

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR AYURVEDA, SIDDHA & UNANI (ASU) DRUGS

Reporting Form for Suspected Adverse Reactions to ASU Drugs

- Please note :** (I) Information about the patients, prescribers and reporters will remain confidential.
 (II) It is requested to report ALL suspected reactions as soon as possible, even if complete information is not available. Please note however that column numbers 1,2,3,4, 6 & 10 are compulsory.

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

Name /Identifier Initials		Patient's Record Number (PRN):	
Ethnicity:	IPD/OPD	Age :	Sex : Male / Female
Address Village/ Town Post/ Via District/ State		Weight:	Prakriti/ Mizaj /
		Occupation:	

2. Description of the suspected Adverse Reactions (please complete boxes below) :

Date and time of initial observations:	
Description of reactions	

3. List of all ASU drugs including drugs of other systems used by the patient during the reporting period :

Name of the medicine	Manufacturer's name/ Batch no./ Manufacture/ Expiry date	Daily dose	Dosage form and route of administration	Date		Reason for use
				Starting	Stopping	

4. Brief details of the suspected ASU Medicine :

a. Composition of the formulation / Part and form of the raw material used
b. Expiry date if any:
c. Remaining part of drug / Product label
d. Please tick : Ayurveda, Siddha, Unani, any other
e. Adjuvant(Anupana):
f. Dietary history(Intake/Restrictions) if any:
g. Whether the drug is consumed under medical supervision or used as self medication.
h. Any other relevant information.

5. Treatment provided (if any) for suspected adverse reaction :

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6. Outcome of the suspected adverse reaction (please complete the boxes below) :				
Recovered / Recovering :	Not recovered	Unknown :	Fatal :	If Fatal Date of death:
Severe: Yes/ No		Reactions abated after drug stopped or dose reduced:		
		Reaction reappeared after re introduction:		
Was the patient admitted to hospital? If yes, give name and address of hospital				
Is any follow up required:				
7. Laboratory investigations done, which provides suspicion of drug involvement :				
8. Please tick, if the patient is suffering with any chronic disorders :				
Hepatic	Renal	Cardiac	Diabetes	Malnutrition Any Others
9. Whether history of allergy / Drug reactions exists:				
10. Identity of the reporter :				
Type (please tick):	Nurse / Doctor / Pharmacist / Health worker / Patient / Manufacturer / Distributor / Supplier / Any others (please specify)			
Name :				
Address :				
Telephone / E – mail if any :				

Signature of the reporter:

Date:

Please send the completed form to:

Name & address of the RPC-ASU / PPC-ASU :

The centre from where the form is received or
 To The Coordinator
 National Pharmacovigilance Resource Centre For ASU Drugs
 I.P.G.T. & R.A., G.A.U., Jamnagar, Gujarat - 361 008, India
 ☎ (O) 0288 – 2553936 , Fax : 0288 – 2676856 / 2553936
 Website : www.ayurveduniversity.com, Email: nprcasu@gmail.com

Who Can Report? :

- Any Health care professionals including, ASU Doctors / Dentists / Nurse / Pharmacists etc.

What to Report? :

- All suspected adverse reactions, Lack of effects, Resistance, Drug interactions, Dependence and Abuse

Where to Report ?

- Peripheral Pharmacovigilance Centre or Regional Pharmacovigilance Centre or National Pharmacovigilance Centre

Confidentiality:

- The patient's identity will be held in strict confidence and protected to the fullest extent. Programme staff will not disclose the reporter's identity in response to a request from the public.
- Submission of report doesn't constitute an admission that, medical personnel or manufacturers or the product caused or contributed to the reaction.