STANDARD OPERATING PROCEDURE (SOP)
GDP/GSP COLD-CHAIN MANAGEMENT

Document Control Information

Document Title:	GDP/GSP Cold-Chain Management SOP
Version:	1.0
Effective Date:	November 2025
Next Review:	November 2026

Approved by: Giorgio Patino Cohen, General Director
Reviewed by: Juan Celis / Rafael Gutierrez, Warehouse Cold Storage Supervisors

1. Purpose

This Standard Operating Procedure (SOP) establishes the principles, responsibilities, and practices required to ensure compliance with Good Distribution Practice (GDP) and Good Storage Practice (GSP) for all pharmaceutical and biological products managed by: (Distribuidora Farmacéutico Pan Americana SA de CV (PanamFarma). It guarantees continuous temperature control and product integrity throughout the supply chain from manufacturing in India to final delivery in Mexico and across Latin America.

2. Scope

This SOP applies to all cold-chain and deep-freeze pharmaceutical products, including monoclonal antibodies, biosimilars, vaccines, immunoglobulins, and other temperature-sensitive medicines handled, stored, or transported by PanAmFarma or its logistics partners. It covers shipment flows from PanAmFarma's manufacturing facilities in India to its COFEPRIS-approved warehouse facilities in Mexico, and subsequently to regional clients and government institutions throughout Latin America using DHL Health Special Services.

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3. Regulatory Framework

PanAmFarma operates under the following international and national standards:

- World Health Organization (WHO) Technical Report Series Annex 9 – Model Guidance for GDP/GSP.
- Pan American Health Organization (PAHO) Good Distribution Practices for Pharmaceutical Products.
- COFEPRIS (Mexico) Guidelines on Storage and Distribution of Medicinal Products.
- United Nations Global Marketplace (UNGM) Supplier Registration #1084189 – Professional Level.

4. Temperature Standards

- Cold Chain Storage (2 °C to 8 °C): Applicable to most biological products including vaccines and insulins.
- Deep Freeze Storage (−20 °C and below): Applicable to monoclonal antibodies and sensitive biologics.

All products are monitored continuously using calibrated data-loggers and temperature sensors with 24-hour recording systems.

5. Responsibilities

- General Director – Overall compliance oversight.
- Warehouse Cold Storage Supervisors (Juan Celis and Rafael Gutierrez) – Implementation and recordkeeping of GDP/GSP standards.
- Quality Assurance Department – Internal audits, corrective actions, and training.
- Logistics Coordinator – Verification of DHL Health Special Services temperature integrity during transit.
- Receiving Clients – Verification of temperature data upon receipt and reporting of any deviation within 24 hours.

6. Operational Procedures

- Temperature-controlled packaging is validated and pre-conditioned before each shipment.
- Data loggers are placed in each shipment and verified at dispatch and receipt.
- DHL Health Special Services is mandated to maintain cold-chain integrity under WHO GDP standards.
- Upon arrival in Mexico, products are transferred to PanAmFarma's COFEPRIS-approved cold storage rooms within two hours of customs release.
- Deep-freeze products are stored in dedicated −20 °C to −70 °C freezers with alarm monitoring and backup power supply.

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7. Deviation Management and Corrective Actions

All temperature excursions are recorded and investigated immediately by the Warehouse Supervisors and Quality Assurance team. Corrective and preven tive actions (CAPA) are implemented and documented per WHO/PAHO GDP guidelines.

8. Training and Review

All personnel involved in storage and distribution undergo annual GDP/GSP training. This SOP is reviewed annually by the Quality Department and re-app roved by the General Director.

9. References

- WHO Technical Report Series Annex 9 – Model Guidance for the Storage and Transport of Time-and Temperature-Sensitive Pharmaceutical Products.
- PAHO Regional Guidelines for Good Storage and Distribution Practices.
- COFEPRIS NOM-059-SSA1-2015 – Good Manufacturing Practices for Medicinal Products.
- UNGM Supplier Registry #1084189 – Professional Level Supplier Status (Distribuidora Farmacéutico Pan Americana SA de CV).

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