CITIZEN CHARTER

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare

Government of India

Sector 23, Raj Nagar, Ghaziabad 201002

Website: www.ipc.gov.in; Email: lab.ipc@gov.in

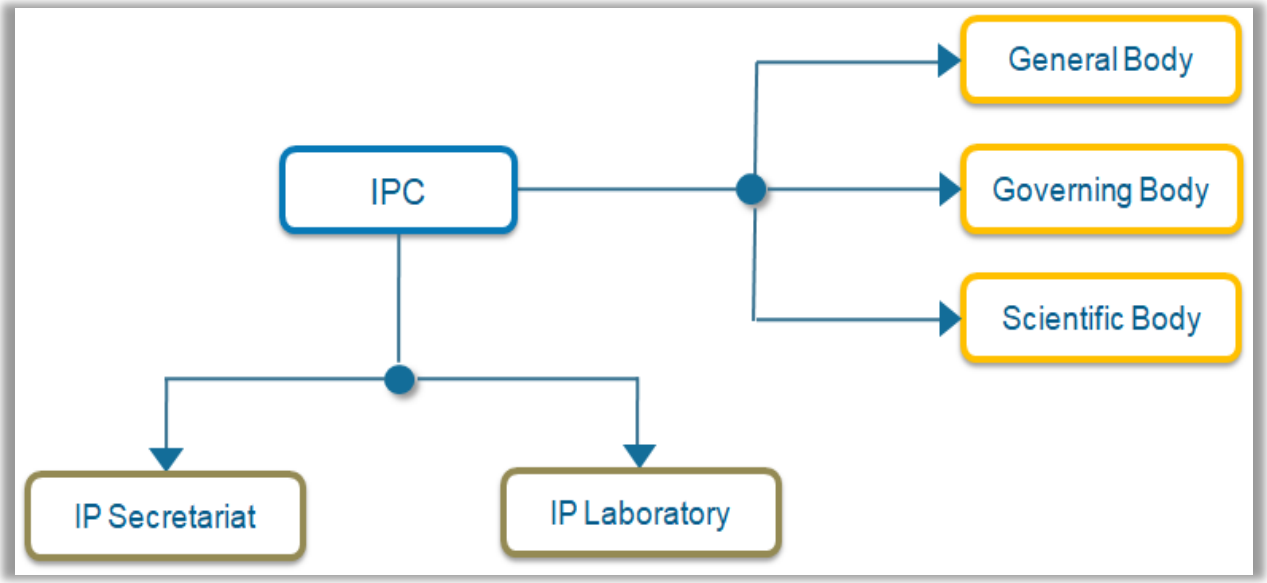
INDIAN PHARMACOPOEIA COMMISSION

CITIZEN CHARTER

ORGANIZATION STRUCTURE

The Government of India created an autonomous Institute in the form of the Indian Pharmacopoeia Commission (IPC) to deal with matters relating to the timely publication of the Indian Pharmacopoeia (IP) which is the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940. IP specifies the standards of identity, purity and strength of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India.

The IPC has become fully operational from 1st January, 2009 under the administrative control of the Ministry of Health and Family Welfare, Government of India. The Secretary, Ministry of Health and Family Welfare, is the Chairperson and the Chairman-Scientific Body is the Co-Chairman of the Commission. The Secretary-cum-Scientific Director is the Chief Scientific and Executive Officer of the IPC.



Organization Structure of the IPC

IPC Vision

To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis.

IPC Mission

To promote public and animal health in India by bringing out authoritative and officially accepted standard for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

