AKUMS DRUGS & PHARMACEUTICALS LTD. AND ITS SUBSIDIARIES

Adverse Drug Reaction (ADR) /Adverse Event (AE) Reporting Form

Type of Report **Initial** ☐ **Follow up** ☐ **Company Reference No.**:

Classification of Report

☐ Adverse Event

☐ Product quality complaint

☐ Medical information

Patient information

Patient Initials: ☐☐☐

Ex:- Rakesh Kumar Singh - R K S

Country: _____

Age at time of event:

Date of Birth (dd/mm/yyyy): D D M M Y Y Y Y

Sex ☐ M ☐ F ☐ Other

Weight (Kg) / ☐☐☐ Height (cm) ☐

Adverse Event

Is the adverse event serious? Yes ☐ No ☐

If yes, please indicate why it is serious? (Check all that apply)

Death (dd/mm/yyyy): _____ Disability/ ☐ Life threatening ☐

Congenital anomaly/birth defect / ☐ Hospitalization ☐ Other important medical events / ☐

If patient died, cause of the event:

Intensity of the adverse reaction ☐ Mild ☐ Moderate ☐ Sever

Date of onset of the event D D M M Y Y Y Y If the event stopped, date D D M M Y Y Y Y

Time (if available) ☐☐ : ☐☐ Time (if available) ☐☐ : ☐☐

Describe event or product complaint with treatment details, if any:

Outcome / Information on recovery and any sequelae: Recovered ☐ Recovering / ☐ Recovered with sequelae ☐

Other ☐ Not recovered ☐ Fatal ☐ Unknown ☐

Relevant tests/ laboratory data (with dates):

Other relevant history, including pre-existing medical conditions (eg. allergies, race pregnancy, smoking, alcohol use, hepatic/ renal dysfunction, etc.):

Suspected Medication(s)

S. No.	Name (Brand/Generic)	Batch No. / Lot No.	Exp. Date	Dose Used	Route Used	Frequency (OD, BD etc.)	Therapy dates		Indication
							Start date	Stop date	

Action Taken:

Drug Withdrawn ☐ Dose increased ☐ Dose Reduced ☐

Does not changed ☐ Not applicable ☐ Unknown ☐

Event abated after use stopped or dose reduced:

Yes ☐ No ☐ Unknown ☐ Not applicable ☐

Event reappeared after reintroduction:

Yes ☐ No ☐ Unknown ☐ Not applicable ☐

Relationship of the adverse event with the drug: Related ☐ Not Related ☐

Concomitant Medication (s) excluding treatment of reaction (name, dose, frequency, route and therapy dates):

Reporter:

Name and address:

Tel No. (with STD code) /Mobile No.:

E-mail ID:

Healthcare professional: Yes ☐ No ☐ Occupation :

Signature:

Date of this report:

Please send this form to: Corporate Pharmacovigilance Department, Akums Drugs & Pharmaceuticals Ltd. And its Subsidiaries, Plot no 19, 20, 21, Sector-6A, IIE, SIDCUL Haridwar (UK) 249403, India

OR send us the scan copy of this form to below email ID

Email id: globaldrugsafety@akums.in

If any additional data, then please attach with this form