

Ayurved Seva Sangh's
Ayurved Mahavidyalay Nashik
Policy for Pharmacovigilance in the Institution

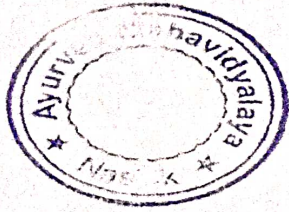
1. Establishment of department/office consisting of internet, computer, sitting arrangements and man power i.e One Co-ordinator and one Clerk/Assistant.
2. Working Area- The pharmacovigilance centre Established in this college shall work in Nashik city only.
3. Establishment of pharmacovigilance committee as under-

Sr.No.	Name	Designation in the Institute	Designation in PV Committee
			Chairman
1	Dr. Vinay Sonambekar	Principal	Member
2	Dr. Shishir Pande	HOD Rasashastra	Member
3	Dr. Archana Bhaskarwar	HOD Dravyaguna	Member
4	Dr. Rajan Kulkarni	HOD Kayachikitsa	Member
5	Dr. Vinay Sonambekar	HOD Shalyatantra	Member
5	Dr. Pushpalata Ingale	HOD Shalakya	Member
7	Dr. Abhay Kulkarni	HOD Swasthavrutta	Member
8	Dr. Ashutosh Yardi	HOD Nidan	Member
9	Dr. Archana Jadhav	HOD Stirog	Member
0	Dr. Kirti Kate	HOD Balrog	Member
1	Dr Savita Kulkarni	HOD Panchakarma	Member
2	Dr. Abhay Patkar	HOD Agadtantra & Toxicology	Member

4. Printing or suspected ADR's format & distribution of this form to the clinical departments.
5. Review procedure-
 - a. Observations related to pharmacovigilance shall be submitted to coordinator from clinical departments, if any.
 - b. Pharmacovigilance review committee meeting shall be organized within 3 days from the date of receipt of complaint issue in which the decision

or committee shall documented and reported to all clinical departments and to the higher centre if any.

- c. Bi- monthly pharmacovigilance review committee meeting will be organized as a part or routine if no issue is reported.
6. Reporting suspected ADR to the higher centre-
After thorough discussion in the meeting suspected ADR shall be reported in writing to the higher centre of pharmacovigilance and simultaneously shall be submitted to the apex centre through portal (online
7. Training and awareness program - Training and awareness program shall be held for practitioners, medical officers, clinicians, pharmacists in the area or Nashik city twice in a year at centre.




Principal

Ayurved Mahavidyalaya, Nashik

I/C. Principal
Ayurved Mahavidyalaya, Nashik

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

Reporting Form for Suspected Adverse Reactions to ASU Drugs

- Please note:**
- i. All consumers / patients and reporters information will remain confidential.
 - ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

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

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

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

Date and time of initial observation	
Description of reaction	

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

Medicine Name	Manufacturer Batch no.	Daily dose	Form Route of administration	Date		Reason for use
				Starting	Stopped	

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 (any one)
Ayurveda, Siddha, Unani, any other
- e. Adjuvant
- f. Dietary 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 for suspected adverse reaction

6. Out come of the suspected adverse reaction (please complete the boxes below)

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 introduction:		
Was the patient admitted to hospital? If yes, give name and address of hospital				

7. Any laboratory investigations done which provides suspicion of drug involvement:

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

Hepatic Renal Cardiac Diabetes Malnutrition Any Others

9. H/O previous allergies / Drug reactions:

10. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / 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: The centre from where the form is received or to

Name & address of the RRC-ASU / PPC-ASU

The Coordinator
National Pharmacovigilance Resource Centre For ASU Drugs
I.P.G.T. & R.A., G.A.U., Jamnagar, Gujarat - 361 008
☎ (O) 0288 – 2553936 , Fax : 0288 – 2553936
Website : www.ayurveduniversity.com, Email: nprcasu@gmail.com

Who Can Report?

⇒ Any Health care professionals like ASU Doctors / Dentists / Nurse / Pharmacists etc.

What to Report?

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

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.