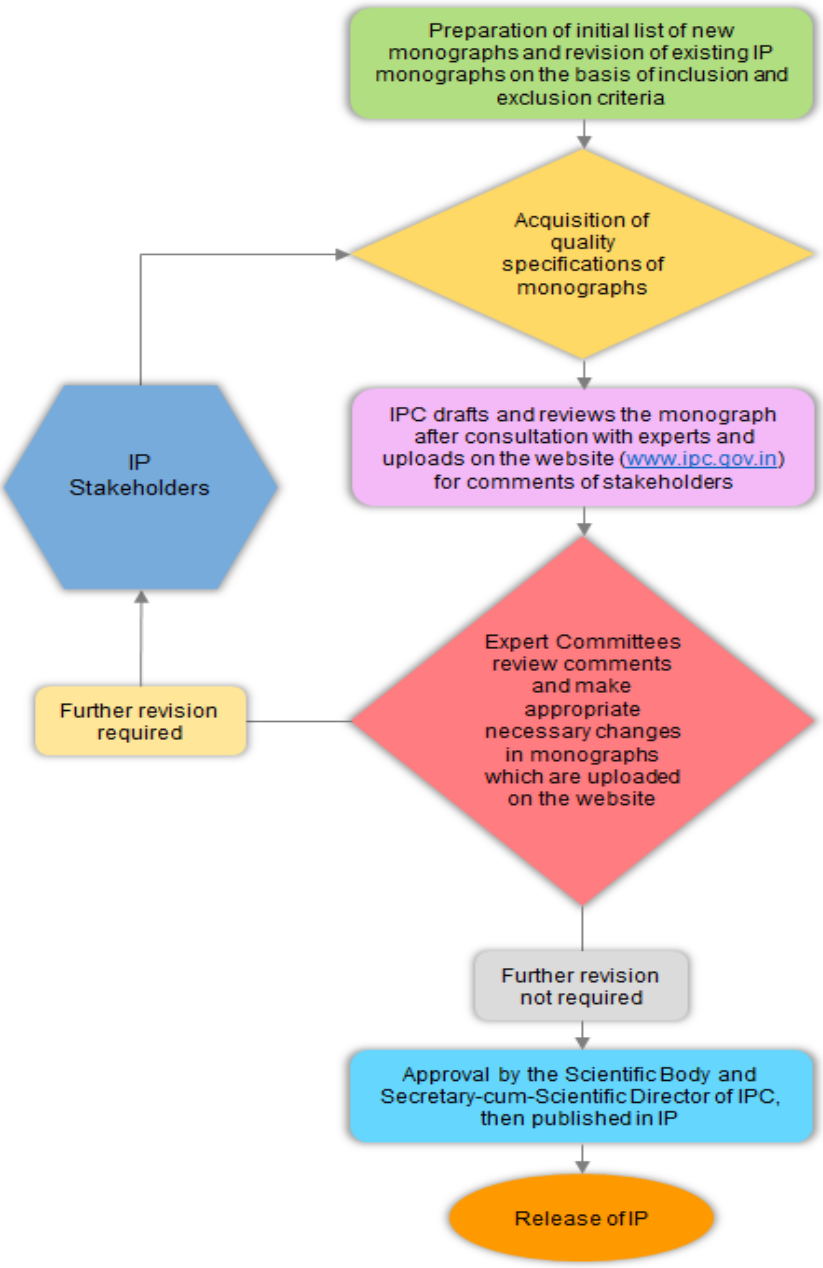
IPC Mandate

Ministry of Health and Family Welfare has assigned following mandates to the IPC:

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia (IP), including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices and to keep them updated by revision on a regular basis,
- To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms,
- To take note of the different levels of sophistication in analytical testing/ instrumentation available while framing the monographs,
- To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products,
- To collaborate with pharmacopoeias like the Ph. Eur., BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards,
- To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgrading /revision,
- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles /materials,
- To publish the National Formulary of India (NFI) for updating medical practitioners and other healthcare professionals,
- To act as a National Coordination Centre for Pharmacovigilance Programme of India (PvPI).

MONOGRAPH DEVELOPMENT PROCESS

The inclusion of monographs in the IP is based on specific criteria with priority given to drugs used in National List of Essential Medicines. To ensure transparency in the standards-setting process, proposals on new monographs are publicized on the IPC website besides obtaining comments through consultations in specialized Expert Working Groups. 'Guidance Document for Drafting and Formatting of Monographs for Indian Pharmacopoeia' and 'Monograph Submission Checklist' is also available on IPC website.



