

GUIDELINES OF INDIAN RAILWAY PHARMACOPOEIA

1. Indian Railway Pharmacopoeia is a guide to the medical officers and staff of the Railways regarding indents, procurement, storage, control and distribution of drugs and other medicinal items, Drugs have been grouped, based on their pharmacological actions, listed in generic nomenclature and have been allotted Railway pharmacopoeia numbers (Ph. No.) Pharmacopoeia number is a five digits number, intended for proper identification of items and is a unique number. This number should not be changed and must strictly be adhered to. The list of drugs provided in Pharmacopoeia is not exhaustive, however, it is expected to be a useful guide. As such, there is no bar on procurement of any items, which are not included in Indian Railway Pharmacopoeia.
2. Medical Officers of health units will indent items required to be stocked in health units generally. It is observed that certain drugs which are usually not stocked in health unit stores are also prescribed by specialist medical officers of hospitals for continued use of patients. In such cases, the health unit medical officers may include such stores also, in their annual indents so that patients can conveniently collect such medicines from their respective health units once in a month for chronic conditions like Peptic Ulcer, Hypertension, Ischaemic heart disease, Thyroid disease, Tuberculosis, Leprosy, Diabetes, Bronchial Asthma, Psychiatric diseases etc.
3. **Registration:** The registration of drug manufacturing firms will be processed by the respective CMD of the zone in whose jurisdiction the manufacturing plant is located so that the inspection of the manufacturing premises etc. is convenient. Extant instructions and procedures for registration of new firms be followed. CMDs may insist that the firms seeking registration may submit documents such as certificates of good manufacturing practice (GMP), certificates as per the standards laid down by World Health Organisation or ISO 9000 certificate etc. Registration of a firm by one particular zone will not automatically entitle its registration in other zones also, as the firm may/may not have to the capacity to supply the material to other zones. The duration of registration will be for two years initially and then it can be renewed by the zone. Renewal of registration of a firm would not call for following the entire procedure afresh and can be done on the basis of performance of the firm. CMDs at their discretion can accord registration for supply of certain specified items only and registration need not be construed as a blanket registration. Broad guidelines for registration of various firms at zonal headquarter level, are given at Annexure-VI.
4. Medical Director may exercise the same powers as CMD in the same powers as CMD in the absence of Chief Medical Director.

5. **Procedure for indenting:** Indents of drugs and other medicinal items be prepared in triplicate as per computerised format given vide Annexure-I. This format be made available to all hospitals and health units under their control by Divisional Hospitals/Central Hospital/controlling Hospital. Drugs be indented in group-wise order; listed separately. Even within a group, if a particular constituent e.g. a salt is different in one formulation from the other or the strength of one particular constituent is a variance with other, then further sub-grouping of an item may be considered. Hospitals and health units will send their indents to their controlling Officer i.e. Sr.DMO(I/c)/MS/CMS/MD as the case may be. The latter will consolidate the demands and send a consolidated indent to CMD's office.
- 5.1 **Decentralized procurement of certain items:** Small value items can be procured in a decentralized manner. Items, which are proposed to be procured by Central Hospital/ Divisional hospitals themselves, are to be submitted in a separate list duly giving the quantities and estimated values. As a guideline, all items, whose aggregate value is less than Rs.10,000/- per year is to be procured by such controlling officers themselves. The list is submitted to CMDs for favour of information only and not for supply. Such purchases at Central Hospitals/ Divisions are not to be reckoned as local purchases, as these are not local purchases in the strict senses and the procurement is decentralized only for administrative convenience. Such purchases are to be made duly following the procedures indicated i.e. by inviting limited tenders/single tender as applicable. It may however be ensured that the rates are not in any case higher than the 'special hospital rates' indicted by the manufacturers/suppliers and payment is to be made on bill system, only by cheques.
- 5.2 **Specifications:** All indents be neatly typed in block letters duly indicating quantities correctly in Kg/gms., mgms., ltrs/ml etc, as the case may be. In case of ampoules/vials/capsules/tablets etc., the number should be mentioned precisely. The strength of active ingredient/ingredients of the product be specified unambiguously. All drugs be indented by generic names only. Fixed dose combinations are to be avoided as far as possible.
- 5.3 **Proper Packing:** Broadly, 90% of tablets/capsules are to be procured in strip packs, for use in the OPD and about 10% in loose packing, for use in the indoor. However, percentages may vary according to local conditions as decided by respective CMDs. Similarly, syrups/elixirs /ointments/creams etc. may be indented in small packs of 100 to 200 ml./20 gms/10 gms/tubes for convenient distribution among out patients through dispensaries.

