

KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LTD.

(A GOVT. OF INDIA ENTERPRISE)

Materials Dept.: Arka The Business Centre, Plot No 37 ,NTTF Main Road, Peenya Industrial Area, 2nd Phase Bengaluru-560058

CIN No: U24231KA1981GOI004145 PHONE 080 23571590

Website: www.kaplindia.com



OPEN TENDER ENQUIRY: TENDER NO. KAPL/QAD/020/2125

TENDER ENQUIRY FOR 25MMX4.6MMX5Um, ODS, PORUS SILICA AT Karnataka Antibiotics and Pharmaceuticals Ltd (herein after "KAPL"), BENGALURU

This tender document contains 14 Pages

Tender Enquiry No.	KAPL/QAD/020/2125
Tender issuing date	30.12.2024
Pre-bid meeting date & time	Not Applicable
Due date & time for bid submission	06.01.2025 till 13.00 Hrs.
Mode of bid submission	TWO BID SYSTEM
Type of tender	OPEN TENDER ENQUIRY (OTE)
Details of contact person	Deputy Manager (Materials) 080-23571590/255

Registered & Corporate Office:

Arka The Business Centre

Plot No 37, NTTF Main Road

Peenya Industrial Area, 2nd Phase

Bengaluru-560058

Telephone No. 080 – 23571590

email: hodpurchase@kaplindia.com/hodpurchase@kaplindia.com

website: www.kaplindia.com

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SECTION I: NOTICE INVITING TENDER

1. E-tenders are invited from eligible and qualified tenderers for supply of following goods:

Schedule No.	Brief Description of Goods / Services	Quantity (Nos.)	Remarks
01	25MMX4.6MMX5Um ,ODS PORUS SILICA	01 Nos.	TWO-BID SYSTEMS COMMERCIAL & TECHNICAL SEPARATE ENVELOP COVER
02	HPLC COLUMN 30CMX3.9MM,10MIC,C18 BONDED TO SILIC	01Nos.	
03	SUNFIRE C18 COLUMN,100A, 5Um,4.6MMX25 CM	01NoS	

2. Procedure for bid submission:

- Interested bidders may obtain further information about this requirement from the above office selling the documents. They may also visit our website purenep@kaplindia.com mentioned above for further details.
 - Quotation must be submitted in two sealed covers (TECHNICAL & COMMERCIAL BID) separately and to be placed in one envelop else your proposal will not be considered.
- The tenderer shall satisfy KAPL that they are competent and authorized to submit tender and/or to enter into a legally binding contract with the KAPL. To this effect, any person giving a tender shall render documentary evidence that his signature on the tender submitted by him is legally binding upon himself, his firm or company as the case may be.
 - For those tenderers whose technical bids do not satisfy the eligibility criteria, their financial Bids will not be opened.
 - In the event of any of the above-mentioned dates being declared as a holiday/ closed day for the purchase organization, the tenders will be sold / received / opened on the next working day at the appointed time.
 - KAPL reserves the right to cancel the tender at any stage without assigning the reasons thereof.

Yours faithfully,

For and on behalf of KAPL

Deputy General Manager

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SECTION II : TERMS AND CONDITIONS OF THE TENDER

1. Tenders are to be uploaded on e-tendering portal puren@kaplindia.com only in Two part bid system.
2. **Part-I – Prequalification Bid & Techno-commercial Bid:** Scanned copy of Technical offer (catalogue/brochure etc.), GST, PAN, Bank details etc., along with all sections & annexures of this tender.
3. **Delivery Schedule:** Successful bidder shall complete supply of entire material as per purchase order within **4 weeks** from the date of issue of purchase order.
4. **Security Deposit / Performance Security: -**
 - a. Within 21 days after the issue of notification of award by KAPL, the supplier shall furnish performance security to KAPL for an amount equal to (5%) five per cent of the total value of the contract.
 - b. The Performance security shall be denominated in Indian Rupees or in the currency of the contract and shall be in one of the following forms:
 - i. Account Payee Demand Draft drawn on any commercial bank in India, in favour of Karnataka Antibiotics and Pharmaceuticals Limited.
 - ii. Fixed Deposit (FDR) from a scheduled commercial bank in India;
 - iii. Online payment in an acceptable form.
5. As on the date of submission of bid against this tender, bidder should not be in the list of ineligible/ blacklisted/ banned/ debarred entity by KAPL/any Government Agency for participating in its tenders.
6. Bidder may visit KAPL , before submitting the offer after taking due permission for visiting to understand the requirements.
7. No counter conditions shall be accepted.
8. Bidders are advised to write the page number on each page of the Technical Bid documents submitted.
9. The KAPL reserves the right to accept the offer by individual items and reject any or all tenders without assigning any reason thereof and does not bind itself to accept lowest quotations.
10. Manufacturer's name and country of origin of materials offered must be clearly specified. Please quote whether your organization is large scale industry or small scale industry. If you have NSIC/MSE/MSI/DGS&D Certificate, please attach it to the quotation. Mention your

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registration details.

