SOP No MUM/CPC/02/2011

ADVERSE EVENT REPORTING FORM



	lo. MUM/CPC/002/R01	(In Confidence)	Quilo co.
1. Pa	ENT INFORMATION atient Initials :	3. Sex: M F 4. Age at time of event: years OR 5. Date of Birth: (dd/mm/yyyy)	6. Weight: Kg
1. C 2. If	Death (dd/mm/yyyy) Hospitalization - initial or pro	erse event is considered to be serious : (Check all that apply) Disability or Permanent damage Life-threatenin	birth defect
3. If 4. C T 6. C	f the adverse event is not serious, Date of onset of event: Time (if available)	(hh/mm) (dd/mm/yyyy) 5. If event stopped, date: Time (if available) : of reaction(s), including body site and severity as well as description	Moderate Severe (dd/mm/yyyy) (hh/mm) on of signs and symptoms.
	nformation on recovery and an	y sequelae: Recovered Recovering Not recovered Fatal	Recovered with sequelae Unknown
F	Setting where event occurred: Hospital Out-Patient Relevant tests / laboratory data, in	Home Nursing Home Cluding dates:	
	Other relevant history, including pre nepatic / renal dysfunction, etc.	existing medical conditions: (e.g. allergies, race, pregnancy, smoking	and alcohol use,
- 11. T -	reatment of adverse event :		

	2	. Brand Nam		. Dosage for & labeled s	m trength	4. Lo	t No./B	atch No.	5. Expiry Date	6. Manufacturer
# 1										
# 2										
# 3										
# 4										
7. Daily Dose (Specify units - mg, ml, mg/kg)		8. Frequency		9. Route of administration		10. Indication for use of suspected drug			11. Therapy dates (if unknown, give duration Start End	
# 1									(dd/mm/yyyy) Therapy duration:	(days)
# 2									(dd/mm/yyyy) Therapy duration:	(days)
# 3									(dd/mm/yyyy) Therapy duration:	
# 4									(dd/mm/yyyy) Therapy duration:	
12. Event abated	after use	e stopped oi	r dose re	educed :		13. Ev	ent rea	ppeared a	after reintroduction :	
#1 Yes	No	Not a	applicat	ole 📗		Yes	\neg	No	Not applicab	le 🗍
	_=	<u> </u>							1	
ш	No the adve		applicat th the dr		tick in app	Yes propriate	box)	No Relat	Not applicab	le ot related
4. Relationship of	the adve	erse event wit oducts and the	th the dr nerapy d Da (Spe	rug: (Please lates includir ily dose cify units-	ng self med Route	oropriate dication e of	and he	Relate rbal remed	ed Notes: (exclude those u	ot related seed to treat the event) Stopping
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Generic name # 1 # 2	the adve	erse event wit oducts and the	th the dr nerapy d Da (Spe	rug: (Please lates includir ily dose cify units-	ng self med Route	oropriate dication e of	and he	Relate rbal remed	Starting date (dd/mm/yyyy) (dd/mm/yyyy)	sed to treat the event) Stopping date (dd/mm/yyyy) (dd/mm/yyyy)
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