- 5.4 **Time schedule of centralized Procurement – Calendar of events:** Proforma for submission of annual indent is appended at Annexure-I. Health units, hospitals under the Divisional, Central and Superspeciality hospitals shall start preparing indents on the first of July each year for the ensuing year. Divisional, Superspeciality and Central hospitals should send their consolidated indents to CMDs by 5th of August. CMD's office shall scrutinize and finalize indents by 5th of September and send a copy of CMDs' sanction to each Divisional/Central/Superspeciality hospital for their record. CMD's office shall initiate the process of procurement from 20th of September onwards.
- 6 **Tips for calculation of annual indents:** The quantities indented shall be the estimated requirements for one full year e.g. if the indent process starts in the year 2003, the quantity indented will be for the year 2004-2005. For assessing the quantity consumed in the past year, the actual quantities expended from July to June of the year be taken. (Of course balance on hand is to be subtracted from the total quantity assessed i.e. expected balance as on 31st December) e.g. Ampicillin Capsules consumed in the previous one year i.e. July, 2002 to June 2003 is 60,000 capsules. Average monthly expenditure would be $60000/12 = 5000$ capsules. Anticipated expenditure from July 2003 to December 2003 would be $6 \times 5000 = 30,000$ capsules. Suppose that the balance on 1st July 2003 is 35,000, then balance on 31st December 2003 would be $35,000 - 30,000 = 5,000$ capsules. The quantity to be indented for 2004-2005 will be $60,000 - 5,000 = 55,000$ (one year's consumption i.e. 60,000 minus balance on 31st December on 2003 i.e. 5,000). Quantities indented should reckon the anticipated increase or decrease in consumption, if any. Based on local circumstances and needs, some vital items be kept in buffer stock, which however should not be in excess of 10% of anticipated annual demand. CMDs are empowered to decide about buffer stock..
- 6.1 **Items not listed in Pharmacopoeia:** Some items proposed to be indented may not find their names in Indian Railway Pharmacopoeia. In such cases, it is advised that certain additional information besides the usual information such as generic name, strength of the active ingredient etc. The following information may also be provided:
- Justification for indent
 - Particulars of manufacturer – such as name, address etc.
 - Likely supplier/Authorized Dealer/Dealers etc.
 - Anticipated value of the unit and aggregate costs.
 - Desirability of including in the pharmacopoeia if this item is expected to be procured regularly and the aggregate cost would exceed Rs.10000

