Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ ✓ Follow-up Case ☐

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: T

2. Age or date of birth: 48

3. Gender: M ☐ F ✓ Other ☐

4. Weight (in Kg.) 65kg

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy) 05.02.23

6. Event / Reaction stop date (dd/mm/yyyy) 05.02.23

7. Describe Event/Reaction management with details , if any

A 48 year old female patient was admitted with c/o of UTI,

Cap. Tetracycline - 500mg - BD was given.

Adr : Hypersensitivity

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ *(please tick anyone)*

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life threatening ☐ Disability

☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered

☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i	Tetracyclin	-	[illegible]	[illegible]	500mg	P/O	BD	5/2/23	5/2/23	Hypersensitivity	suspected
ii											
iii											
iv#											

9. Action taken after reaction *(please tick)*

10. Reaction reappeared after reintroduction of suspected medication *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i	-	-	✓	-	-	-	-	-	-	-
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i	-	-	-	-	-	-	
ii							
iii#							

Additional Information :

After dose reduced patient has recovered.

D. REPORTER DETAILS *

16. Name & Address : T. Jinja, Pharm. D III year JKKMIHSCP

Pin : _____ Email : jinjajohn2@gmail.com

Contact No- : _____

Occupation : Student Signature : hjs

17. Date of this report (dd/mm/yyyy) : 05/2/23

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

Principal
KK Munirajah Institute of Health Sciences
College of Pharmacy, T.N.Palayam,

T.N.Palayam Erode Dt.

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Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: M.S
2. Age or date of birth: 35 yrs
3. Gender: M ☐ F ✓ Other ☐
4. Weight (in Kg.) 58 Kg

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy): 17/2/2023
6. Event / Reaction stop date (dd/mm/yyyy): 17/2/2023
7. Describe Event/Reaction management with details , if any

Patient had Adverse drug reaction of ringing in the ears (tinnitus). Drug (Aspirin given the indication of pain relief Dose: 325mg, Every 4-6hrs

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ *(please tick anyone)*
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i	Aspirin	-	70D1086	2027	325mg	P/O	QAD	17/2/23	17/2/23	Pain relief	Suspected
ii											
iii											
iv#											

9. Action taken after reaction *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	✓	–	–	–	–	–
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication *(please tick)*

Yes	No	Effect unknown	Dose (if re-introduced)
–	–	–	–

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i	–	–	–	–	–	–	–
ii							
iii#							

Additional Information :

Principal
KK Munirajah Institute of Health Sciences
College of Pharmacy, T.N.Palayam,
Gobi (Tk), Erode (Dt) - 638 506

T.N.Palayam Erode Dt.

Signature and Name of Receiving Personnel :

D. REPORTER DETAILS *

16. Name & Address : M. Pragatheeswari PHARM-D IIIyr
KKMIHSCP
Pin : _____ Email : pragathimanic@gmail.com
Contact No- : _____
Occupation : Student Signature : M.Pragathi

17. Date of this report (dd/mm/yyyy) : 17/2/2023

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

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Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: S
2. Age or date of birth: 40 Years
3. Gender: M ✓ F ☐ Other ☐
4. Weight (in Kg.) 60kgs

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy) 23/02/23
6. Event / Reaction stop date (dd/mm/yyyy) 23/02/23
7. Describe Event/Reaction management with details , if any

A 40 yrs Male patient was admitted with the chief compliants of Severe Hypertension. The patient was treated with Tablet Lisinopril. Indication of Hypertension

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ *(please tick anyone)*
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization-Initial/Prolonged
- ☐ Congenital-anomaly
- ☐ Disability
- ☐ Other Medically important

15. Outcome:
- ☐ Recovered
- ☐ Recovering
- ☐ Not Recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i	Lisinopril	-	T8123	2025	10mg	P/O	BD	23/02/23	28/02/23	Hypertension	Suspected.
ii											
iii											
iv#											

9. Action taken after reaction *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	-	-	✓	-	-	-
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication *(please tick)*

Yes	No	Effect unknown	Dose (if re-introduced)
-	-	-	-

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i		-	-	-	-	-	-
ii							
iii#							

Additional Information :

K.K. Munirajah Institute of Health Sciences College of Pharmacy T.N.Palayam Erode Dt.

