THE SCHAZOO PHARMACEUTICAL LABORATORIES (Pvt.) Ltd.

QUALITY ASSURANCE DEPARTMENT

ANNEXURE NO. 1

To be used in conjunction with SOP# QA/2/034

If you suspect an adverse reaction may be related to one or more drugs/complementary remedies, please complete this form.

Name of the reporting person: _______________Date of Reporting:______________ Department/Clinic:________________

Type of non conformance: (a) Adverse Drug Reaction ☐ (b) Side Effects ☐ (c) Spontaneous Adverse Event ☐

Patient detail: Patient Name:________________ Sex: M/F N.I.C No._________________ Weight (kg):______________

Date of Birth:______________ Hospital or Clinic Name:______________ City:_____________ Contact No._______________

Suspected Drug(s): Please describe the reaction(s) and any treatment given:

Outcome

Recovered: ☐ Recovering : ☐

Continuing: ☐ Other: ☐

Date reaction(s) Started:________________________ Date reaction(s) Stop:_____________________

Do you consider the reaction to be serious? Yes / No

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

☐ Patient died due to reaction
☐ Life threatening
☐ Incapability Congenital abnormality
☐ Involved or prolonged in patient hospitalization
☐ Involved persistent or significant disability or
☐ if medically significant, please give details:

Other Drug(s) (Including self medication and complementary remedies)

Did the patient take any other medicines/complementary remedies in the last 3 months prior to the reaction? Yes /No.

If yes please give the following information if known:

Drug (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for

Additional relevant information e.g medical history, test results, known allergies, suspected drug interactions, for reactions relating to use a medicine during pregnancy. Please state all other drugs taken during pregnancy, the last menstrual period.

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Please list any medicines obtained from the internet:____

Reporter Details

Name and Professional address: ___________________

____

Telephone number: ___________________

E. mail ___________________

Signature & Date: ___________________

Clinician (if not the reporter)

Name and Professional address: ___________________

____

Telephone number: ___________________

E. mail ___________________

Signature & Date: ___________________

Send E. mail to: PCV@schazoo-spl.com

Send post to: The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.,

Kalalwala Stop, 20KM Lahore - Jaranwala Road, District Sheikhupura, Pakistan.

QA Department: **PCV number:**__________________ **Signature /date:**____________________

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