- 6.2 **Non Pharmacopoeia items:** Indent of surgical items, instruments & other medical equipment (costing less than Rs. One lac each) should be submitted as per proforma given in annex-V.
7. **Supplementary indents:** The reasons for exceeding consumption norms previously determined should be explained by the medical officer in charge of the store to controlling officer/CMD. In case, certain medicines are being consumed at a pace, faster than originally expected, Sr.DMO(I/c)/MS/CMS/Dir.CRI/MD may place a supplementary indents duly justifying the placements of supplementary indents, item wise
- 7.1 **Distribution of Stores to peripheral units:** Stores (medicines) for health units can be supplied once in three months or conveniently by the divisional medical stores. The vouchers of items supplied should be in triplicate duly indicating the quantities in figures and words. One copy should be retained by the Store and the other two copies are to be sent to the respective health units alongwith the stores. The health units on receipt of stores as per lists, shall return one copy duly receipted and certified that the items have been taken into their stock along with ledger particulars etc. to the Divisional/Hospital Medical Stores for pairing the same with the copy originally retained by them. Each copy will indicate the number of items supplied and each item shall be indicated both in figures and words.
- 7.2 **Adherence to target dates:** It may also be ensured that the indents are submitted positively by the target dates. By this process of indenting, it is expected that most of the items required for the ensuing year are procured and within the budget funds allocated for the year.
8. **Procedures for procurement:** It will not be practicable for CMD to invite open tenders for supply of drugs. Only limited tenders from short listed firms are to be invited. While registration of supply/manufacturing firms is in vogue, some reputed brand leaders might not have registered with Railways. In such case the competent authority, CMD/AGM may decide on including such firms as per Railway's needs. Time honoured practice of purchases through limited tenders from short listed suppliers has been working well. Items are normally procured on a limited tender, single tender proprietary basis as per the needs and justification.
- 8.1 **Compendium of suppliers of drugs:** To ensure regular supply of good quality of medicines, the indicated method of placing firms on approved list be followed. There are multination/several reputed national firms, which supply some items, however not manufactured by them. It is desirable that the items are procured from manufacturers only wherever feasible. Notwithstanding this clause, CMDs at their discretion may procure such items through other agencies also duly recording, the reasons.

- 8.2 **Priorities in procurement:** Items indented are to be subjected to ABC and VED (Vital, Essential and Desirable) analysis at CMD's office. 'A' items are to be processed for procurement on priority alongwith vital/essential groups. Dates for opening limited tender quotations after notification shall be decided by the concerned CMD, based on local conditions, urgency etc. However normally it shall not be less than three weeks from the date of notification/invitation.
- 8.3. **CMD's discretion about items not listed in pharmacopoeia:** As the number of drugs are increasing and the manufacturing/supplying firms are also increasing in proportionately in number, it is felt that it is not practicable to include all the items of drugs in the Indian Railway Pharmacopoeia. Items included in the Pharmacopoeia serve only as a reference guideline. CMDs have the discretion to include additional items, depending on local needs, circumstances, practices etc.
- 8.4 **Delegation of Powers:** Pathology/Biochemistry lab equipment available at different institutions are of different brands and makes, so a variety of lab items/consumables may be required for different hospitals. In such circumstances, central procurement may be a cumbersome exercise for a large number of items in small quantities. Hence, it is the discretion of CMDs whether to procure such items at their headquarters or delegate powers down below as necessary.
- 8.5 In a few items, not listed in Railway Pharmacopoeia, are considered necessary to be procured by the CMD, then the same can be procured by calling for limited tenders/single tender as the case be, depending upon essentiality/urgency etc.
- 8.6 **Drug Analysis Reports:** Supply orders may contain instructions that batch wise drug analysis reports be enclosed along with supply. However such certificates may be superfluous from certain reputed national/multinational firms and they may not be insisted to provide such analysis report along with supplies. CMDs of respective zones have powers to decide about the waiver of such a clause.
- 8.7 **Imprints:** Medicines supplied to Railway Units should also have a stamp or print stating "for Railway Use Only" & "Not for sale" on strips of tablets or sealed bottles, as the case be.
- 8.8 **Products of Human Origin:** Drugs of human origin should also have a certification stating "Free from HIV", 'Hepatitis 'B' and 'Hepatitis 'C' e.g. anti haemolytic factors immunoglobulins and Human Albumin etc.

