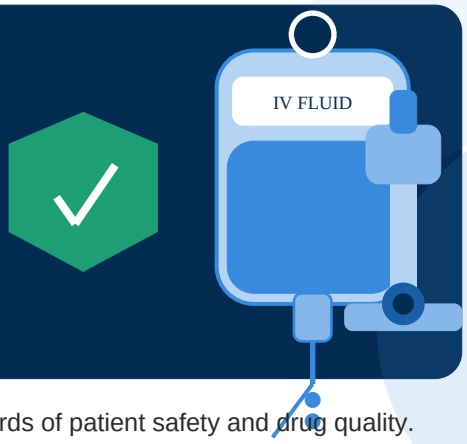
PHARMACOVIGILANCE

Adverse Drug Reaction & Safety Reporting

Life Infusion Pharmaceuticals Pvt. Ltd.

CDSCO / PvPI Compliant | Schedule Y



Life Infusion Pharmaceuticals Pvt. Ltd. is committed to the highest standards of patient safety and drug quality. In compliance with the **Central Drugs Standard Control Organisation (CDSCO)** guidelines and the **Pharmacovigilance Programme of India (PvPI)**, we maintain a dedicated system for collecting, evaluating, and reporting adverse drug reactions (ADRs) and product complaints.

What to Report

Adverse Drug Reactions (ADR)

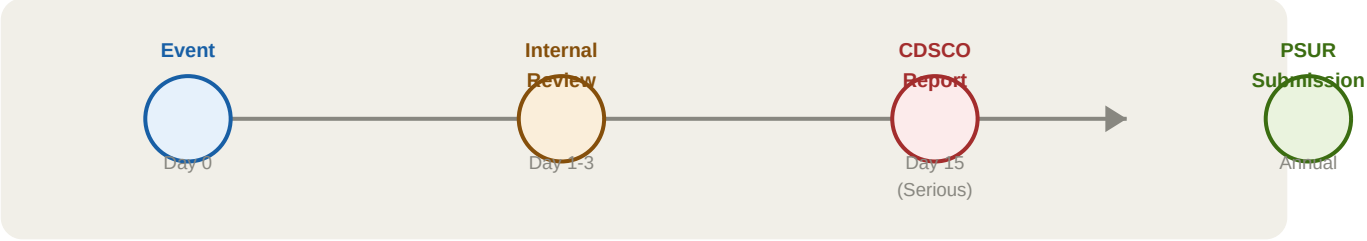
Product Quality Complaints

Medication Errors

Lack of Efficacy

- **Adverse Drug Reactions (ADR):** Any noxious, unintended response to a medicinal product — including unexpected side effects, allergic reactions, or patient harm following IV fluid administration.
- **Serious Adverse Events (SAE):** Events resulting in death, life-threatening condition, hospitalisation, persistent disability, or congenital anomaly.
- **Product Quality Complaints:** Visible particulate matter, discolouration, leakage, container/closure defects, incorrect labelling, or packaging errors.
- **Medication Errors:** Wrong product dispensed, dose confusion, or administration errors related to our products.
- **Lack of Efficacy:** Situations where the product fails to achieve the intended clinical outcome.

Regulatory Reporting Timelines



Event Type	Reporting Deadline	Submitted To
Serious ADR — fatal / life-threatening	Within 15 calendar days	CDSCO / PvPI
Serious ADR — non-fatal / non-life-threatening	Within 90 calendar days	CDSCO / PvPI

Non-serious ADR	Quarterly / Annual PSUR	CDSCO
Product quality complaints (critical)	Within 3 working days (internal)	QA Dept. + CDSCO
Periodic Safety Update Reports (PSUR)	Annually	CDSCO

How to Submit a Report

Online Form	Visit lifeinfusionpharma.com/pharmacovigilance and complete the ADR/complaint form. Submissions are acknowledged within 24 hours.
Email	Send a detailed description with batch number, product name, and patient outcome to: pv@lifeinfusionpharma.com
Phone / Fax	Call our PV Officer directly on +91 87141 33663 during business hours (Mon–Sat, 9 AM–5 PM).
PvPI Helpline	Report directly to the national programme by calling 1800-180-3024 (toll-free, Mon–Fri 9 AM–5:30 PM).
ADR PvPI App	Download the 'ADR PvPI' app from Google Play Store to submit reports directly to the national database.
Written Report	Post completed CDSCO Suspected ADR Reporting Form (available at ipc.gov.in) to our Pharmacovigilance Officer.

Our Pharmacovigilance Officer

Pharmacovigilance Officer

Registered with CDSCO / PvPI

Life Infusion Pharmaceuticals Pvt. Ltd.

Email: pv@lifeinfusionpharma.com

Phone: +91 87141 33663

Address: Kinalur, Kozhikode, Kerala

Patient Rights & Confidentiality

All reports submitted through this system are treated with strict confidentiality. Personal information of the reporter and patient is protected under the **Information Technology Act, 2000** and our Privacy Policy. Reporters will not face any penalty or disadvantage for submitting a good-faith report. Life Infusion Pharmaceuticals does not disclose reporter identity to third parties without explicit consent, except as required by CDSCO or other competent regulatory authorities.

Regulatory References

CDSCO	Central Drugs Standard Control Organisation	cdsco.gov.in
PvPI / IPC	Pharmacovigilance Programme of India	ipc.gov.in
WHO-UMC	Uppsala Monitoring Centre — VigiFlow	vigiflow.who-umc.org
Schedule Y	Drugs & Cosmetics Rules, 1945 — PV requirements	egazette.gov.in

PvPI Helpline: **1800-180-3024** Mon–Fri 9 AM – 5:30 PM | Toll-Free | ppc@ipcindia.net

www.ipc.gov.in | www.cdsco.gov.in

This document has been prepared in compliance with CDSCO Pharmacovigilance guidelines and Schedule Y of the Drugs & Cosmetics Rules, 1945. Life Infusion Pharmaceuticals Pvt. Ltd. | Kinalur, Kozhikode, Kerala | info@lifeinfusionpharma.com | +91 87141 33663

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