11. Complete details and ISI specification if any must accompany the quotation. Make/brand of the item shall be stated wherever applicable. If you have got any counter offer as suitable to the material required by us, the same may be shown separately.
12. All drawings sketches and samples, if any, sent along with this enquiry must be returned along with quotations duly signed.
13. All supplies are subject to inspection and approval before acceptance. Manufacturer/ supplier warranty certificates and manufacturer/Government approved lab test certificate shall be furnished along with the supply, wherever applicable.
14. The KAPL reserves the right to modify the quantity specified in this enquiry.
15. The prices quoted should be firm till the supplies are completed. Please quote the rates in words and figures. Rates quoted should be door deliver basis at destination including all charges otherwise the quotation is likely to be rejected. Prices quoted for free delivery at destination (i.e., Bengaluru) will be given preference. If there is no indication regarding the FOR, in the quotation, then it will be considered as FOR destinations. Price quoted should be net and valid for a minimum period of three months from the date of opening of the quotation.
16. (i) The technical bids shall be opened in the first instance and these bids shall be scrutinized and evaluated by the competent committee/ authority with reference to the parameters prescribed in the tender document. Subsequently, in the second stage the financial bids of only technically acceptable offers as decided in first stage shall be opened for further scrutiny and evaluation. Intimation regarding opening of financial bids shall be given to acceptable tenderers to enable them to attend the financial bid opening, if they so desire.
 - ii) The method of evaluation of bidder for awarding the contract shall be on basis of overall lowest bidder (L1) for delivery up to KAPL, Bengaluru.
 - (iii) All responsive tenderers shall be evaluated as per the terms & conditions of the tender. The basis for arriving at the lowest responsive bidder shall be as per the price quoted for landed cost at Bengaluru including GST, packing & forwarding charges, freight, insurance and any other charges etc. and input credit shall be deducted to arrive at the effective price. Effective price shall be considered for arriving the lowest responsive bidder.
 - (v) Bidder has to quote GST rate as per the HSN code provided in Section XI: Price Schedule. In case of any mismatch in HSN code with respect to offered product, same shall be decided in consultation

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with winning bidder

17. Payment of GST is primarily the responsibility of the seller and will not be paid unless the percentage value is clearly mentioned in the quotations. If no indication regarding GST is recorded in the quotation, the GST will be considered as included.
18. Delivery period required for supplying the material should be invariably specified in the quotation.
19. **Liquidated Damage:** In case your quotation is accepted and order is placed on you, the supply against the order should be made within the period stipulated in the order. KAPL reserves the right to recover any loss sustained due to delayed delivery by way of penalty. Failure to supply the material within the stipulated period shall entitle KAPL to impose liquidated damages without assigning any reasons @ 0.5% (Half Percent) of the total value of the item covered in order as LD per week or part thereof subject to a **maximum of 10%** (Ten Percent) which you unconditionally and expressly agree to unless extension is obtained in writing from the office on valid ground before expiry of delivery period.
20. **Risk Purchase Clause:** If the deliveries are not maintained and due to that account KAPL is forced to buy the material at your risk and cost from elsewhere after due notice to you, the loss or damage that may be sustained there by will be recovered from the defaulting supplier.
21. **Payment terms:** 100% (Hundred Percent) within 30 (Thirty) days on receipt and acceptance of entire material as per purchase order at destination and on production of all necessary documents.
22. **Settlement of Disputes through Arbitration:** In case of a dispute between the Bidder & KAPL, all possible attempts should be made to settle such dispute activities by & between the parties. In case the dispute could not be settled mutually by & between the parties the same would be settled by an Arbitration Proceeding strictly in compliance with the Arbitration & Conciliation Act, 1996.
The Managing Director of KAPL reserves exclusive right to appoint the Arbitrator & the decision of the Arbitrator will be final & binding on all the parties.
23. **Legal Jurisdiction:** The Courts of Bengaluru (Karnataka State) shall alone have jurisdiction to decide on any legal matter of dispute whatsoever arising out or in respect of the contract.
24. **Force Majeure:** In the event of any unforeseen event directly interfering with the supply of stores arising during the currency of the contract, such as war, hostilities, acts of the public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes, lockouts, or acts of God, the Contractor shall, within a week from the commencement thereof, notify the same in writing to the Purchaser with reasonable evidence thereof. Unless otherwise directed by KAPL in writing, the supplier shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event. If the force majeure condition(s)