- 8.9 **Procurement order for supply:** Purchase orders for supply of items like intravenous infusions, dialysis fluids etc. can be issued with supply instructions such as 'to be supplied in installments of two, three or four' as the case may be, so many months apart so that the stock do not occupy bulk of the medical store space. Payment terms also are to be specified clearly whether the payment will be after receipt of each installment or on receipt of the entire quantity.
- 8.10 In case of Products containing analogous pharmacological agents, ingredients etc. with comparable therapeutic properties with minor variations the choice of procurement of such items rests with the CMD of the zone.
9. **Stocked items –non-stocked items:** It is not intended that each Railway hospital/health unit should stock every item listed in the Pharmacopoeia. Several drugs exhibiting comparable pharmacological and therapeutic action have been included in various groups hence it is logical that some drugs with similar action need not be kept in stock. As a hospital/health unit will dispense drugs prescribed, by their medical officers, the medical store need not kept such drugs, which are not usually prescribed by their doctors. Decision regarding stocking an item of medicine/drug in the medical store or otherwise will be left to the discretion of respective CMDs based on the consumption of the drugs within their jurisdiction. However, as a guideline, essential drugs enumerated in WHO's recommendations be stocked in the hospitals/health units.
10. **Performance register:** The experiences, good and bad, with regard to purchase of items or dealing with firms may be diligently recorded and the information is to be exchanged with other Railways and also with the Board in a yearly meeting that would take place either exclusively for such purpose or otherwise. Information about rates/terms and conditions obtained for comparable/acceptable quality of drugs may also be exchanged.
11. Various instructions, circulars, with regard to the powers and procedure for procurement of medical stores in respect of (i) drugs and medicines (ii) other items of medical stores like instruments, appliances, surgical dressings, x-ray items, other hospital items etc. are given in Annexure-II.
12. **Rate Contract Items:** It is observed that supplies are not made within the stipulated delivery schedule in time by firms at times as per rate contract/running contract terms. In such circumstances, CMDs can procure such rate contract items directly from the market duly following the

procurement procedures according to local needs and schedule of powers duly recording reasons.

13. **Repeat Tender – Single Offer :** In response to limited tender enquiries at times only a single offer may be received. In such cases, the advised course is to repeat tender invitation procedure duly adding the names of some more prospective suppliers wherever such scope exists. Even after a repeated tender enquiry, if only one offer is received from only single firm, then the tender can be accepted provided the rates are found reasonable and certified as such by the accepting authority.
14. **Local Purchases:** As distinct from the above purchases, day-to-day local purchases are made in hospitals/health units for certain items, which are not available in hospital stores. Under normal circumstances not more than 15% of the total budget allocated for medicines in a year should be incurred on day-to-day local purchases.
 - 14.1 ADMO(I/C)/DMO(I/C)/Sr.DMO(I/c)/MS/CMS/MD will take personal care to see that the drugs which they have indented would meet the requirement of 12 months (full year). Resort for local purchase of such items should be exceptional. Units resorting to LP in excess of 15% of their total budgetary allotment of medicines should give valid reasons for the scrutiny of respective CMD. Personal approval of Sr.DMO(I/c)/MS/CMS/MD has to be obtained in each case before local purchase. Local purchases are generally resorted to when there is (i) non-supply/delayed supply of against annual indents (ii) the annual supply is consumed earlier than scheduled, (iii) specific brand requirements of individual patients due to idiosyncrasies even when a different brand is available etc. and (iv) drugs which are not in common use with short shelf lives, hence not kept in stock.
15. **Supply of latest stocks:** To ensure that medicines/drugs have a reasonable shelf life, the supply instructions should contain a clause that the supplier should supply a recently manufactured stock only. However, the material should not have been manufactured more than six months prior to the date of supply to consignees.
 - 15.1 Items which are likely to be used sparingly or have a short shelf life may not be stocked and be purchased conveniently locally as and when required. Items, which are regularly required even though in small quantities, may however be stocked.
16. **Index of manufacturers:** An index of the manufacturers, along with the product they manufacture and also an index of manufacturers of various items of drugs, is published almost every year by the Ministry of Industry

and Supply. Zonal Railways are advised to procure and keep updated copies of such publications. It will serve as a useful guide for reference.

