



Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

सत्यमेव जयते

QUALITY CONTROL & QUALITY ASSURANCE



About

PMBI ensures the availability of quality medicines at affordable prices through its exclusive Pradhan Mantri Bhartiya Janaushadhi Kendras.

WHO-GMP Certified Suppliers

- All products are procured from WHO-GMP certified manufacturers through transparent tendering Process.
- Manufacturing facilities/premises of the manufacturers are regularly inspected by a dedicated Procurement and Quality Assurance wing of PMBI confirming provisions of Drugs and Cosmetics Act 1940 and the Rules thereunder 1945 and WHO-GMP Standards to ensure availability of standard quality medicine to all. Empanelled NABL Laboratories are also inspected/audited conforming GLP guidelines.

TWO-STAGE TESTING AT NABL LABS

Quality of all products are ensured at two stages starting from testing of products at the manufacturers end and retesting at empanelled NABL accredited laboratories on receipt of goods at warehouses. Submission of Certificate of analysis (CoA) is mandatory at the time of delivery of goods to confirm whether it has passed the quality standards at manufacturers end.

WELL EQUIPPED WAREHOUSES

All warehouses of PMBI are well equipped with state-of-the-art facilities like regular monitoring of temperature, relative humidity (Rh), adept at storage of cold chain items, separation and storage of items based on the nature of drugs/medicines, round the clock CCTV surveillance etc. FIFO method is maintained to minimise shelf-life complaints.

GMP-GDP NORMS FOR WAREHOUSING

- Proper storage conditions are maintained to ensure quality, safety and efficacy of products confirming goods warehousing practices. Besides this suitable space is provided with atomized

- facilities of racking, stocking, handling, packaging and dispatch of products to Janaushadhi Kendras. All the facilities are regularly inspected as per Good Warehousing Practices and Goods Distribution Practices.
- Qualified and well-trained team of quality and logistics department placed at warehouses, jointly ensure the compliance laid under Drugs and Cosmetics Act 1940, Good Laboratory Practices and Good Warehousing Practices to provide best quality products to the people of India.
- Stock control system is maintained so that only validated products are issued for distribution.
- End-to-End Quality Management System are followed to provide standard quality medicines at the last mile.

Sampling and Testing

Random sampling is done for every single batch of medicines delivered to warehouses for second stage of testing at empanelled NABL accredited Laboratories.



Testing is done in accordance with the procedure/ Standard Operating Procedure (SOP) laid down in Pharmacopeial reference (IP/BP/USP etc.) / Standard Testing Procedure (STP).



Test Reports are validated by Quality Control department and details are furnished to Quality Assurance Department for approving the consignment for sale.



Analytical testing Facilities at NABL laboratories empanelled with PMBI



**Analytical testing
is done to ensure the
drugs / medicine are of
standard quality as per Drugs
and Cosmetics Act 1940 and rules
thereunder 1945.**

**Some of the important analytical parameters
followed by PMBI to confirm the standard quality
of the drugs.**



**Physical
Appearance**



**Related
Substances (RS)**



**Average
Weight**



**Uniformity
of weight**



**Uniformity of
contents**



Assay



Dissolution



Disintegration



Sterility



Hardness



Friability



Leak Test, etc.

Robust Quality Check System



Medicines are
WHO-GMP and **NABL** certified.



Latest HPLC process to check the % of purity of drugs



Inferences of Analytical Testing

Quality Assurance department signals the distribution of the passed batches once the report is furnished by **Quality Control** department.



Any batch if declared "Not of Standard Quality (NSQ)" actions are initiated as per defined SOP conforming the Drug and Cosmetics Act 1940 and Rules made there under 1945 and tender provisions. Whole batch of such drugs are recalled from all Janaushadhi Kendras and disposed off as per prescribed procedure.



Hon'ble Prime Ministers vision behind implementing PMBJP

”

To bring down the **healthcare budget** of every citizen of India through providing **Quality Generic Medicines at affordable prices.**



- **Narendra Modi** Hon'ble Prime Minister of India

Quality Assurance (QA)

- Regarding product complaints arising after the sale of PMBI products, investigation is done & control sample is reviewed.
- This team also does random sampling from Janaushadhi Kendras and control samples at warehouses and re-test them at NABL labs for assuring the quality over the entire shelf-life of the medicine. Accordingly, corrective and preventive actions (CAPA) is taken.
- PMBI has started comparative study of branded products and Jan Aushadhi Generic products.





**World Health Organisation -
Good Distribution Practice (WHO-GDP)**
based warehousing system to maintain
efficacy of the medicines



*Locate your nearest
Jan Aushadhi Kendra on
your mobile*

DOWNLOAD NOW!
**JAN AUSHADHI
SUGAM**

MOBILE APP from



Scan QR Code



Pharmaceuticals & Medical Devices Bureau of India (PMBI)
B-500, Tower B, 5th Floor, World Trade Center, Nauroji Nagar,
New Delhi - 110029



@pmbjppmbi



www.janaushadhi.gov.in



National Toll Free Helpline
1800 180 8080

July, 2024