Version no. 1.1

PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

Where to report: Duly filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to shatrunjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

1. General Information:

Date of report: _____

Date of event: _____

2. Type of report:

☐ Initial ☐ Follow-up (Ref. no. _____)

3. Reporter details:

Name: _____

Address: _____

Contact No.: _____

E-mail address: _____

4. PPE Type:

☐ Gloves ☐ Coverall ☐ Goggles ☐ N-95 Masks ☐ Shoe Covers ☐ Face Shield ☐ Body Bags

☐ Triple Layer Medical Mask ☐ Sanitizer ☐ Other (Specify): _____

5. PPE Details:

Brand name: _____

Manufacturer name and address: _____

Importer name and address: _____

Distributor name and address : _____

Marketed by: _____

License No. / Registration No. : _____

Model No.: _____ Batch No.: _____

Unique Certification Code : _____ Test Standard : _____

Manufacturing Date : _____ Expiry Date : _____

PPE Current Location: ☐ Device destroyed ☐ Still in use ☐ Return to manufacturer

6. Location of event:

☐ Point of Entry (Immigration counters, customs and airport security)

☐ Hospital Setting

☐ In-patient Services

☐ Emergency Department

☐ Pre-hospital (Ambulance) Services

☐ Other Supportive/ Ancillary Services (Laboratory, Mortuary, Sanitation)

☐ Health Workers in Community Setting

☐ Quarantine facility

☐ Home Quarantine

☐ Other (Specify): _____

7. Type of event:

Serious: ☐ Non-Serious

☐ Death

☐ Life Threatening

☐ Disability or permanent damage

☐ Hospitalization / Prolonged Hospitalization

☐ Congenital anomaly / birth defect

☐ Any other serious _____

8. User details:

Initials: _____

Age: _____

Gender (M/F/O): _____

Outcome: ☐ Recovered ☐ Not yet recovered

☐ Death ☐ Other: _____

9. Detailed Description of Event:

10. Hospital/Quarantine facility details:

Facility Name: _____

Address: _____

Contact Person: _____