17. **Desirability of stocking alternate brands of vital medicines:** Zonal Railways often encounter difficulties in procuring their requirements from suppliers due to some of the following reasons. (a) contractor offering lowest rates, sometimes do not comply or are not able to supply the quantities in full/as per ordered delivery schedule, (b) for therapeutic efficacy, comparison and evaluation, it is desirable that two or more brands of a same medicinal preparation are available in the store. It is noticed that at times a particular patient may not respond to one brand or may be allergic to a particular brand, but, he/she may respond satisfactorily to the other brand/brands without any adverse effects. So alternate brands of some items may be kept in stock in limited quantities.
 - 17.1 It is not be prudent to purchase the entire quantity of an item from one firm only even if it has offered the lowest rate. Purchase of other brand/brands of a formulation can be made from other tenderers duly taking into consideration the nature of drug, local needs etc., wherever necessary. Such a practice would cover eventualities such as delayed/non compliance and to usher in competitiveness among firms.
(Letter no. 80/H/4/15 dated 28th May, 1980)
 - 17.2 **Import of drugs in exceptional situations:** Drugs, which are not available in the country and are required to be imported for individual patients, shall be procured duly following the extant procedures. It is advisable to contact the Railway Adviser/Dy. Adviser of Indian Mission abroad, if such officers are based in the countries from where the drugs are proposed to be imported.
 - 17.3 **Rate Running Contracts:** Items having high costs, uncertain demand and urgent need, such as anti cancer drugs, interferons immunosuppressive drugs etc. are preferably procured through rate running contracts, wherever such arrangements are available and feasible so that being expensive items, wastages can be minimized by not keeping them in stock.
18. **Quality Control:** It is advised that about 5% of items /medicines/drugs/formulations be sent for analysis to analytical laboratories as a routine. For each item selected to be sent for analysis, two representative sample packs (packets) are to be collected by Sr.DMO(I/c)/MS/CMS/MD. One sample pack (packets) should be kept in the personal custody of the officer and the other pack (packet) should be sent to the drug analytical laboratory. In case, the medicine/drug is found to be not conforming to the standards, appropriate action is to be decided upon by CMD concerned. However, if the firm challenges the report, then

the second allocated sample pack/bottle (2nd portion) which was retained by Sr.DMO(I/c)/MS/CMS/MD as the case may be, will serve as a check sample for comparison. It should be noted that the pack/bottle so retained by Sr.DMO(I/c)/MS/CMS/MD is not disturbed/tampered with or opened at any stage till a final decision is taken. The sample retained is to be kept in a sealed packet duly Superscribing details such as date of collection, serial number, the name of the item, batch number, name of the manufacturer, etc. particulars are to be entered in register kept with custodial officer. On receipt of the report, the sample can be disposed off as warranted by the report. To ensure group-wise distribution of analysis procedure within the 5%, CMDs can decide to distribute group-wise allocation of items to headquarter hospital and divisions. This will avoid duplication of efforts. The information on analysis reports be shared between various units advantageously.

- 18.1 Medical Officers are advised to refer matters about medicines/drugs of doubtful quality etc. on priority to their respective controlling officer i.e. Sr.DMO(I/c)/CMS/MD as the case may be for arranging analysis and investigation in case a drug does not give expected therapeutic results or shows abnormal deterioration discoloration, fragility, sedimentation, crystallization or defective packing etc. While sending a particular item for analysis to a laboratory, it must be ensured that only a sealed bottle/pack is sent duly being particulars such as name, its batch number, date of manufacture and the name of the manufacturer, etc. the sample should be sent to the Government laboratory or any other reputed laboratory within the jurisdiction of CMD, if available. Funds towards analysis fees may be booked under the head of drugs. No separate allocation exists towards analysis costs.
- 18.2 There should be a separate clause in the tender conditions that “For all drugs purchased by Railways, the analysis cost of will be borne by the respective firm, if the items on analysis is found to be not conforming to the standards . However, if the same found satisfactory on analysis, the cost should not be borne by the firm but by the administration.”
19. **Monitoring of inventories:** It is advisable that monthly consumption norms are worked out well in advance item-wise and efforts are made to confine the consumptions within that quantity determined. Close monitoring is necessary. Each Medical Store should have a proper monitoring system concerning the consumption of drugs and it will be worthwhile following the procedure as indicated in the proforma vide annexure-III.
- 19.1 **Monitoring of payment of bills to firms and budget control:** Each Medical Store should maintain “Day Book of Receipts of medical stores”

