Air Handling Units (AHUs) of Building 2 and 3 were inspected and found satisfactory.

4.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report, **Sinovac (Dalian) Vaccine Technology Co. Ltd located at No.36 2nd Life Road, DD Port, Economic and Technical Development Zone Dalian, P.R. China** was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of Biologics.

All the non-compliances observed during the inspection listed in the full report were addressed by the manufacturer to a satisfactory level prior to the publication of the MCAZ PIR.

Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

The site will be reinspected **3 years** from the date of the last inspection in line with the risk based reinspection frequency determination.

5.0 References

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
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
2. WHO Good Manufacturing Practices: water for pharmaceutical use. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report*. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
3. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report* Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5, Annex 9
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
4. Supplementary guidelines on good manufacturing practices: validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report*. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
5. WHO good practices for pharmaceutical microbiology laboratories. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report*. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2 <http://www.who.int/medicines/publications/pharmprep/en/index.html>
6. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. *WHO Expert Committee on specifications for pharmaceutical preparations. Forty-third report*. Geneva, World Health Organization, 2009. (WHO Technical Report Series, No. 953), Annex 2 <http://www.who.int/medicines/publications/pharmprep/en/index.html>
7. WHO guidelines on quality risk management. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report* Geneva, World Health Organization, 2025
Sinovac (Dalian) Vaccine Technology Co. Ltd, final cGMP Inspection Report, 9th July–15th July, 2025

Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2

<http://www.who.int/medicines/publications/pharmprep/en/index.html>

8. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty Ninth Report* Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty Ninth Report* Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
10. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *Forty-fourth report of the WHO Expert Committee on specifications for pharmaceutical preparations*, World Health Organization, 2010 (WHO Technical Report Series 957, 2010), Annex 1
<http://www.who.int/medicines/publications/pharmprep/en/index.html>