DEEF Pharmaceutical Ind. Co.

Individual Case Safety Report

ANNEXURE-RA003/A01

1. Date : …../…../…….. **ICSR No. : ICSR_ _-_ _ _ _**

2. Patient Details

Patient name (Optional): …….. Date of birth: …../…../…… Sex: □ M □ F

Weight: …… kg Height: ……cm Race:…….. Nationality: ……..

Health Institution: …….. Medical Record No: ……..

Type of notification: □ initial □ Follow up

3. Adverse Drug Reaction Description

Adverse event including relevant tests/lab data and dates *(The reaction site, seriousness , and treatment should be included)*	**Other relevant history, including preexisting medical conditions** *(diagnosis, allergies, pregnancy, hepatic, renal impairment, alcohol, smoking, etc.)*
……	……
……	……
……	……
……	……
……	……
……	……
……	……

Date of event started:	Date of event disappeared, if applicable:

4. Action Taken

□Drug withdrawn. □ Dose reduced. □ Dose increased. □ Unknown.

□ Not applicable.

5. Seriousness of ADR (Tick all applicable)

□Patient died, date: ……/……/…….

□Life threatening □ Permanent disability □ Hospitalization □ Congenital anomaly

□Prolonged hospitalization more than 24 hr

□Required intervention to prevent permanent impairment/ damage

□ Required Emergency Room (ER) visit □ Other……..

6. Outcome of ADR (Tick all applicable)

The patient □ Recovered, date :…./…./……
□ Recovering □ No improvement □ Unknown

Event subsided after stopping (de-challenge)
□No □ Yes □ Unknown

Event reappears after reintroducing (re-challenge)
□No □ Yes □ Not applicable

Specific antagonist used
□No □ Yes, specify:

7. Suspected Drug(s)

Brand Name: ……., Dosage form: ……., Strength…….

Batch No.:…….. Mfg.: …. /……., Exp.: …./ …….

Route used:…….. Dosage regime:……

Treatment period: from:…. /…. /…… to: …/ …./ ……

Indication:…….....

Concomitant medicines:……..

Recently discontinued medications: …….

Work environment in which the error occurred:……

Previous allergic history: …….

The relationship between the suspected drug and the ADR is:

□Unlikely □ possible □ Not related □ unknown

8. Reporter:

Reporter name :	**Profession (Specialty):**	
Address:	**E-mail:**	
Phone / Mobile:	**Date:**	**Signature:**

This form can be used by:

- Physician.
- Pharmacist.
- Dentist.
- Nurses.
- Other healthcare providers.

Use this form to report adverse reactions from:

- Medications (drugs or biologicals).
- Vaccines.
- Herbal remedies.

How to report:

- Fill out the reporting form.
- Attach additional information, if needed.
- Use a separate form for each product.

Please submit completed forms to:

- **P.O Box 221313 Riyadh 11311**
- **Tel. : +966-11-4027575**
  +966-0114029696
- **Fax: : +966-11-4028585**
- **E-mail: MedRaPV@deef.com**