as per Indian Railway Medical Manual, which shall also have a column indicating the date on which the bills have been submitted to the office. The office in turn will maintain a register indicating the date on which the bills have been received, the date when the bills have been passed and sent to respective Accounts Office and the date on which the Accounts Deptt. have finally passed the bill and prepared the cheques for payment to the firms. This should be monitored regularly by Medical Officer In charge of the Administration. Another register, 'Non-payment Register' should also be maintained where particulars such as remarks about supplies in terms of quality, deficiencies, bill particulars etc. be entered duly connecting unpaid bills. Similarly, for exercising budget control, each Divisional/Central hospital office or an equivalent hospital office will also maintain the register called "Commitment Register" which shall record the anticipated financial expenditure committed in terms of purchase orders etc. progressively. This is basically for monitoring the budget expenditure. Serially as the purchase orders are issued, the particulars of PO and the aggregate value of the order is entered. This will enable the unit to monitor the commitments made.

- 19.2 **Date expiry drug register:** All medical stores shall maintain a date expiry drug register in their respective stores, as per extant instructions placed at Annexure VII. All items of drugs/medicines are entered on their receipt in the register in the page allotted month-wise as per date of expiry of the items. The month of expiry of the item is the criteria, which decides where (month & year) the item is to be entered. It will be a double spread page, the particulars such as name of item, date of receipt, quantity received, date and batch of manufacture, name of manufacturers, ledger folio number where the item is entered in the stock ledger, followed by 4 vertical columns and a wider column left for remarks. The critical monitoring will start four quarters prior to the date of expiry and the quantity balances are to be entered quarter-wise starting from 12 months before expiry. This will help in monitoring the pace of movement (utilisation of the drug) and suitable action can be taken well before date of expiry and the balance can be utilized or exchanged with similar stock of longer date of expiry from other users. The medical officer incharge will notify all the medical officers under his control about such items with dates of expiry their quantity etc. If necessary, respective CMD may also be informed alongwith other divisional incharges to facilitate expeditious action. The CMD in turn may inform other zones for similar action. All efforts are to be made to utilise the drugs and the medicines should not be allowed to be wasted without utilisation. If prompt and effective steps are not taken by the stores incharge, the matter may be brought to the notice of CMD and responsibility for the lapse is to be fixed.
20. It is desirable that the data on medical stores is available on computer and a terminal be fixed in the hospital store or a personal computer be located

in store and operated by computer literate staff. This aspect has to be given due priority.

21. **Delivery Schedule:** Non-delivery of drugs/stores should be reported to the CMD when the supply is not received within the delivery date. CMD shall use his discretion to extend the date of delivery or otherwise. Railways rights can be reserved in such cases as per the discretion of CMD or the penalty can be waived duly recording reasons therein.
22. **Acceptance of Open Delivery of Consignments:** While taking delivery of medicines and other medical stores from the Railway station if there is any doubt regarding the condition of the package etc., open delivery in the presence of station staff may be accepted and extant instruction/procedure for taking inventory, duly making a report on the shortage, if any, etc. be followed.
23. **Audit of medical prescriptions:** Regular Medical Audit regarding “prescribing habits of medical officers” be conducted and also be discussed in the clinical meetings so that prescriptions in the hospitals/health units are scientific and rational.