NC 04/ MOM 8B: No Process of capturing and reporting of Adverse drug reaction was evidenced

- Till date no case of adverse drug reaction has come to the clinic but if it comes in future then we are explaining its mechanism here.

- We have an ADR form, if any case occurs then need to fill the attached form & mailed to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com pharmacovigilance website

Jeena Sikho Lifecare Ltd.
M-118, First Floor
Shastri Nagar, Delhi-110052

Shuddhi AYURVEDA

JEENA SIKHO LIFECARE LTD

M-118, First Floor, Shastri Nagar, Delhi 110052

CGHS EMPANELLED PANCHKARMA CENTER

8005633391

Procedure of ADR case filed

Purpose – To provide guideline for monitoring adverse drug reaction event and ensure its proper reporting.

Scope- Hospital Wide

Protocol – The person noticing the reaction i.e. doctor/ patient immediately inform the concern doctor and clinical management is initiated then & there.

2. The doctor informs the in charge pharmacy & main medicine store.
3. The ADR form filled up by the concern doctor.
4. Drug Responsible for adverse reverse is identified.
5. All patient rooms & areas where the drug has been issued are advised not to use the drug of that particular batch.
6. Informed to medical superintendent
7. All such events are monitored and evaluated and appropriate action taken depending on the nature of the adverse reaction
8. Such action may take the form of observation or in extreme case withdrawal of the drug
9. Drug causing adverse reaction is closely monitored and analyzed

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SHUDDHI AYURVEDA PANCHKARMA CLINIC

(A Unit of Jeena Sikho Lifecare Pvt. Ltd)
M-118 FIRST FLOOR, SHASTRI NAGAR, DELHI-110052

ADR REGISTER

(Adverse Drug Reaction)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals

Report #

To be filled in by Pharmacovigillance centres receiving the form.

A. Patient information

1 Patient identifier initials _____ In confidence

2 Age at time of event: _____ or Date of Birth: _____

3 Sex ☐ M ☐ F

4. Weight_____ Kgs

B. Suspected Adverse Reaction

5 Date of reaction started (dd/mm/yy):

6. Date of recovery (dd/mm/yy):

7. Describe reaction or problem

12 Relevant tests/ laboratory data, including dates

13 Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking alcohol use, hepatic/ renal dysfunction, etc.)

14. Seriousness of the reaction

☐ Death (dd/mm/yy)_____
☐ Life threatening
☐ Hospitalization-initial or prolonged
☐ Disability
☐ Congenital anomaly
☐ Required intervention to prevent permanent impairment/ damage
☐ Other (specify)_____

15. Outcomes

☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)_____

C. Suspected medication(s)

Sl No.	8. Name (brand and / or generic name)	Manufacturer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

Sl. No. As per C	9 Reaction abated after drug stopped or dose reduced					10 Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced, dose
i										
ii										
iii										
iv										

11 Concomitant medical products and therapy dates including self medication and herbal remedies (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16 Name and Professional Address: _____

Pin code: _____ E-mail: _____

Cell No / Tel No with STD Code: _____

Speciality _____ Signature

17 Occupation

18 Date of this report

Dr. Ravinder Kumar Jeena
M-118, First Floor,
Shastri Nagar, Delhi-110052

My self Dr Ravinder Kaur

SHUDHI AYURVEDA PANCHKARMA CLINIC.

Issuing Register - ADR
(Adverse Drug Reaction)

Ravinder Kaur
30/6/21
5:30pm

Shuddhi Ayurveda Panchkarma Clinic
(A unit of Jeena Sikho Life Care Pvt Ltd.)
M-118, Ist Floor, Shastri Nagar,
Delhi-110052

Jeena Sikho Lifecare Ltd.
M-118, First Floor,
Shastri Nagar, Delhi-110052

31/3/22

No Any ADR found in this month.

Ravinder Kaur
31/3/22. 5:50pm.
Shuddhi Ayurveda Panchkarma Clinic
(A unit of Jeena Sikho Life Care Pvt Ltd.)
M-118, Ist Floor, Shastri Nagar,
Delhi-110052

Jeena Sikho Lifecare Ltd.
M-118, 1st Floor,
Shastri Nagar, Delhi-110052

30/4/22

No Any ADR found in this month.

Ravinder Kaur
30/4/22 5:30pm
Shuddhi Ayurveda Panchkarma Clinic
(A unit of Jeena Sikho Life Care Pvt Ltd.)
M-118, Ist Floor, Shastri Nagar,
Delhi-110052

Ravinder Kaur

Jeena Sikho Life Care Ltd.
M-118, First Floor,
Shastri Nagar, Delhi-110052

31/5/22

No Any ADR found in this month.

Ravinder Kaur
31/5/22 5:32pm

Shuddhi Ayurveda Panchkarma Clinic
(A unit of Jeena Sikho Life Care Pvt Ltd.)
M-118, Ist Floor, Shastri Nagar,
Delhi-110052

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