

Public governance and operating-control snapshot

This public overview summarizes the quality, governance, and controlled operating-system themes reflected across Berhan Pharma's manuals and SOP framework. It is designed as a trust document for customers, partners, and institutional reviewers.

Governance posture

Policy-led, auditable, and evidence-oriented management approach.

Distribution controls

Receiving, storage, cold chain, dispatch, complaint handling, and recall-oriented discipline.

Document integrity

Controlled document issue, review, distribution, and record handling.

Digital integrity

Computerized-system and data-integrity awareness across enterprise records.

Reference frameworks reflected in the public quality narrative

- EFDA Directive No. 872/2022 and GDP/GSP-aligned distribution controls
- ISO 13485:2016 medical device quality-system alignment
- ISO 14971:2019 risk-management alignment
- ISO 9001:2015 quality-management alignment
- ISO 14001:2015 environmental-management alignment
- ISO 45001:2018 health and safety alignment
- ISO/IEC 27001:2022 information-security alignment

Controlled Operating Pillars

Selected themes derived from public manuals and SOP catalogue

Computerized Systems & Data Integrity

ERP/WMS and related system controls designed for traceability, integrity, and auditable records

Representative controlled SOP catalogue areas

- Quality Management System
- Storage & Warehouse Control
- Dispatch, Delivery & Customer Receiving
- Product Recall & Market Withdrawal
- Document & Records Control
- Computerized Systems & Data Integrity
- Receiving & Inbound Checks
- Cold Chain & Temperature Control
- Complaint & Compliance Handling
- Supplier Qualification & Monitoring
- Self-Inspection & Internal Audit
- Training & Competency