Process for Monograph Development

INDIAN PHARMACOPOEIA COMMISSION

IP Monograph Submission Checklist (Version.2)

S. No.	Requirements	Status
1.	Name of the Monograph	
2.	Name of the Molecule	
3.	Category (Therapeutic/ Prophylactic)	
4.	Monograph Source	
5.	Regulatory Approval (CDSCO)	
6.	Name & Profile of Innovator	
7.	Name of Manufacturers	
8.	Pharmacopoeial Status: ☐ BP ☐ EP ☐ USP ☐ JP ☐ Int. Pharmacopoeia ☐ Other Pharmacopoeias.....(please specify)	
9.	References (Scientific / Technical/ Others) ☐ Merck ☐ Martindale ☐ Others.....(please specify)	
10.	Pharmacopoeial Comparison (Annexure)*	
11.	Justification for adopting any specific Pharmacopoeia	
12.	Justification for deviation for Innovator's specification, if available	
13.	Route of Synthesis (if applicable)	
14.	Availability of Samples & Standards with COA for method verification	
15.	Donation of Candidate material for Reference Standard development (Min. quantity 100 gm or more depending on nature of molecules)	
16.	Analytical Specifications & Methods	
17.	Analytical Method Validation Data	
18.	Stability Data including data of forced Degradation studies	

*For descriptive information annex separately

Brief Summary & Justification

	Name	Designation	Signature	Date
Prepared by				
Reviewed by				
Approved by				

Monograph Submission Checklist

IP REFERENCE STANDARDS AND IMPURITY STANDARDS

IPC develops and establishes the IP Reference Standards (IPRS) and Impurity Standards to be used during the quality control analysis of the drugs. The updated list of the IPRS and Impurity Standards is available on IPC website. Stakeholders may purchase these standards directly from the IPC as no distributor/agent is authorized by the IPC to sale these products.

ANALYTICAL SERVICES

IPC offers various analytical services (including NMR, FTIR, elemental analysis,LC-MS/MS, TGA, DSC, ICP-MS) forindustry and Govt. Institutes/academia on chargeable basis. Detailsof the testing charges are available on the IPC website.

Types of Samples Received at IPC for Analysis

S. No.	Category of samples	Testing Fees (Y/N)
1	New Drugs Samples (NDS)	N
2	Misc (CMSS/Cough Syrups)	Y
3	ILC	N
4	Industry/ Individual's/ Academia	Y

Note: For each category of drug substance/product, the requirements are different and mainly based on manufacturers specifications.

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Govt. of India
Sector 23, Raj Nagar, Ghaziabad-201002
Phone: 2783392, 2783400, 2783401 Fax : 2783311
Email : ipclab@vsnl.net, Website : www.ipc.gov.in

Analysis Request Form

Dated: ……..

From (Address and contact details)

……

……

E-mail ……

PLEASE PROVIDE COMPLETE DETAILS IN CAPITAL LETTERS

Sample Name			
This sample was sent to your lab earlier		**YES**	**NO**
Batch No.;		**Sample Qty.:**	
Date of Mfg.:		**Date of Exp:**	
Mfg. by		**Mfg Lic. No.:**	
Supplies by:			
S.No.	**Test Required**		**Claim/Limit/Method**
1.			
2.			
3.			
4.			
5.			

Received by
Name:……

Sample given by
Name:……

For Office use only

Expected Date of Completion……

	Industry	**Govt. Institution**
Instrument usage Charges		
Goods and Service Tax @18%		
Total charges		

Remarks ……

Signature

NATIONAL FORMULARY OF INDIA (NFI)

IPC publishes the NFI to promote rational use of medicines in the country. NFI can be purchased by placing order to the IPC.

PURCHASE AND PAYMENT OPTIONS

Orders for purchasing IPC publications (including IP, NFI etc.) and IP Reference Standards/Impurity Standards are to be placed in the prescribed 'Supply Order Forms'. The payment can be make either through Demand Draft or NEFT/RTGS.

