KEROLI HEALTHCARE PVT. LTD.
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QUALITY STATEMENT

Every product backed by documented quality.

Keroli Healthcare Pvt. Ltd. sources products exclusively from WHO-GMP and Schedule M certified manufacturers. This statement sets out our certifications, our quality assurance framework, and the regulatory framework governing our operations.

1. Certifications & Licences

Certification	Issuing Authority	Number	Scope
Drug Licence 20B	State Drug Control Department, Maharashtra	MH-PL1-630311	Wholesale — Sale of Drugs
Drug Licence 21B	State Drug Control Department, Maharashtra	MH-PL1-630312	Retail / Distribution of Drugs
FSSAI Registration	Food Safety and Standards Authority of India	21526019002342	Food and Health Supplement Products

All certifications listed above are current. Certified copies are available to qualified business partners on request, following business verification.

2. Quality Assurance Framework

A six-stage quality framework governs every product we market — from manufacturer qualification through to post-market pharmacovigilance.

01 **Manufacturer Qualification**
Every manufacturing partner is assessed against WHO-GMP and Schedule M requirements before onboarding. Facility audits and documentation review are mandatory.

02 **Product Approval**
Each product is approved for marketing only after verification of the manufacturing licence, product approval, and batch release documentation from the facility.

03 **Certificate of Analysis**
A valid COA from the manufacturer's in-house QC laboratory accompanies every product batch supplied by Keroli Healthcare.

04 **Storage & Cold Chain**
Products are stored and transported under conditions specified in the approved labelling. Temperature-sensitive products are handled under cold chain protocols.

05 **Regulatory Compliance**
All marketing activities comply with the Drugs & Cosmetics Act 1940, DCGI guidelines, and the Drugs and Magic Remedies Act 1954. No prohibited claims are made.

06 **Pharmacovigilance**
Active post-market surveillance. Adverse event reports are collected and submitted to the CDSCO PvPI programme. Quality complaints are investigated within 30 days.

3. Regulatory Framework

Regulation / Standard	Relevance
Drugs and Cosmetics Act, 1940	Drug licence, product approval, marketing compliance
Drugs and Cosmetics Rules, 1945 — Schedule M	GMP standard applied to all manufacturing partners
Drugs and Magic Remedies Act, 1954	Advertising compliance — no curative or magical claims
DPCO — Drug Price Control Order, 2013	Pricing compliance for scheduled formulations
Pharmacovigilance Programme of India (PvPI)	Adverse drug reaction reporting obligations
DPDP Act, 2023 / IT Act, 2000	Digital operations and data protection
WHO Technical Report Series 986 (GMP)	International standard applied to manufacturing partners

4. Documentation Available on Request

- Certificate of Analysis (COA) — per product batch
- WHO-GMP certificate of the manufacturing partner
- Manufacturer authorisation letter
- Product permission / approval documents
- Batch release documents on confirmed orders
- Free Sale Certificate (Form 26) and WHO-COPP for export
- MSDS / Safety Data Sheets

5. Pharmacovigilance

Adverse drug reactions and product quality complaints may be reported to **pharmacovigilance@kerolihealthcare.com** or through the reporting form at kerolihealthcare.com/legal/pharmacovigilance. Reports are acknowledged and, where applicable, submitted to the CDSCO Pharmacovigilance Programme of India. Reporting an adverse event does not constitute an admission of liability by Keroli Healthcare or its manufacturing partners.

ISSUED	ISSUED BY	DOCUMENT
16 July 2026	**Keroli Healthcare Pvt. Ltd.**	**Quality Statement**

This document is issued for information to licensed healthcare professionals, hospitals, distributors, and institutional buyers. It does not constitute medical advice and makes no therapeutic or curative claims.