After Dose reduced Patient has recovered.

D. REPORTER DETAILS *

16. Name & Address : N. GURU MOORTHY, PHARM.D 4th YEAR. JKKMIHSCP.

Pin : _____ Email : gurumoorthinanjappan2000@gmail.com

Contact No- : 7200711886.

Occupation : Student. Signature : N. Guru

17. Date of this report (dd/mm/yyyy) : 23/02/23

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

\# Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

Principal
KK Munirajah Institute of Health Sciences
College of Pharmacy, T.N.Palayam,
Gobi (Tk), Erode (Dt) - 638 506

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AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: M
2. Age or date of birth: 62 Yrs
3. Gender: M ✓ F ☐ Other ☐
4. Weight (in Kg.) 70 kg

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy): 08-12-2023
6. Event / Reaction stop date (dd/mm/yyyy): 08-12-23
7. Describe Event/Reaction management with details , if any

A 62 yrs male patient had Adverse drug reaction of Muscle pain (myalgia) caused by simvastatin-20mg-OD. It given for Indication of cholesterol lowering.

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ *(please tick anyone)*
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i	Simvastatin	-	BD703	2028	20mg	P/O	OD	08-12-23	08-12-23	Lowering cholesterol	Suspected
ii											
iii											
iv#											

9. Action taken after reaction *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	✓	-	-	-	-	-
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication *(please tick)*

Yes	No	Effect unknown	Dose (if re-introduced)
-	-	-	-

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i	rosuvastatin	40mg	P/O	OD	08-12-23	08-12-23	Lowering cholesterol
ii							
iii#							

Additional Information :

Nil

Institutes of Health Sciences College of Pharmacy T.N.Palayam Erode Dt.

D. REPORTER DETAILS *

16. Name & Address : M. SURYA PRAKASH PHARM.D
III-YEAR- JKKMIHSCP

Pin : _____ Email : marisurya002@gmail.com

Contact No- : 9514351703

Occupation : Student Signature : M

17. Date of this report (dd/mm/yyyy) : 08-12-2023

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

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AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: S.R
2. Age or date of birth: 35yrs
3. Gender: M ☐ F ☑ Other ☐
4. Weight (in Kg.) 60kg

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy) 18/2/2023
6. Event / Reaction stop date (dd/mm/yyyy) 18/2/2023
7. Describe Event/Reaction management with details , if any

A 35 yrs old female patient has admitted for indication of severe pain. The Drug morphine has started and the respiratory depression & addiction caused by the drug.

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization-Initial/Prolonged
- ☐ Congenital-anomaly
- ☐ Disability
- ☐ Other Medically important

15. Outcome:
- ☐ Recovered
- ☐ Recovering
- ☐ Not Recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i	Morphine	-	CD10P86	2027	2mg/ml	P/O	TDS	18/2/23	18/2/23	Painrelief	Suspected
ii											
iii											
iv*											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	-	-	✓	-	-	-
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)
-	-	-	-

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i	-	-	-	-	-	-	-
ii							
iii*							

Additional Information :

After reducing the dose, the Patient has recovered

D. REPORTER DETAILS *

16. Name & Address : R.P.Dithika Pharm-D 5th-yr JKKMIHSCP

Pin : _____ Email : dithi4324@gmail.com

Contact No- : _____

Occupation : student Signature : Rd

17. Date of this report (dd/mm/yyyy) : 18/2/23

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

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K.K. Munirajah Institutes of Health Sciences College of Pharmacy T.N.Palayam Prop. DI

Principal
KK Munirajah Institute of Health Sciences
College of Pharmacy, T.N.Palayam,