Through Demand Draft	The payment can be make through Demand Draft drawn in favour of "Indian Pharmacopoeia Commission "payable at Ghaziabad (Uttar Pradesh)
Through NEFT/RTGS	The payment can be transfer to the below mentioned account:
A/c Holder Name : Indian Pharmacopoeia Commission ACCOUNT NO. : 21860100013540 BANK NAME : BANK OF BARODA BRANCH NAME : Sanjay Nagar, Ghaziabad, Uttar Pradesh, India IFSC CODE : BARB0SANGHA (0 → Denoting Zero) SWIFT CODE : BARBINBBGHA	

Note: Kindly inform IPC at e-mail ID: lab.ipc@gov.in, publication-ipc@gov.in or after money transaction along with GSTIN No. (if registered), UTR No. and complete postal address for further necessary action. For more information and update, please visit our website www.ipc.gov.in.

SUPPLY ORDER FORM

INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002
Tel No: 0120- 2783392, 2783400, 2783401; Fax: 2783311
Mail: lab.ipc@gov.in, publication-ipc@gov.in
Web: www.ipc.gov.in
PAN No.: AAATI7017F
GSTIN 09AAATI7017F2ZR

For Office use only:

Date Received:……

Order No.:……

Processed by:……

Please Supply (Order must be made in writing by post or fax or e-mail on address as given)

Sr. No.	Title of the Publication(s)	No. of Set(s)/ Copy(ies) Ordered	Amount @ per copy/set	GST as applicable	Total Amount (Rs.)

Name* (please type full name): ……

Name of the Organtzation……

Delivery Address*……

State*……Pin Code*: ……Tel. No/Mob.No*.: ……

E-Mail*: ……GSTIN……

Deman Draft/UTR No*……Date*:…… Bank Name*:……

Type of Consumer* ☐ Student/Institute ☐ Scientist ☐ Teachers ☐ Researcher ☐ Manufacturer ☐ Marketer ☐ Government Authorities ☐Others……

Scope of Utility* ☐ Pharmacopoeia ☐ Administration/Legal Authority ☐ Laboratory ☐ Manufacturing ☐ Research Work ☐ Academic ☐ Others……

MODE OF PAYMENT: (The payment can be make either through Demand Draft or NEFT/RTGS):

The payment shall be made either by **Demand Draft** drawn in favour of **"INDIAN PHARMACOPOEIA COMMISSION"** payable at **Ghaziabad (Uttar Pradesh) or** through NEFT/RTGS to below mention account:-

A/c Holder Name:	Indian Pharmacopoeia Commission
ACCOUNT NO.:	21860100013540
ACCOUNT TYPE:	Saving
BANK NAME:	BANK OF BARODA
BRANCH NAME:	Sanjay Nagar, Ghaziabad, Uttar Pradesh, India
IFSC CODE:	BARB0SANGHA (0 → Denoting Zero)

Demand Draft/UTR No……Date:…… Bank Name:……

Note: Kindly inform us at our e-mail ID: lab.ipc@gov.in, publication-ipc@gov.in after money transaction along with **UTR No.** for further necessary action.

Declaration:

I certify that the book(s) ordered is for the purpose in connection with my trade, business or profession.

Signature: …… Date: ……

We regret that order is not normally accepted over the telephone

Supply Order Form for IPC Publications including IP

SUPPLY ORDER FORM

PAN No.: AAATI7017F **GSTIN 09AAATI7017F2ZR**

Indian Pharmacopoeia Commission Ministry of Health & Family Welfare, Govt. of India Reference Substance Division, Sector-23, Rajnagar,Ghaziabad-201002. (India) Fax: 91(0120) 2783311, E.mail: Sales-ipc@gov.in Website: http://www.ipc.gov.in	**For Office use only** Date Received: …… IPRS Order No.:…….. Processed by: ……

Please Supply

S. No.	Name of IPRS*	Lot No.	Price per Vial	No. of Vials Ordered	Total Price (Rs.)

Please mention Email ID for IPRS certificate for Analysis

Name of the Organization ……

Delivery Address ……

……

…… Pin Code ……

GSTIN…… State Code ……

Tel. No. …… E.mail : ……

Billing Address ……

……

GSTIN…… State Code ……

Tel. No. …… E.mail : ……

Payment shall be made either by Demand Draft drawn in favour of "**INDIAN PHARMACOPOEIA COMMISSION**" payable Ghaziabad **or** NEFT to "**INDIAN PHARMACOPOEIA COMMISSION**, Bank of Baroda, Sanjay Nagar, Ghaziabad, Bank Account Number: 21860100013540, Branch IFSC Code: BARB0SANGHA (fifth character is zero), Type of Bank Account: Saving Account.

