

# Reporting Form for Suspected Adverse Reactions

## National Pharmacovigilance Program for ASU & H Drugs

**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:		Age:
Village / Town:		Sex: Male / Female / Others
Post / Via:		
District / State:		
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:**

**12. Particulars of ADR Reporter:**

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

**Signature of the reporter:**

**Date:**

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

The Coordinator, Intermediary Pharmacovigilance Centre for Ayurveda  
Institute of Teaching and Research in Ayurveda,  
Jamnagar, Gujarat – 361008, India  
Tele Fax : 0288 2676856 / 0288 2553936  
Website: [www.itra.edu.in](http://www.itra.edu.in) ,  
Email: [ipvcjamnagar@gmail.com](mailto:ipvcjamnagar@gmail.com) / [Pharmacovigilance@itra.edu.in](mailto:Pharmacovigilance@itra.edu.in)

**The ADR Probability Scale**

**(Program Coordinator has to fill this scale)**

	<b>Questions</b>	<b>Yes</b>	<b>No</b>	<b>Don't Know</b>
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
	<b>Total Score</b>			

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

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

Signature

**Program Coordinator**

## **Code of Peripheral Pharmacovigilance Centres (74) for ADR Reporting**

### **AYURVEDA**

#### ***Under ITRA, Jamnagar, Gujarat- IPvC***

<i>S. No.</i>	<i>Peripheral Pharmacovigilance centres</i>	<i>Peripheral centre code</i>
1.	Central Ayurveda Research Institute for Drug Development, Kolkata, West Bengal	Ay/ITRA/014
2.	Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru, Karnataka	Ay/ITRA/015
3.	North Eastern Institute of Ayurveda and Homeopathy, Mawdiangdiang Shillong, Meghalaya	Ay/ITRA/016
4.	Vaidyaratnam P.S.Varier Ayurveda College, Kottakkal Kerala	Ay/ITRA/017
5.	Shri BM Kankanawadi Ayurved Mahavidyalya, Belagavi, Karnataka	Ay/ITRA/018
6.	Sri Dharmasthala Manjunatheshwara College of Ayurveda Hospital, Thanniruhalla, Hassan, Karnataka	Ay/ITRA/019
7.	SDM Institute of Ayurveda & Hospital, Bengaluru, Karnataka	Ay/ITRA/020
8.	JSS Ayurvedic Medical College and Hospital, Mysuru, Karnataka	Ay/ITRA/021
9.	Amrita School of Ayurveda, Kollam, Kerala	Ay/ITRA/022
10.	Govt. Ayurveda College, Bangalore, Karnataka	Ay/ITRA/023
11.	JB Roy Ayurveda College, Kolkata, West Bengal	Ay/ITRA/024
12.	Gomantak Ayurved Mahavidhyalaya and Research Centre, Shiroda, Goa	Ay/ITRA/034
13.	30 beds AYUSH Hospital functioning under the DHS, A & N Administration at Port Blair	Ay/ITRA/035
14.	Govt. Ayurved College, Vadodara	Ay/ITRA/044
15.	Shri Swaminarayan Ayurveda College, Kalol, Gujarat	Ay/ITRA/045
16.	JS Ayurved Mahavidyalaya,Nadiad, Gujarat	Ay/ITRA/046
17.	ALN Rao Ayurveda Medical College, Koppa, Karnataka	Ay/ITRA/047
18.	AL Govt. Ayurveda College, Warangal, Telengana	Ay/ITRA/048
19.	Govt. ayurveda Medical College Ernakulam, Kerala	Ay/ITRA/049
20.	Govt. Ayurveda Medical College Nagercoil, Tamilnadu	Ay/ITRA/050
21.	Dept. of Ayush, Civil Hospital, Mizoram	Ay/ITRA/051
22.	Deen Dayal Upadhaya Ayush Hospital, Lakshadeep(U.T.)	Ay/ITRA/052