SHREE SAPTASHRUNGI AYURVED MAHAVIDYALAYA & HOSPITAL
Kamal Nagar, Hirawadi, Panchavati, Nashik - 422 003. | Tel.: (0253) 2621565 (College) | (Hosp.) 2518548
Fax : (0253) 2621638 ● E-mail : ssamnsk@gmail.com ● website : www.ssam.in

S.O.P for Pharmacoviglance Comittee:-

Aim:
To facilitate prompt ADR reporting.

Objective:-
1) Early identification of ADRs
2) To promote ADR reporting culture.
3) Training of hospital staff.
4) Regular meetings for follow up.

Members:-
Chairman: Principal
Coordinator: H.O.D of Rasashastra & Bhaishajyakalpana
Members: H.O.D. of Clinical Dept. of Hospital including Dravyaguna and Agadtantra.

Meeting & Assessment:-
Meeting of committee will be held once in two months. Notification & agenda needs to be informed 7 days prior to general meeting.
Assessment for ADR reporting will be done as per need by committee members.

Mechanism:-
Clinical Data collection,
Analysis of Data
Reporting of Adverse Drug Reactions

Mechanism for improvement:
Reports will be submitted to CDC/IQAC, accordingly improvement & development will be done prior approval from Board of Governances.

Revision / updating of SOP for committee will be done every 5 yearly. If necessary for any update in SOP permission from IQAC/ CDC is mandatory.

Roles and responsibility of committee:

Chairman:
The chairman will conduct all meetings and will function as administrative head of the committee.
Coordinator:

Shree Saptashrungi Ayurved Mahavidyalaya * Nashik * EST.1996

The coordinator shall be responsible for arranging meetings and conducting activities . He/she will have following responsibilities:

- To arrange the meetings, write minutes, circulate and document the same.
- To collect ADR reports from co-chairperson
- To report collected ADRs to peripheral pharmacovigilance center in first week of every month.
- To report all serious adverse reactions to the peripheral pharmacovigilance enter within 24 hrs.
- To organize the awareness generation programs for reporting ADR related to AYUSH drugs.
- To organize and attend training programs/ interactive meetings for interns, PG students, nursing staff and teaching faculty members in the institute.

Members:

Members are HODs of all clinical departments of SSAM Hospital.

They have following responcibilities:

- To monitor on ADR identification & early reporting.
- To encourage PG students, Interns about ADR identification and reporting.
- Availability of notification material and facilities for prompt reporting.
- To assess coordinator for reporting to PPC.

WHAT TO REPORT

a. Death
b. Life threatening (real risk of dying)
c. Hospitalisation (initial or prolonged)
d. Disability (significant, persistent or permanent)
e. Congenital anomaly
f. Required intervention to prevent permanent impairment or damage

The prescribed 'Adverse Drug Event Reporting Form for ASU Drugs' shall be used for the purpose of National Pharmacovigilance Programme for ASU.

WHO CAN REPORT

Any health care professional may report suspected adverse drug events. The Programme shall not accept reports from lay members of the public or anyone else who is not a health care professional. Others can report through the physicians under whom he / she had undergone treatment

WHERE TO REPORT

The reporting on prescribed format will be done to any of the Pharmacovigilance centres.

FORMAT

The ADR form for ASU drugs is given to each clinical department as below:

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PHARMACOVIGILANCE OF AYURVEDA, SIDDHA, UNANI and HOMOEOPATHY (ASU & H) DRUGS

Reporting Form for Suspected Adverse Reactions

Note:

i. Personal information of the consumers / patients / ADR reporter's will be kept confidential.
ii. All suspected reactions are to be reported with relevant details.
iii. All completed forms are to be submitted to the program coordinator of nearby centre.

A / U / S / H	
Code	Ay-NIA/Code of Peripheral Centre/ADR Number/Year
	Ay-IPGT/Code of Peripheral Centre/ADR Number/Year
	Un-NIUM/Code of Peripheral Centre/ADR Number/Year
	Si-NIS/Code of Peripheral Centre/ADR Number/Year
	Ho-NIH/Code of Peripheral Centre/ADR Number/Year

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

Name		Patient Record Number (PRN)
Place of Birth	IPD / OPD	
Address Village / Town Post / Via District / State		Age: Sex: Male / Female
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

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)**

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal
Date of death:</td></tr>
<tr><td colspan="2" rowspan="2">Severe: Yes / No.</td><td colspan="3">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="3">Reaction reappeared after re administration of drug:</td></tr>
<tr><td colspan="2">Was the patient admitted to hospital? If yes, give name and address of hospital</td><td colspan="3"></td></tr>
</table>

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

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:**

Please send the completed form to: The centre from where the form is received or toThe Coordinator, National Pharmacovigilance Centre

All India Institute
of Ayurveda,
Sarita Vihar, New
Delhi - 110 076
Email: pharmacovigilanceayush@gmail.com

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

Signature

Programme Coordinator

Shree Saptashrungi Ayurved Mahavidyalaya Nashik

Principal
Vd. Milind Babarao Awarc
Shree Saptashrungi Ayurved
Mahavidyalaya & Hospital, Nashik