DD No/NEFT No.....Date..... Amount .....

Declaration

*I certify that IPRS(s) ordered is for the purpose of its intended use as per Indian Pharmacopoeia.

Name..... Designation.....Signature.....Date.....

Order and Payment Information for Indian Pharmacopoeia Reference Substances

Order(s) must be made in writing by post or fax or e.mail address given as under:

For any queries please email: Sales-ipc@gov.in

We regret that order is not normally accepted over the telephone.

* **Warning:** For laboratory use only. Not for drug, food, human or animal consumption.

PROFICIENCY TESTING

In order to ensure the quality of test results, IPC conducts proficiency testing (PT) programs for pharmaceuticals in chemical and biological disciplines in accordance with ISO/IEC 17043:2010.

INDIAN PHARMACOPOEIA COMMISSION
INDIAN PHARMACOPOEIA LABORATORY
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad- 201 002.
Tel No: 0120- 2783392, 2783400, 2783401
Mail: lab.ipc@gov.in Web: www.ipc.gov.in

Annexure-V
PT PARTICIPANTS REGISTRATION FORM PT ROUND-03, 2023
Format No: IPC/QSP/049/07/FMT/05

Participant Details (Shipping Address)			**Invoicing Details (If different from shipping address)**
Organization Name			
Address			
District			
PIN			
GST No.			
Email/Mob No.:			
State		Country	

Participant Fee Details			**Date:**
			Amount:
DD No./NEFT No.			
Accreditation Status ISO/IEC 17025	YES/NO		
NABL Certificate No. and location (if any)			
Both accredited and non-accredited laboratories are eligible for participation.			
Quality Manager Name		Designation	
Mobile No.		Email id	

*All Correspondence will be done on the above registered E-mail ID of participant only.

- **Confirmation of registration:** Receipt of registration form will be acknowledged after receiving the payment.
- Fill and scan PDF Format and email to qualityassurance-ipc@gov.in (No hard copy to be sent).
- Fill registration form in legible manner. If GSTIN is in the name of individual/organization other than PT participants, use extra sheet for providing any additional information for billing purpose.
- Registration is temporary till the payment is made. Payments are to be made in advance.
- For any query and clarification please contact us at below details.
- Email: qualityassurance-ipc@gov.in, Phone :9015397123/0120-2783392

Signature of authorized person

Name:

Designation:

PT Participant Registration Form

PHARMACOVIGILANCE PROGRAM OF INDIA (PvPI)

In order to promote rational and safe use of medicines in the country, IPC act as the National Coordination Centre (NCC) for the PvPI. All are encouraged to report the Adverse Drug Reactions (ADR) to the PvPI in following manner:

