

GUIDELINES FOR I.V FLUIDS DISTRIBUTION, STORAGE AND ADMINISTRATION

GUIDELINES ON I.V FLUID'S STORAGE, DISTRIBUTION AND ADMINISTRATION

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1 ABBREVIATIONS

I.V FLUIDS	Intravenous Fluids
LVPs	Large Volume Parenterals



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1. INTRODUCTION

The administration of intravenous fluids is one of the most common and universal interventions in medicine. Crystalloid solutions are the most frequently chosen, by far, with normal saline (NS) and lactated Ringer's (RL) both being frequent choices globally. Of interest, the choice of intravenous fluids has remained one of the most controversial subjects in critical care over the past half a century.

2. OBJECTIVES OF THE GUIDELINES

Intravenous Fluids are liable to Microbial Growth, contamination of Particulate matter leading to adverse drug reaction. LVPs are marketed in various primary packaging materials which needs careful handling to prevent damage from cracks which leads to contamination of fluids meant for I.V administration. In this context the guideline will ensure maximum precautions during temporary storage, transportation and handling.



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3. BACKGROUND

Forms of license to manufacture drugs specified in Schedules C and C(1), excluding those specified in Part XB and Schedule X or drugs specified in Schedules C, C(1) and X and the conditions for the grant or renewal of such Licenses :

A licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) other than Large Volume Parenterals, Sera and Vaccines, drugs specified in Part X B and Schedule X shall be issued in Form 28 and a licence to manufacture for sale or distribution of drugs specified under Schedules C and C(1) (other than Large Volume Parenterals, Sera and Vaccines, drugs specified in Part XB) and Schedule X shall be issued in Form 28-B. A licence to manufacture for sale or for distribution of Large Volume Parenterals, Sera and Vaccines shall be issued in Form 28-D. Before a licence in Form 28 or Form 28-B or Form 28-D is granted or renewed, the following conditions shall be complied with by the applicant.

(1) The manufacturing will be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole time employee and who is _____

(a) A graduate in Pharmacy or Pharmaceutical Chemistry of 1[a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] and has had at least eighteen months' practical experience after the graduation in the manufacture of drugs to which this licence applies; this period of experience may however be reduced by six months if the person has undergone training in manufacture of drugs to which the licence applies for a period of six months during his University course; or

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(b) A graduate in Science of 1[a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] who for the purpose of his degree has studied Chemistry or Microbiology as a principal subject and has had at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(c) A graduate in Medicine of 1[a University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] with at least three years' experience in the manufacture and pharmacological testing of biological products after his graduation; or

(d) A graduate in Chemical Engineering of a University recognised by the Central Government with at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(e) Holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b), clause (c) or clause (d) and is permitted to work as competent technical staff under this Rule by the Central Government.

Provided that any person who was approved by the licensing authority as an expert responsible for the manufacture of drugs for the purpose of rule 76 read with Rule 78 as these Rules were in force immediately before the 29th June, 1957, shall be deemed to be qualified for the purposes of this rule:

1. Provided that for the drugs specified in Schedules C and C(1) meant for veterinary use, the whole time employee under whose supervision the manufacture is conducted may be a graduate in Veterinary Science or general science or medicine or pharmacy of a University, recognized by the Central Government and who has had at least three years' experience in the manufacture of biological products:

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2. Provided further also that for the medical devices specified in Schedule C, the whole time employee under whose supervision the manufacture is conducted may be a Graduate in Science with Physics or Chemistry or Microbiology as one of the subjects; or graduate in Pharmacy; or Degree/Diploma holder in Mechanical or Chemical or Plastic Engineering of a University recognized by the Central government for such purposes.

(2) The factory premises shall comply with the conditions prescribed in Schedule M 2 [and Schedule M-III in respect of medical devices].

(3) The applicant shall provide adequate space, plant and equipment for any or all the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M 2[and Schedule M-III].

(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X of these rules including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit :

Provided that the manufacturing units which before the commencement of the Drugs and Cosmetics (Amendment) Rules, 1977, were making arrangements with institutions approved by the Licensing Authority for such tests to be carried out on their behalf may continue such arrangements upto the 30th June, 1977 : Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the Licensing Authority may permit such tests to be conducted by institutions approved by it under Part XV(A) of these Rules for this purpose.

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(4A) The head of the testing unit referred to in condition (4) shall possess a degree in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a University recognized for this purpose and shall have experience in the testing of drugs, which in the opinion of the Licensing authority is considered adequate.

(5) The applicant shall make adequate arrangements for the storage of drugs manufactured by him.

(6) The applicant shall furnish to the Licensing Authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date of expiry which shall be printed on the labels of such drugs on the basis of the data so furnished.

(7) The applicant shall, while applying for licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines—

- (i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;
- (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations and under the conditions in which the formulations for administration and use are recommended;
- (iii) are stable under the conditions of storage recommended;
- (iv) contain such ingredients and in such quantities for which there is therapeutic justification.; and
- (v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in Rule 122-E, from the licensing authority as defined in clause (b) of Rule 21.

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(8) The licensee shall comply with the requirements of “Good Manufacturing Practices” as laid down in Schedule M.]

[**Explanation.**___For the purpose of this rule, “Large Volume Parenterals” shall mean the sterile solutions intended for parenteral administration with a volume of 100 ml. or more (and shall include anti-coagulant solutions) in one container of the finished dosage formintended for single use.]

4. SCOPE OF THE GUIDELINE

Intravenous Fluids are liable for Fungal / Microbial Growth, contamination of Particulate matter. Adverse Drug reaction with Large Volume Parenteral have been reported from time of time. In this context this guideline will ensure maximum precaution in the use and handling of IV Fluids to avoid any adverse reactions.

The Drugs & Cosmetics Act mandates good presentation in respect of manufacturing and storage of drugs

5. DISTRIBUTION OF I.V. SOLUTION.

Selection of transporter and agreement with transporter.

- Criteria for selection and agreement should include the transporter and the vehicles which meets the acceptance criteria defined as under to ensure safety of the product.

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During transportation transporter should ensure that

- a. The product identity is not lost, & also ensure that cartons and labelling are in good condition.
- b. Adequate precaution should be taken against spillage, breakage or theft or other adverse influences.
- c. The Product and it's pack are secured and not subjected to unacceptable degree of heat, cold, light, moisture or other adverse influences nor to attack by microorganisms or pests.

Training SOP to Transporter

- The transporter and loader of the transporter should be given adequate training from time to time by manufacturer to ensure the safety of product during the loading and transportation by manufacturer.

Truck inspection and acceptance by manufacturer

- The truck should be clean, free of dust and any foreign material
- Should not have holes or should not allow water to come in the vehicle
- Should be free of any protruding object like 'Nail' that can damage the product.
- Loading of truck according to the pattern shall be defined in SOP of the manufacturer.

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- The truck should be loaded on “first out last in” basis to ensure that the corrugated boxes are not damaged during the loading.
- Extra caution to be taken to avoid breakage during Loading and unloading of corrugated boxes.

Quality of secondary packaging

- (a) Robust enough to withstand the transportation conditions
- (b) Box should be tested for its compression and bursting strength.
- (c) The quality of shipper shall be based on compression value and stack-height. The shipper compression value should take into consideration of stack-height and weight of Box. The manufacturer shall document the compression value of shipper in the specification of shipper. The compression value limits shall be minimum of 3 times the load on the bottom most of the Box of the stack. (For example if the Box weight is 13 kg and stack height is 8 the compression value should be minimum of $273\text{kg}/\text{Cm}^2$).
 - The manufacturer should take reasonable care in transportation, to ensure integrity of I.V. containers.
 - The loaded truck should be checked and accepted by manufacturer.
 - The trans-shipment should not be allowed unless authorized by the manufacturer.

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- The distributor should accept the truck against the check list provided by the manufacturer covering safety of corrugated boxes, identity of product .If the truck does not meet the given checklist criteria, the distributor should make necessary investigation and should inform the manufacturer immediately.

The storage at Distributor's warehouse

- The distributor should have a list of following SOPs approved by Manufacturer and should store the product according to these SOPs. The SOP's should cover following :
 - (a) Ware house receiving inspection
 - (b) Product storage
 - (c) Procedure for handling of damaged products
 - (d) Expiry date [product control]
 - (e) Out bound Trailer/ Truck inspection
 - (f) Housekeeping,
 - (g) Pest control
 - (h) Material inspection, identification and segregation
 - (i) Monitoring of storage
 - (j) Facility security
 - (k) Monitoring of temp.
 - (l) Shipping requirements

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The distributor should follow the same procedure covering the risk for transporting the IV solutions to Hospital, as mentioned in point 1, 2, 3

6. Guidelines for Good Storage Practices – Hospitals

To maintain proper practices to ensure Quality, Efficacy and Safety of I.V. Fluids after receiving the same in the Hospital store till the end User's points it is recommended in the tune of recommendation made by the committee appointed by National Human Rights Commission (NHRC) in the year 1999 that the Head of Hospital Pharmacy with the approval and co-operation of the Hospital Pharmacy and Therapeutics Committee must develop a Hospital Formulary to achieve the following including IV fluid requirements:

- Selection of drugs
- Distribution of drugs
- Safe administration of drugs
- Rational use of drugs
- Labelling, including cautionary labelling
- Recall of drugs
- Reporting of drug product defects

The Head of Hospital Pharmacy, in addition, should develop written policies and procedures for reports on all medication errors and adverse drug reactions (ADRs) and set up computerized Drugs Information Service.

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Storage Premises :

- The Storage area must be free from unsanitary conditions(Ex Rodents, insects, Birds, litter etc).
- The floor of the warehouse should be made of hard floor (Concrete /Kota/Epoxy) and must be in a good state of repair and appearance at all times. The floors are kept clean and free of trash, dirt, sippage water, drain water etc. The area must be kept clean and free of refuse.
- The area used for storage of IV fluids should have adequate space and to prevent exposure to direct sunlight.
- Secured area availability for damaged, rejected and expired goods.
- Ensure adequate pest control program in place and shall be carried out at a minimum frequency of a year. The Pest control shall cover treatment for Termite and Rodents.

Receipt:

- The Hospital personnel responsible for Receipt should cross check the consignment against the order. The stocks should be received in intact condition and in case any deviation observed in the shippers should be separated and informed to the supplier / Manufacturer immediately.
- If the consignments suspected to be exposed to harsh adverse weather conditions during transportation should be segregated & informed to the supplier.

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Storage

Products should be stored Batch wise and Product wise on raised platforms. The storage should not hinder the cleaning and should have sufficient space for movement of stocks and handling.

Products are to be stored in a manner that prevents damage due to excessive vertical stacking heights as per Manufacturers Instructions and in no case not to exceed eight stacks.

The products must not get exposed to direct sunlight, rain etc.

Store the products as per product storage condition (As per label) to prevent deterioration of finished product on storage.

Monitor and record the temperature of storage area on daily basis.

Procedure for Issue of IV fluids:

- The Product Label should be free of defacements, tears or cuts which prevent readability of code and batch number identification.
- The products shall be issued on the basis of First Expiry First Out (FEFO)
- Before issue physically inspect for leakage and presence of particulate matter and appearance of Extraneous floating materials (Black or White).

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- The damaged, expired or contaminated product should be segregated from the stock and kept under lock and Key and intimate the Manufacturer/supplier immediately for necessary action.
- The bottles must be carried from stores to ward in a proper trolley or container with utmost care to avoid any damage to the same.

7. Guidelines for Administration of I. V. Fluids

Introduction

- The majority of patients admitted to hospital at the beginning of the 21st Century will become a recipient of a vascular access device at some stage.
- Demands for acute hospital beds, changes in treatment regimens, changes in government policy and greater patient participation in treatment decisions are challenging the traditional perception that infusion therapy should be confined to the hospital environment.
- As a consequence of the advances in technology, a range of vascular access devices are emerging that can meet the clinical requirements of individual patients at the same time as suiting their lifestyles, making community-based infusion therapy an increasingly viable option.

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- However, the diversity of vascular access devices does have implications for practice; nurses, and clinicians must ensure that each patient receives the most appropriate infusion therapy.

Staff education

- Physician/nurse/Paramedical staff inserting devices and/or providing infusion therapy should be competent in all clinical aspects in this regard and have competency in clinical judgment with evidence based practice.

Infection control

- All infusion related procedures require the use of aseptic technique, observation of standard precautions and product sterility.
- Thorough hand-washing techniques must be employed before and after clinical procedures.
- Sterile gloves and Personal protective equipment (PPE) must be used when performing infusion procedures.
- Morbidity and mortality rates associated with VAD associated infections should be reviewed, evaluated and reported on a regular monitored, reviewed basis.

Hand-washing

- Hand-washing should be performed before and immediately after each episode of patient contact.

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- This include clinical procedures, and before putting on and after removing gloves.

Expiry dates

- Medications must not be administered, and products and equipment must not be used beyond their expiry dates.
Cleaning and sterilizing reusable equipment
- All medical equipment, dressings and solutions used during invasive procedures must be sterile.
- All medical equipment such as drip stands, mechanical and electronic infusion devices etc. must be cleaned routinely and following patient use.
- Cleaning should be followed by disinfection, if necessary, in line with local policy.
- Sterilisation and disinfection solutions must be in accordance with manufacturers' guidelines.
- Disinfection solutions must be bactericidal, virucidal, fungicidal, sporicidal and tuberculocidal.
- Single-use devices are meant for single use only and must not be re-used.

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Product defect reporting

- All product defects must be reported in writing to the appropriate department within the organisation & to national regulatory agencies

Documentation

Documentation in the patient's nursing and/or medical record must contain complete information regarding infusion therapy and vascular access, and adverse drug reactions

Documentation of the VAD

- Type of device, size / gauge / length of VAD, number of Lumen.
- The manufacturer, lot/batch and number, and expiry date.
- External catheter length at the insertion site.

Documentation of complications of VAD use

- Document any complications and side-effects of infusion therapy.
- Date, time and situation when complication(s) noted. When using the VAD, Strategies used to manage complications and evaluation of effectiveness.

Add-on devices

- Aseptic technique must be used and standard precautions must be observed for all add-on device changes.

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Manual flow control devices

- The rate of infusions can be routinely regulated by manual flow control devices to ensure accurate delivery of the prescribed therapy.
- The health care professional responsible for monitoring the patient should be accountable for the use of manual flow control infusion devices.
- The health care professional should demonstrate knowledge and competency which has been assessed relative to electronic infusion devices, and is responsible for monitoring the patient and is accountable for the use of electronic flow control infusion devices

Blood/fluid warmers

- Devices used for blood/fluid warming must be specifically designed for that purpose to prevent haemolysis.

Injection and access caps/ports

- Injection and access caps/ports (which include injection caps, needle-free caps, catheter hubs or administration ports integral to an administration set) must be decontaminated using aseptic technique prior to accessing.
- When accessing injection and access caps/ports it must be accomplished by using the smallest gauge, shortest needle that will accommodate the prescribed therapy.
- Primary and secondary solution administration sets used for a continuous infusion must be changed at least every 72 hours and

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immediately upon suspected contamination or when the integrity of the product or system has been compromised.

- Primary and secondary administration sets must be changed using aseptic technique, observing standard precautions and following manufacturers' recommendations.

Insertion site preparation

- Prior to VAD placement / insertion, the intended site should be decontaminated with the appropriate antimicrobial solution using aseptic technique

Device placement

- All vascular access device placements should be for definitive therapeutic and/or diagnostic purposes.
- Aseptic technique must be used and standard precautions should be observed during vascular access device placement.
- Only one vascular access device should be used for each cannulation attempt.

Site care

- Vascular access device site care must be performed using aseptic technique and observing standard precautions, and should coincide with dressing changes.
- When performing site care, observation and evaluation of the device and surrounding tissue, the integrity of the device and security of the connections should be checked and documented.

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Vascular access device removal

- The removal of any vascular access device must only be undertaken by an appropriately trained practitioner and documented.

Good Administration Practices of IV Fluids

- Container must be carefully checked before administration of IV fluid
- Read the instructions on product label carefully
- Read PIL (Product Information Leaflet) before administration
- Pay special attention to compatibility data
- Use standard IV sets for administration
- Ensure single stroke push up for IV set spike at identified location

Conclusion सत्यमेव जयते

- Infusion therapy has increased in complexity over the years.
- These guidelines are intended to help individual practitioners ensure that patients receive the most appropriate care for their individual circumstances.

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To maintain the aforesaid good practices it is recommended that all the persons involved should be well qualified and properly trained at the time of induction and at regular intervals thereafter.