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mentioned above be in force for a period of 90 days or more at any time, either party shall have

Signature & Seal		Name of Authorized	
Place & Date:		Signatory:	

the option to terminate the contract on expiry of 90 days of commencement of such force majeure by giving 14 days' notice to the other party in writing. In case of such termination, no damages shall be claimed by either party against the other, save and except those which had occurred under any other clause of this contract prior to such termination.

25. **Fore-Closure Clause:** If at any time during the continuation of this contract, the use of material ordered in this contract is completely banned or due to drastic change in Government policy its use as, raw material is discontinued or is declared hazardous to public health or cause rising to civil commotion, epidemics, wide-spread strikes and 21 days' notice of such eventualities is given by purchaser to the seller, the seller without any right to enforce the contract, will agree to the fore-close the performance of balance portion of this contract and in that event no claim for damages or loss will be lodged against the purchaser.
26. **Rights of Rejection:** KAPL reserves the right to reject any or all the applied bids without assigning any reason whatsoever.
27. **Preference for Micro and Small Enterprises (*MSEs):** Public procurement policy for Micro and Small Enterprises (MSEs) order, 2012 as notified by Govt of India (GOI) along with its amendments as available in www.msme.gov.in shall be applicable to this tender.
28. I/we engage to supply the material(s) to your engineering store, KAPL and comply the following:
 - a) Tender schedule and technical specification indicated.
 - b) Item/tender specific conditions for this tender.
 - c) Terms and conditions enclosed.
 - d) General conditions of contract signed by me at the time of supplier registration (for registered suppliers/ enclosed).
 - e) I/we confirm that set off for the GST, etc. Paid on the inputs have been taken into consideration in the above quoted price and further agree to pass on such additional duties as sets offs as may become available in future under GST, etc.
 - f) This offer is valid for 90 (Ninety) days from the date of opening of the tender.
 - g) That as on the date of submission of bid against this tender we are not in the list of ineligible/ blacklisted/ banned/ debarred entity by KAPL/any Government Agency, for participating in its tenders. (Annexure-B enclosed)
 - h) That the rates quoted are not higher than the rates quoted for same item to KAPL and anyother Government/ Undertakings.

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Address:		Tel. No./Fax. No./Mobile No. Email Id:	
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SECTION IV: QUALITY CONTROL REQUIREMENTS & COMPLIANCE STATEMENT

- Quality:** Quality is essence of this tender. The bidder shall supply the material as per the specifications mentioned in Technical & Material Specifications. The material supplied will be inspected at our factory. Quantity as ascertained on receipt of above material at our site will be treated as quantity supplied wherever the package/materials are received intact.
- Rejection:** Materials not meeting our specification will be rejected outright and the rejected material shall be taken back within 7 days at the cost and risk of the supplier and replacement should be made within 15 days from the date of intimation. No payment shall be made for rejected item.

A) Technical Compliance Statement:

S. No.	Technical Specifications	Whether agreed by the bidder	Deviation if any
1	25CMX4.6MMX5Um, ODS POROUS SILICA	01	
2	HPLC COLUMN 30CMX3.9MM, 10MIC, C18 BONDED TO SILICA	01	
3	SUNFIRE C18 COLUMN, 100A, 5Um, 4.MMX25CM	01	

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IP/2022

DEXTROMETHORPHAN HYDROBROMIDE

Heavy metals (2.3.13). 0.5 g complies with the limit test for heavy metals, Method A (40 ppm).

Chlorides (2.3.12). Dissolve 2.5 g in 50 ml of boiling water; cool, dilute to 100 ml with water and filter. 5 ml of the filtrate diluted to 15 ml complies with the limit test for chlorides (0.2 per cent).

Ethanol-soluble substances. Not more than 1 per cent, determined by the following method. Boil under a reflux condenser 1 g with 20 ml of ethanol (95 per cent) for 5 minutes and filter while hot. Evaporate 10 ml of the filtrate on a water-bath, dry the residue at 105° and weigh.

Protein. Not more than 0.5 per cent, determined by the following method. Carry out Method A for the determination of nitrogen (2.3.30), using 5 g, weighed, and 30 ml of nitrogen-free sulphuric acid. Calculate the content of protein by multiplying the percentage of nitrogen in the substance under examination by 6.25.

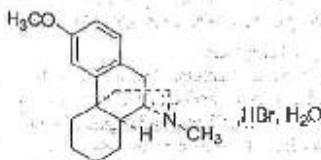
Reducing substances. Not more than 10 per cent, calculated as dextrose, $C_6H_{12}O_6$, determined by the following method. Weigh a quantity containing 2 g of the dried substance, add 100 ml of water, shake for 30 minutes, dilute to 200.0 ml with water and filter. To 10 ml of cupri-tartrate solution add 20.0 ml of the filtrate, mix and heat at a rate such that the solution is brought to boil in 3 minutes. Boil for a further 2 minutes and cool quickly. Add 5 ml of a 30 per cent w/v solution of potassium iodide and 10 ml of 1 M sulphuric acid, mix and titrate immediately with 0.1 M sodium thiosulphate using starch solution, added towards the end of the titration, as indicator. Repeat the procedure using 20.0 ml of a 0.1 per cent w/v solution of ascorbic acid in place of the filtrate beginning at the words "To 10 ml of...". Carry out a blank titration using 20 ml of water in place of 20.0 ml of the sample filtrate. The blue obtained with the sample filtrate, is not greater than the blue obtained with the dextrose solution.

Ash (2.3.19). Not more than 1 per cent.

Loss on drying (2.4.19). Not more than 12 per cent, determined as 1.0 g by drying in an oven at 110°.

Storage. Store protected from moisture.

Dextromethorphan Hydrobromide



$C_{17}H_{23}NO_2 \cdot HBr \cdot H_2O$

Mol. Wt. 370.3

Dextromethorphan Hydrobromide is *enantiomer*-3-methoxy-9 α -methylmorphinan hydrobromide monohydrate.

Dextromethorphan Hydrobromide contains not less than 99.0 per cent and not more than 101.0 per cent of $C_{17}H_{23}NO_2 \cdot HBr$ calculated on the anhydrous basis.

Category. Cough suppressant.

Description. An almost white crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with dextromethorphan hydrobromide IPRS or with the reference spectrum of dextromethorphan hydrobromide.

B. When examined in the range 230 nm to 360 nm (2.4.7), a 0.01 per cent w/v solution in 0.1 M hydrochloric acid shows an absorption maximum only at 278 nm.

C. It gives the reaction of bromides (2.3.1).

Tests

Appearance of solution. A 5.0 per cent w/v solution in ethanol (95 per cent) is clear (2.4.1), and colorless (2.4.1).

Acidity or alkalinity. Dissolve 0.4 g in carbon dioxide-free water with gentle heat, cool and dilute to 20 ml with the same solvent. Add 0.1 ml of methyl red solution and 0.2 ml of 0.01 M sodium hydroxide. The solution is yellow and not more than 0.4 ml of 0.01 M hydrochloric acid is required to change the colour to red.

Specific optical rotation (2.4.22). +28.0° to +30.0°, determined in a 2.0 per cent w/v solution in 0.1 M hydrochloric acid.

N,N-Dimethylaniline. Dissolve 0.5 g in 20 ml water with the help of gentle heat on a water-bath, cool and add 2 ml of 2 M acetic acid, 1 ml of a 1 per cent w/v solution of sodium nitrite and sufficient water to produce 25 ml. The resulting solution is not more intensely coloured than that obtained by treating at the same time and in the same manner a solution containing 5 µg of N,N-dimethylaniline in 20 ml of water.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE - Use freshly prepared solutions.

Test solution. Dissolve 10 mg of the substance under examination in the mobile phase and dilute to 10.0 ml with the mobile phase.

Reference solution (a). Dissolve 2 mg of dextromethorphan impurity A IPRS in 2 ml of the test solution and dilute to 25.0 ml with the mobile phase.

Reference solution (b). Dilute 1.0 ml of the test solution to 200.0 ml with the mobile phase.

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DEXTRAMETHORPHAN HYDROBROMIDE

IP 2002

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: dissolve 3.11 g of *dicussate sodium* in a mixture of 400 ml of water and 600 ml of *acetonitrile*. Add 0.56 g of *sodium nitrate*, adjusted to pH 2.0 with *glacial acetic acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 20 µL

1 ml of 0.1 M *sodium hydroxide* is equivalent to 0.03523 g of $C_{17}H_{25}NO_2 \cdot HBr$.

Storage: Store protected from light.

Name	Relative retention time	Correction factor
Dexamethorphan impurity B ¹	0.4	—
Dexamethorphan impurity C ²	0.8	0.2
Dexamethorphan impurity D ³	0.9	—
Dexamethorphan (Retention time is about 22 minutes)	1.0	—
Dexamethorphan impurity A ⁴	1.1	—

¹anti-17-methylmorphinan-3-ol,

²anti-3-methoxy-17-methylmorphinan-10-one,

³anti-(14S)-3-methoxy-17-methylmorphinan,

⁴anti-3-methylmorphinan.

Inject reference solution (a). The test is not valid unless the resolution between the peaks due to dexamethorphan and dexamethorphan impurity A is not less than 1.5.

Inject reference solution (b) and the test solution. Run the chromatogram twice the retention time of the principal peak. In the chromatogram obtained with the test solution the area of any peak due to dexamethorphan impurities A, B, C and D, each of, is not more than the area of the principal peak in the chromatogram obtained with reference solution (0.5 per cent) and the area of not more than one such peak has an area greater than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (0.25 per cent), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of the areas of all the secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Sulphated ash (2.3.18). Not more than 0.1 per cent

Water (2.3.43). 4.0 to 5.5 per cent, determined on 0.2 g

Assay. Dissolve 0.3 g in 20 ml of *ethanol* (95 per cent) and titrate with 0.1 M *sodium hydroxide*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

Dexamethorphan Hydrobromide Syrup

Dexamethorphan Hydrobromide Syrup is a solution of Dexamethorphan Hydrobromide in a suitable flavoured vehicle.

Dexamethorphan Hydrobromide Syrup contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of dexamethorphan hydrobromide, $C_{17}H_{25}NO_2 \cdot HBr \cdot H_2O$.

Usual strength: 13.5 mg in 5 ml.

Identification

A. To 50 ml, add 20 ml of water, 5 ml of 2.5 M *sodium hydroxide* and extract with three quantities, each of 40 ml of *hexane*, collect the *hexane* layer and filter through *anhydrous sodium sulphate* placed over absorbent cotton wetted with *hexane*. Evaporate the combined extracts at 50° under nitrogen to dryness, dissolve and dilute the residue in 10 ml of *chloroform*; the solution is dextrorotatory (2.4.22). Retain the *chloroform* solution for test B.

B. Evaporate the *chloroform* solution obtained from test A to a water-bath to dryness, dissolve the residue in 2 ml of 1 M *sulphuric acid* and add 1 ml of a solution prepared freshly by dissolving 700 mg of *mercuric nitrate* in 4 ml of water, adding 100 mg of *sodium nitrate*, mixing and filtering; the solution gives no colour, but after heating, a yellow to red color develops in about 15 minutes.

Tests

Other tests. Comply with the tests stated under Oral Liquid.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a volume of the syrup containing about 10 mg of Dexamethorphan Hydrobromide to 100.0 ml with water.

Reference solution. A 0.01 per cent w/v solution of *dexamethorphan hydrobromide IPRS* in water.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a filtered and degassed solution of 0.007 M *sodium nitrate* in a mixture of 70 volumes of *acetonitrile* and 30 volumes of water, adjusted to pH 3.4 with *glacial acetic acid*,

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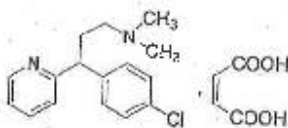


4P 2022

CHLORPHENIRAMINE INJECTION

Labelling. The label states that the preparation is meant for external use only.

Chlorpheniramine Maleate



$C_{16}H_{19}ClN_2C_4H_4O_4$

Mol. Wt. 319.9

Chlorpheniramine Maleate is (RS)-3-(4-chlorophenyl)-1-(pyridin-2-yl)propyl dimethylamine hydrogen maleate

Chlorpheniramine Maleate contains not less than 98.0 per cent and not more than 101.0 per cent of $C_{16}H_{19}ClN_2C_4H_4O_4$, calculated on the dried basis.