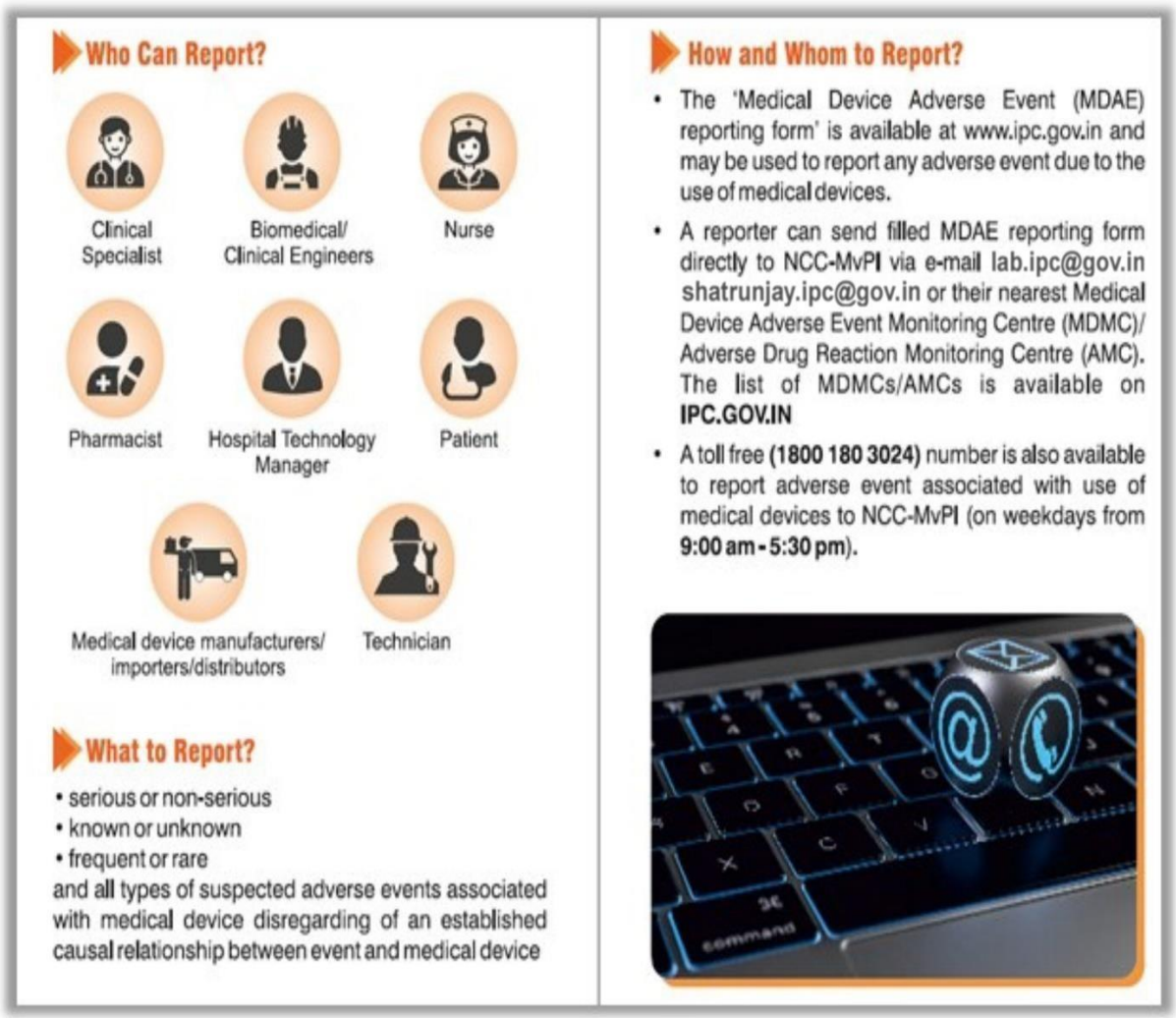
Enrollment as ADR Monitoring Center Under PVPI

New Pharmacy Colleges, Medical Colleges, Institutes, and Hospitals who wish to enroll as ADR Monitoring Center (AMC) under PvPI, may submit the Enrollment Form for new AMC which is available at: https://ipc.gov.in/mandates/pvpi/adr-monitoring-centers.html.

All other relevant information about PvPI is available at www.ipc.gov.in.

MATERIOVIGILANCE PROGRAM OF INDIA (MvPI)

MvPI aims to collect data on medical device related adverse events systematically and scientifically analyze them to aid in regulatory decisions and recommendations on safe use of medical devices. MvPI monitors medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to evaluate the benefit-risk ratio of medical devices. MvPI generates independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.



List of Medical Device Monitoring Centres Pan India

https://www.ipc.gov.in/images/387MDMCs_Details_.pdf

Tools for Medical Device Adverse Event Reporting

https://www.ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/mvpi-toolkit.html

Medical Device Adverse Event Reporting Tools for the MvPI

MvPI Internship Programme

https://www.ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/mvpi-internship-programme.html

Feel free to contact us in case of any query send us on shatrunjay.ipc@gov.in