Arco Lab Pvt Ltd	**TITLE: AE/ADR REPORTING FORM**

Date received:

SUSPECT DRUG INFORMATION:

Product: _____

Indication for use: _____

Dosage: _____

Route: _____ Lot #: _____ Expiry Date: _____

Start Date (dd/mmm/yyyy): _____ Stop Date (dd/mmm/yyyy): _____

Other (duration): _____ Therapy ended? ☐Yes ☐No ☐Unknown

REPORTER INFORMATION Please check the appropriate check box (√):

☐Physician (MD) Specialty: _____ ☐ Dentist (DDS/DMD) ☐Pharmacist ☐ Nurse

☐Sales Rep ☐Consumer ☐Other: _____

Name: First_____ Last name: _____

Address: _____

_____

Phone: _____ Fax: _____

E-mail: _____

PATIENT INFORMATION**:**

Sex: ☐Male ☐Female ☐Unknown Patient Initials: _____

Date of Birth (dd/mmm/yyyy): _____ Age: ____ Weight: _____ ☐lbs ☐kg

Pregnant: ☐Yes ☐No ☐Unknown If yes, due date (dd/mmm/yyyy): _____

SERIOUS OUTCOME CRITERIA: Please check the appropriate check box (√)

Death	☐ Yes ☐ No ☐ Unknown
Life-Threatening	☐ Yes ☐ No ☐ Unknown
Hospitalization (required or prolonged)	☐ Yes ☐ No ☐ Unknown. Specify Dates:
Disability/Incapacity	☐ Yes ☐ No ☐ Unknown
Congenital anomaly	☐ Yes ☐ No ☐ Unknown
Other medically significant condition	☐ Yes ☐ No ☐ Unknown If yes, specify:

ADVERSE EVENT INFORMATION:

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Event Details:

Start Date: _____	Stop Date: _____
Suspect drug withdrawn?	□ Yes □ No □ Unknown
Suspected drug dose reduced? If yes, did the event improve?	□ Yes □ No □ Unknown □ Yes □ No □ Unknown
Suspected drug reintroduced? If yes, did the event reoccur?	□ Yes □ No □ Unknown □ Yes □ No □ Unknown

Note: **Please check the appropriate check box (√)**

RELEVANT MEDICAL HISTORY: (Including pre-existing medical/surgical conditions)
Current Conditions: (Specify dates, if known)

Prior conditions: (Specify dates, if known)

Allergies: Yes (Specify:) □ None □ Unknown

CONCOMITANT MEDICATIONS: (Includes prescription, OTC and herbal/natural products)

Generic/Trade Name	**Indication**	**Dose/Route/Frequency**	**Start Date (dd/mmm/yyyy)**	**Stop Date (dd/mmm/yyyy)**

ADVERSE EVENT INFORMATION: (Include relevant tests/laboratory data and any treatment patient received,

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diagnosis made)

(Attach additional sheet if necessary)

CONSENT TO CONTACT HEALTHCARE PROFESSIONAL (HCP): □ Yes □ No

CALLER GAVE CONSENT TO PASS DETAILS TO PHARMACOVIGILANCE: □ Yes □ No

(If yes, name of individual providing consent and date):

_____

Name of individual obtaining consent:

_____

Details of HCP:

Name:	
Profession	
Contact Details:	
Address	
Telephone Number	
Fax/ email	

Filled by (Name): _____

Reviewed by (Name)_____