SUSPECTED ADVERSE DRUG REACTION (ADR) REPORTING FORM

CONFIDENTIAL

If you are suspicious that an adverse reaction may be related to a drug or a combination of drugs, PLEASE COMPLETE THIS FORM and send it to the nearest Pharmacovigilance Centre /Medical Product Division.

A. PATIENT INFORMATION

1. Patient Details*

Patient name or Initials:_____Age/Sex:_____

Weight (if known):_____Ward/Dept/Unit:_____

2. Relevant Tests/Laboratory Data (If any):

3. Other Relevant Information (*including pre-existing medical conditions viz. allergies, pregnancy, alcohol use, renal dysfunction, diabetes etc.*):

B. SUSPECTEDDRUG(S) *

DRUG NAME	PRESCRIBEDFOR /INDICATION	MANUFACTURED BY:	BATCH NO/EXPDATE	ROUTE	DOSE/ STRENGTH	DATESTARTED	DATE STOPPED

C. SUSPECTED DRUG REACTION(S)*

1.DESCRIPTION OF THE REACTION	2.MANAGEMENT/ TREATMENT OF THE REACTION	Date of Reaction Started:_____ Time of Reaction Started: _____ Date of Reaction Stopped:_____ Time of Reaction Stopped:_____ 3. **OUTCOME:**(TICK ALL THAT IS APPROPRIATE) Recovered ☐ Recovering ☐ Continuing ☐ Not recovered ☐ Fatal ☐ Unknown ☐

4. **DO YOU CONSIDER THE REACTION TO BE SERIOUS?** YES☐ NO☐

If yes, please indicate why the reaction is considered to be serious (tick all that is appropriate)

☐ i. PATIENT DIED DUE TO REACTION
☐ ii. HOSPITALIZATION
☐ iii. LIFE THREATENING
☐ iv. SIGNIFICANT DISABILITY

☐ v. MEDICALLY SIGNIFICANT (including congenital anomaly) *give details*: _____

D. OTHER MEDICATIONS (INCLUDING SELF-MEDICATION, (HERBAL AND TRADITIONAL MEDICINES)

DID THE PATIENT TAKE ANY OTHER MEDICINES PRIOR TO THIS REACTION? YES☐ NO☐

DRUG NAME (Both Generic and Brand)	Dosage	Route	Date Started	Date Stopped

E. REPORTER DETAILS*

NAME:_____DESIGNATION:_____

ADDRESS: _____

CONTACT NO._____DATE:_____

SIGNATURE:_____

Please send this form to National Pharmacovigilance Centre (MPD) telephone:

FOR OFFICIAL USE BY BFDA:

Dateofreceiptof thereport: Receivedby:

ReportIDno. ProductMAH:

Actiontaken: