



1	ईमेल आईडी   Email ID : buyer1.esis.mumbai@gembuyer.in संपर्क   Contact : 022-25645520- जीएसटीआईएन   GSTIN : 27MUMO04429F1D0 पता   Address : Esis hospital LBS marg mulund, MUMBAI, MAHARASHTRA-400080, India	Unbranded Amlodipine	-	175	11-Jun-2024	10-Aug-2024
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### Product Specification for Unbranded Amlodipine

विनिर्देश   Specification	उप-विनिर्देश   Sub-Spec	मूल्य   Value
GENERAL	Product Description	Amlodipine 5 mg
	Conformity to Standard	IP
	Strength	5mg
	Dosage Form	Tablet
	Route of Administration	ORAL
	Shelf Life (in months)	24
CERTIFICATION	Drug Manufacturing License Number	NB-152/84 & SP-96/84
	Drug Manufacturing License Date	14/05/1984
	GMP Certification Number	DCD/SPL-1/CR-63/2021-22
	GMP Certification Date	31/05/2021
	WHO GMP Certification Number	DCD/SPCL/CR170/21-22
	WHO GMP Certification Date	01/06/2021
	Non-conviction Certificate Number	DCD/SPL.CELL/CR-1660/20-21
	Non-conviction Certificate Date	19/02/2021
PACKING	Certification for Manufacturing Premises	NA
	Other Statutory Markings on the Packing of the Drug	STORE PROTECTED FROM MOISTURE
	Primary Packing	10 TABS
	Secondary Packing	10X10 TABS
	Final Packing	320X10X10

**टिप्पणी | Note:** Seller has given an undertaking that it has made arrangements for getting the stores from an authorized distributor / dealer / channel partner of the OEM of the offered product. At the time of delivery of goods, Seller will provide necessary chain documents (in the form of GST Invoice) to prove that the supplied goods are genuine and are being sourced from an authorized distributor / dealer / channel partner of the OEM. In case of any complaint about genuineness of the supplied products, Seller shall be responsible for providing genuine replacement supplies.

### ईपीबीजी विवरण | ePBG Detail

NA

### नियम और शर्तें | Terms and Conditions

#### 1. Special terms and conditions- Version:2 effective from 28-07-2021

##### 1.1 Special Terms and Conditions for 103 Drugs reserved for Central Public Sector Enterprises (CPSEs)

- Pharmaceuticals Purchase Policy by Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, GOI in respect of 103 (one hundred and three) medicines would be valid till the final closure/strategic disinvestment of the pharma PSUs as per OM No. F.No.50017/01/2018-PSU dated 04<sup>th</sup> December, 2019
- Pharmaceuticals Purchase Policy will extend only to Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals and their subsidiaries where Government of India owns 51%(fifty one percent) or above shares.
- The pricing of these drugs would be done by National Pharmaceutical Pricing Authority (NPPA) using the cost based formula as mentioned in the Drugs Price Control Order, 1995 as per the latest amendments. In case the prices are revised by the NPPA, prices will be changed accordingly, and revised rate shall be applicable for all supplies made on or after the date of revision.
- All Provision of Drug & Cosmetic act 1940 as amended till date and rules made there under will always be applicable.

5. CPSEs should hold valid drug license/import License, valid GMP/WHO GMP, valid Non conviction certificates from the concerned drug controller for the manufacturer/import of the medicine/drug. If revalidation of drug license has been applied for, the buyer should be informed accordingly and the copy of application to State Drug/Licensing authority must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date.
6. Loan license arrangement shall not be allowed under any circumstances.
7. Each batch of the drugs shall be dispatched under self-certification scheme duly supported by their own test reports. The consignees shall be at liberty to draw control samples and send it to laboratories approved by the State Drug Controllers / run by State Government/NABL approved laboratories without any intimation to the supplier. If this new test report is contradictory with the test report submitted by CPSE, the cost incurred on the whole process of testing shall be borne by the seller and the whole failed batch will be replaced by the CPSE. Also, if at any stage of use the supplies are found substandard, the whole failed batch will be replaced by the CPSE, even if the supplies have been consumed in good faith and the facts will be notified to the Drug Controller of India / State Drug Controller for taking necessary action.
8. The classification of defects into different categories will as per guidelines issued by the Drug Controller of India and action will be taken accordingly.
9. The supplies should not have passed more than 1/6th of the total shelf life of the product at the time of receipt of the store.
10. It is the responsibility of the seller to intimate Government e-Marketplace (GEM) about any quality complaints of the drugs/medicines reported by any buyer/consignee.
11. Order should be placed for the quantities in multiples of the primary packing.
12. Minimum lead time for delivery will be 45 days.
13. Bar coding - The buyer can opt for bar coding only if the order placed on any CPSE is for minimum quantity of tablet/capsule- 5.0 lakhs numbers or injection- 1.0 lakh number or ointment- 25000 numbers or syrup- 5000 numbers. The bar coding will be GSI complied.
14. Labels of all containers, cartons, vials, strips etc. should invariably be marked in block letters "Government supply not for sale" with the indelible ink for supplies made to the Government.
15. PACKING & MARKING: Packing and Marking will be as per provisions of applicable Pharmacopeia and as specified under Drugs and Cosmetics Act. 1940 as amended to date. In addition-
  1. Primary and Secondary Packing: The store will be supplied in the packing as approved by the NPPA.

Technical Specifications of Primary & Secondary Packing:-

- i. Aluminium/Blister - 25 Micron
- ii. Aluminium/Strip - 30 Micron
- iii. 5 Ply Corrugated Box G.S.M.:- 1) 1st layer,- 240,  
2) 2nd, 4th,- 100 each,  
3) 3rd, 5th,- 80 each,  
B.S.:- NLT 9Kg/cm<sup>2</sup>

- iv. PVC (Rigid PVC film uncoated) - 250 micron

1. PVDC (Rigid PVC film coated with polyvinylidene chloride (PVDC) - 250 micron/60 GSM

Efluite -

G.S.M of layers:-

1. a) White duplex (outer) - 310
2. b) Narrow fluite (semi craft brown):- 100
3. c) Semi craft paper brown: 100

B.S.-: NLT 5 Kg/cm<sup>2</sup>

1. Marking:

Each packing shall also be marked with:

1. a) Manufacturer's name and address.
2. b) Batch No. License No. and date of manufacture and date of expiry.
3. c) Quantity contained therein.
4. d) Any other particulars as specified under Drugs and Cosmetics Act. 1940 as amended to date.

1.2 Special Terms and Condition for 103 Drugs reserved for Central Public Sector Enterprises (CPSEs)

1. Pharmaceuticals Purchase Policy by Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, GOI in respect of 103 (one hundred and three) medicines would be valid for a period of five years from the date of issue of orders (10th Dec 2013).

2. Pharmaceuticals Purchase Policy will extend only to Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals such as Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bangal Chemicals and Pharmaceuticals Limited (BCPL), Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) and their subsidiaries where Government of India owns 51% (fifty one percent) or above shares.

3. This would be applicable to purchases by Central Government Departments, there Public Sector Undertakings, and Autonomous Bodies, etc. This would also be applicable to purchase of medicines by State Governments under Health Programmes funded by Government of India such as the National Rural Health Mission etc.

4. The pricing of these drugs would be done by National Pharmaceutical Pricing Authority (NPPA) using the cost based formula as mentioned in the Drugs Price Control Order, 1995. The latest prices are fixed by NPPA including 16% discount vide F.No. 51017/01/2013-PSU (Vol. II) dated 08.08.2017. In case the prices are revised downward by the NPPA, prices will be changed accordingly and reduced rate shall be applicable for all supplies made on or after the date of reduction.

5. All Provision of Drug & Cosmetic act 1940 as amended till date and rules made there under will always be applicable.

6. In case pharma CPSEs and their subsidiaries fail supply the medicines, the buyer would be at liberty to make purchases from other manufacturers. If the pharms CPSEs or their subsidiaries fail to perform as per the contract, they would also be subject to payment of liquidated damages or any other penalty as per the terms of the contract.

7. Drug License - CPSEs should hold valid drug license/import License from the concerned drug controller for the manufacturer/import of the medicine/drug. If revalidation of drug license has been applied for, the buyer should be informed accordingly and the copy of application to State Drug/Licensing authority must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date and that has been deleted by licensing authority.

8. CPSEs should have valid Good Manufacturing Practice (GMP/WHO-GMP) as per revised schedule M of the Drugs & Cosmetic Rules for indigenous drugs. GMP certificate if revalidated/extended during the bid period, the same to be informed to the buyer.

9. CPSEs should have valid Non-Conviction Certificate from the concerned drug controller.

10. Loan license arrangement shall not be allowed under any circumstances.

11. Each batch of the drugs shall be dispatched under self-certification scheme duly supported by their own test reports. The consignees shall be at liberty to draw control samples and send it to laboratories approved by the State Drug Controllers / run by State Government/NABL approved laboratories without any intimation to the supplier. If the new test report is contradictory with the test report submitted, the cost incurred on the whole process of testing shall be borne by the seller. Also, if at any stage of use the supplies are found substandard, NO PAYMENT will be made for the entire rejected/substandard batch of that particular item, even if the supplies have been consumed in good faith and the facts will be notified to the Drug Controller if India / State Drug Controller for taking necessary action.

12. The classification of defects into different categories will as per guidelines issued by the Drug Controller of India and action will be taken accordingly.

13. Losses if any due to biological deterioration of the product during the shelf life of potency will be made good by the seller.

14. The supplies should not have passed more than 1/6th of the total shelf life of the product at the time of receipt of the store.

15. It is the responsibility of the seller to intimate Government e-Marketplace (GEM) about any quality complaints of the drugs/medicines reported by any buyer/consignee.

16. Order should be placed for the quantities in multiples of the primary packing.

17. Minimum lead time for delivery will be 60 days .

18. Bar coding - The buyer can opt for bar coding only if the order placed on any CPSE is for minimum quantity of tablet/capsule- 5.0 lakhs numbers or injection- 1.0 lakh number or ointment- 25000 numbers or syrup- 5000 numbers. The bar coding will be GSI complied.

19. Labels of all containers, cartons, vials, strips etc. should invariably be marked in block letters "Government supply not for sale" with the indelible ink for supplies made to the Government.

20. PACKING & MARKING: Packing and Marking will be as per provisions of applicable Pharmacopeia and as specified under Drugs and Cosmetics Act. 1940 as amended to date. In addition-

A) Primary and Secondary Packing: The store will be supplied in the packing as approved by the NPPA.

Technical Specifications of Primary & Secondary Packing:-

i. Aluminium/Blister - 25 Micron

ii. Aluminium/Strip - 30 Micron

iii. 5 Ply Corrugated Box G.S.M.:- 1) 1st layer,- 240,

2) 2nd, 4th,- 100 each,

3) 3rd, 5th,- 80 each,

B.S.-: NLT 9Kg/cm<sup>2</sup>

iv. PVC (Rigid PVC film uncoated) - 250 micron V. PVDC (Rigid PVC film coated with polyvinylidene chloride (PVDC) - 250 micron/60 GSM) Efluite - G.S.M of layers:- a) White duplex (outer) - 310 b) Narrow fluite (semi craft brown):- 100 c) Semi craft paper brown: 100 B.S.-: NLT 5 Kg/cm<sup>2</sup>

B) Marking: Each packing shall also be marked with: a) Manufacturer's name and address. b) Batch No. License No. and date of manufacture and date of expiry. c) Quantity contained therein. d) Any other particulars as specified under Drugs and Cosmetics Act. 1940 as amended to date.

1.3 Special Terms and Condition for 103 Drugs reserved for Central Public Sector Enterprises (CPSEs)

- 1.3.1 Pharmaceuticals Purchase Policy by Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, GOI in respect of 103 (one hundred and three) medicines would be valid for a period of five years from the date of issue of orders (10th Dec 2013).
- 1.3.2 Pharmaceuticals Purchase Policy will extend only to Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals such as Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) and their subsidiaries where Government of India owns 51% (fifty one percent) or above shares.
- 1.3.3 This would be applicable to purchases by Central Government Departments, their Public Sector Undertakings, and Autonomous Bodies, etc. This would also be applicable to purchase of medicines by State Governments under Health Programmes funded by Government of India such as the National Rural Health Mission etc.
- 1.3.4 The pricing of these drugs would be done by National Pharmaceutical Pricing Authority (NPPA) using the cost based formula, as mentioned in the Drugs Price Control Order, 1995. The latest prices are fixed by NPPA including 16% discount vide F. No. 51017/01/2013-PSU(Vol. II) dated 08.08.2017. In case the prices are revised downward by the NPPA, prices will be changed accordingly and reduced rate shall be applicable for all supplies made on or after the date of reduction.
- 1.3.5 All Provision of Drug & Cosmetic act 1940 as amended till date and rules made there under will always be applicable.
- 1.3.6 In case pharma CPSEs and their subsidiaries fail to supply the medicines, the buyer would be at liberty to make purchases from other manufacturers. If the pharma CPSEs or their subsidiaries fail to perform as per the contract, they would also be subject to payment of liquidated damages or any other penalty as per the terms of the contract.
- 1.3.7 Drug License –CPSEs should hold valid drug license / import License from the concerned drug controller for the manufacture / import of the medicine/drug. If revalidation of drug license has been applied for, the buyer should be informed accordingly and the copy of application to State Drug / Licensing authority must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date and that has not been deleted by licensing authority.
- 1.3.8 CPSEs should have valid Good Manufacturing Practice (GMP / WHO-GMP) as per revised schedule M of the Drugs & Cosmetic Rules for indigenous drugs. GMP certificate if revalidated/ extended during the bid period, the same to be informed to the buyer.
- 1.3.9 CPSEs should have valid Non-Conviction Certificate from the concerned drug controller.
- 1.3.10 Loan license arrangement shall not be allowed under any circumstances.
- 1.3.11 Each batch of the drugs shall be dispatched under self-certification scheme duly supported by their own test reports. The consignees shall be at liberty to draw control samples and send it to laboratories approved by State Drug controllers / run by State Government/NABL approved laboratories without any intimation to the supplier. If the new test report is contradictory with the test report submitted, the cost incurred on the whole process of testing shall be borne by the seller. Also, if at any stage of use the supplies are found substandard, NO PAYMENT will be made for the entire rejected / substandard batch of that particular item, even if the supplies have been consumed in good faith and the facts will be notified to the Drug Controller of India / State Drug Controller for taking necessary action.
- 1.3.12 The classification of defects into different categories will as per guidelines issued by the Drug Controller of India and action will be taken accordingly.
- 1.3.13 The supplies should not have passed more than 1/6th of the total shelf life of the product at the time of receipt of the store.
- 1.3.14 It is the responsibility of the seller to intimate Government e-Marketplace (GEM) about any quality complaints of the drugs/medicines reported by any buyer/consignee.
- 1.3.15 Order should be placed for the quantities in multiples of the primary packing.
- 1.3.16 Minimum lead time for delivery will be 60 days.
- 1.3.17 Bar coding- The buyer can opt for bar coding only if the order placed on any CPSE is for minimum quantity of tablet/capsule- 5.0 lakhs numbers or injection- 1.0 lakh number or ointment-25000 numbers or syrup -5000 numbers. The bar coding will be GS1 complied.
- 1.3.18 Labels of all containers, cartons, wrappers, vials, strips etc. should invariably be marked in block letters "Government supply not for sale" with the indelible ink for supplies made to the Government.
- 1.3.19 PACKING & MARKING: Packing and Marking will be as per provisions of applicable Pharmacopeia and as specified under Drugs and Cosmetics Act. 1940 as amended to date. In addition-
- 1.3.19.1 Primary and Secondary Packing: The stores will be supplied in the packing as approved by the NPPA.
- 1.3.19.1.1 Technical Specifications of Primary & Secondary Packing:-
- Aluminium / Blister - 25 Micron
  - Aluminium / Strip - 30 Micron
  - 5 Ply Corrugated Box G.S.M.: -
    - 1st layer: - 240 ,
    - 2nd, 4th, - 100 each,
    - 3rd, 5th, - 80 each,B.S.: - NLT 9Kg / cm<sup>2</sup>
  - PVC (Rigid PVC film uncoated) - 250 micron
  - PVDC (Rigid PVC film coated with polyvinylidene chloride (PVDC) - 250 micron / 60 GSM
- 1.3.19.1.2 Efluite -
- G.S.M of layers: -
- White duplex (outer) 310
  - Narrow fluite (semi craft brown): - 100
  - Semi craft paper brown: 100
- B.S.: - NLT 5 Kg / cm<sup>2</sup>.
- 1.3.19.2 Marking :
- 1.3.19.2.1 Each packing shall also be marked with:
- Manufacturer's name and address.
  - Batch No. License No. and date of manufacture and date of expiry.
  - Quantity contained therein.
  - Any other particulars as specified under Drugs and Cosmetics Act. 1940 as amended to date.

2. General Terms and Conditions-

- 2.1 This contract is governed by the [General Terms and Conditions](#), conditions stipulated to this Product/Service as provided in the Marketplace.
- 2.2 This Contract between the Seller and the Buyer, is for the supply of the Goods and/ or Services, detailed in the schedule above, in accordance with the General Terms and Conditions (GTC) unless otherwise superseded by Goods / Services specific Special Terms and Conditions (STC) and/ or BID/Reverse Auction Additional Terms and Conditions (ATC), as applicable

नोट: यह सिस्टम जनरेटेड फाइल है। कोई हस्ताक्षर की आवश्यकता नहीं है। इस दस्तावेज़ का प्रिंट आउट भुगतान/लेनदेन उद्देश्य के लिए मान्य नहीं है।

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