S.No.	Details Needed
4.	Links for Mechanism of collection, analysis and reporting of ADRs

PPvCs (Coordinator & Program Assistant)

Data from Each Center
Analysis of the reports

IPvCs (Coordinator & Program Associate)

Compiled Data of All Centres

NPvC (Coordinator & Technical Program Officer)

DCC, Ministry of AYUSH

ADR format attached. **(Annexure-3)**

Pharmacovigilance Program for ASU & H Drugs
Reporting Form for Suspected Adverse Reactions

Note:

Personal information will be kept confidential.
All suspected reactions are to be reported with relevant details.

Ay-AIIA	Ay-NIA	Ay-IPGT	Un-NIUM	Si-NIS	Ho-NIH
Code of Peripheral Centre		**ADR Number / Year**			

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Patient Initials		Patient Record Number (PRN)
Place of Birth	IPD / OPD	
Address Village / Town Post / Via District / State		Age: Sex: Male / Female / Others
Diagnosis:	Constitution and Temperament:	

2. Description of the suspected Adverse Reactions

Date and time of initial observation	
Description of reaction	

3. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Any Others (Specify, if others)

4. Addictions, if any? If yes, please specify:

5. H/O previous allergies / Drug reactions, if any: If yes, please specify:

6. List of all ASU & H drugs used by the patient during the period of one month:

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Date of		Reason for use	Any unwanted occurrences
				Starting	Stopped / Continued		

7. List of other drugs used by the patient during the period of one month:

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Date of		Reason for use	Any unwanted occurrences
				Starting	Stopped / Continued		

8. Details of the drug suspected to cause ADR:

a. Name of the drug:
b. Manufacturing date and Expiry date (if available):
c. Remaining pack / label (if available):
d. Consumed orally along with (water / milk / honey / or any other)
e. Whether any dietary precautions have been prescribed?
   If yes, please specify:

f. Whether the drug is consumed under medical supervision or used as self medication.
g. Any other relevant information associated with drug use:

9. Management provided / taken for suspected adverse reaction

10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	Reaction reappeared after re administration of drug:			
Was the patient admitted to hospital? If yes, give name and address of hospital				

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR:

The ADR Probability Scale
(Program Coordinator has to fill this scale)

	Questions	Yes	No	Don't Know
1	Are there previous conclusive reports on the reactions?	+1	0	0
2	Did the ADR appear after the suspected drug was administered?	+2	-1	0
3	Did the ADR improve when the drug was discontinued a specific antagonist was administered?	+1	0	0
4	Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0
5	Are there alternatives causes that could solely have caused the ADR?	-1	+2	0
6	Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0
7	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
8	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
9	Was the adverse event confirmed by objective evidence?	+1	0	0
	Total Score			

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

The suspected Adverse Event is	Grade - 1 (Mild)	
	Grade - 2 (Moderate)	
	Grade - 3 (Severe)	
	Grade - 4 (Threatening)	
The suspected Adverse Event is	Serious	
	Non-Serious	
The suspected Adverse Event is due to	Physician	
	Patient	
	Drug	
	Other Factors* (Explain other factors)	

12. Particulars of ADR Reporter:

Please tick:	Patient / Attendant / Nurse / Doctor / Pharmacist / Health worker / Drug Manufacturer / Any others (please specify)
Name:	
Address:	
Telephone / E - mail:	

Signature of the reporter: **Date:**

Signature of the Program Coordinator

Please send the completed form to: The centre from where the form is received or to

The Coordinator, National Pharmacovigilance Coordination Centre
All India Institute of Ayurveda, Sarita Vihar, New Delhi - 110 076
Email: pharmacovigilanceayush@gmail.com / ayush-pharmavig@aiia.gov.in