Adverse Event Reporting Form | **Source Data Code :**

PATIENT

Name (Initial) ……	**Age :** ……	**Ethnic :** ……	**Body Weight :** ……	**Job :** ……

Sex (mark X) :

Male..... ☐

Female : ☐

Pregnant..... ☐

Not pregnant..... ☐

Unknown..... ☐

Main Disease/Diagnosis :

Outcome of Main Disease (mark X) :

☐ Recovered
☐ Death
☐ Recovered with sequelae
☐ Not yet recovered
☐ Unknown

Concurrent disease/other conditions (mark X) :

☐ Renal injury
☐ Liver injury
☐ Alergy
☐ Other medical conditions
☐ Factor of industry, farm,chemistry
☐ Other

Adverse Event (AE)

Reaction Descriptions :	**Date onset :**	**Outcome of Adverse Event (mark X) : Date:……**
		☐ Recovered ☐ Death ☐ Recovered with sequelae ☐ Not yet recovered ☐ Unknown

History of AEs :

DRUGS

Name (Trade Name/Generic Name/Industry)	**Dosage Form**	**Batch No.**	**Mark X for suspected drug**	**Administration**				**Indication**
				Route of adminis-tration	**Daily Dose**	**Start date of therapy**	**End date of therapy**	
1.	.....	.....	.....					
2.	.....	.....	.....					
3.	.....	.....	.....					
4.	.....	.....	.....					
5.	.....	.....	.....					
6.	.....	.....	.....					
7.	.....	.....	.....					
8.	.....	.....	.....					
9.	.....	.....	.....					
10.	.....	.....	.....					

Additional information (example : reaction after stop the drug, treatment to overcome the AEs)

Laboratory Data (if available).

Date of laboratory test :

……..., date..……..20….
Sign of reporter

(……)

CONFIDENTIAL | **NATIONAL DRUG ADVERSE EVENT MONITORING**

SHIPMENTS REPLY
PRKB NO:13/PRKB/JAT/AREA-IV/2013

SENT WITHOUT STAMPS

TO :
PT.POS INDONESIA (PERSERO)
KEPALA KANTOR POS
JAKARTA 13000

To be submitted to:
PUSAT MESO NASIONAL
Directorate of Distribution Control of
Therapeutic Product and Household Product
National Agency of Drug and Food Control
Jl. Percetakan Negara No. 23, Kotak Pos No. 143 Jakarta 10560
Phone. : (021) 4245459, 4244755 ext. 111
Fax. : (021) 4243605, 42885404
E-mail : Indonesia-MESO-BadanPOM@hotmail.com
ditwas_dist_ptpkrt@pom.go.id

SENDER :

Name :

Expertise :

Address :

Phone No :

EXPLANATION :

1. Advese Event Drug Monitoring (AEDM) conducted in Indonesia in collaboration with WHO-Uppsala Monitoring Center (Collaborating Center for International Drug Monitoring) are intended to monitor all the adverse event of drugs that were found in the use of drugs.
2. Results of the evaluation of all collected information will be used for the marketed drugs re-evaluation of marketed drug and to take appropriate actions that required.
3. Feedback will be sent to the sender/reporter.

NARANJO ALGORITHM

No.	Pertanyaan/ Questions	Scale		
		Ya/Yes	Tidak/No	Tidak Diketahui/ Unknown
1	Apakah ada laporan efek samping obat yang serupa? *(Are there previous conclusive reports on this reaction?)*	1	0	0
2	Apakah efek samping obat terjadi setelah pemberian obat yang dicurigai? *(Did the ADR appear after the suspected drug was administered?*	2	-1	0
3	Apakah efek samping obat membaik setelah obat dihentikan atau obat antagonis khusus diberikan? *(Did the ADR improve when the drug was discontinued or a specific antagonist was administered?)*	1	0	0
4	Apakah Efek Samping Obat terjadi berulang setelah obat diberikan kembali? *(Did the ADR recure when the drug was readministered?)*	2	-1	0
5	Apakah ada alternative penyebab yang dapat menjelaskan kemungkinan terjadinya efek samping obat? *(Are there alternative causes that could on their own have caused the reaction?)*	-1	2	0
6	Apakah efek samping obat muncul kembali ketika plasebo diberikan? *(Did the ADR reappear when a placebo was given?)*	-1	1	0
7	Apakah obat yang dicurigai terdeteksi di dalam darah atau cairan tubuh lainnya dengan konsentrasi yang toksik? *(Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?)*	1	0	0
8	Apakah efek samping obat bertambah parah ketika dosis obat ditingkatkan atau bertambah ringan ketika obat diturunkan dosisnya? *(Was the ADR more severe when the dose was increased or less severe when the dose was decreased?)*	1	0	0
9	Apakah pasien pernah mengalami efek samping obat yang sama atau dengan obat yang mirip sebelumnya? *(Did the patient have a similar ADR to the same or similar drugs in any previous exposure?)*	1	0	0
10	Apakah efek samping obat dapat dikonfirmasi dengan bukti yang obyektif? *(Was the ADR confirmed by objective evidence?)*	1	0	0
	Total Score			

NARANJO PROBABILITY SCALE:

Score	**Category**
9+	Highly probable
5 - 8	Probable
1 - 4	Possible
0-	Doubtful