Category. Antihistaminic.

Description. A white, crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with chlorpheniramine maleate IPRS or with the reference spectrum of chlorpheniramine maleate.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Appearance of solution. A 10.0 per cent w/v solution is clear (2.4.1), and not more intensely colored than reference solution DYS6 (2.4.1).

pH (2.4.24). 4.0 to 5.0, determined in a 1.0 per cent w/v solution.

Related substances. Determine by thin-layer chromatography (2.4.17), coating the plate with silica gel GF254.

Mobile phase. A mixture of 50 volumes of cyclohexane, 40 volumes of chloroform and 10 volumes of diethylamine.

Test solution. A 5.0 per cent w/v solution of the substance under examination in chloroform.

Reference solution. Dilute 1.0 ml of the test solution to 100.0 ml with chloroform and mix. Dilute 5.0 ml of the resulting solution to 25.0 ml with chloroform.

Apply to the plate 10 μ l of each solution. After development, dry the plate in air and examine under ultraviolet light at 254 nm. Any secondary spot in the chromatogram obtained

with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution. Ignore any spot remaining on the line of application.

Sulphated ash (2.3.14). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 50 mg of the substance under examination in the mobile phase and dilute to 50.0 with the mobile phase. Dilute 10.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution. A 0.02 per cent w/v solution of chlorpheniramine maleate IPRS in the mobile phase.

Chromatographic system

- a stainless steel column 30 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (10 μ m).
- column temperature: 25°.
- mobile phase: a mixture of 20 volumes of acetonitrile and 80 volumes of a buffer solution prepared by dissolving 8.57 g of ammonium dihydrogen phosphate in 1000 ml of water, adjusted to pH 3.0 with orthophosphoric acid and filter.
- flow rate: 1.2 ml per minute.
- spectrophotometer set at 225 nm.
- injection volume: 20 μ l.

The retention time of principal peak is about 11 min. test.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.6 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{16}H_{19}ClN_2C_4H_4O_4$.

Storage. Store protected from light and moisture.

Chlorpheniramine Injection

Chlorpheniramine Maleate Injection

Chlorpheniramine Injection is a sterile solution of Chlorpheniramine Maleate in Water for Injections free from dissolved air and containing suitable buffering and stabilising agents.

Chlorpheniramine Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of chlorpheniramine maleate, $C_{16}H_{19}ClN_2C_4H_4O_4$.

Usual strength. 10 mg in 1 ml.

Description. A colourless solution.

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(A GOVT. OF INDIA ENTERPRISE)

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CIN No: U24231KA1981GOI004145 PHONE 080 23571590

Website: www.kaplindia.com



ANALYTICAL METHODOLOGY

Product Name:-	Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Syrup-100 mL
Label Claim:-	Each 5 mL of Syrup Contains: Dextromethorphan Hydrobromide IP.....10 mg Chlorpheniramine Maleate IP..... 4 mg Flavoured Syrup Base..... Q.S

Pharmacopeia status: IN-HOUSE

Identification Test for Dextromethorphan Hydrobromide -

The retention times of the peaks of the Dextromethorphan Hydrobromide sample solution corresponds to those of the standard solution, as obtained in the Assay

Identification Test for Chlorpheniramine Maleate -

The retention times of the maleic acid and Chlorpheniramine peaks of the sample solution corresponds to those of the standard solution, as obtained in the Assay

ASSAY for Dextromethorphan Hydrobromide and Chlorpheniramine Maleate -

By HPLC-In-House Method

Solution A: 5.44 g/L of monobasic potassium phosphate, pH adjusted to 3.00 with phosphoric acid.

Solution B: Acetonitrile.

Diluent: Acetonitrile and Solution A (5:95)

Standard Solution: - Weigh accurately 100 mg of Dextromethorphan Hydrobromide working standard and 40 mg of Chlorpheniramine Maleate into a 100 mL clean & dry volumetric flask, add about 70 mL diluent and sonicate for 5 min, allow to equilibrate to room temperature and dilute to volume with diluent & mix.

Further dilute 5 mL of above solution to 50 mL, with diluent.

Sample solution: - Weigh equivalent to 5 mL of syrup into a 100 mL of clean & dry volumetric flask, add about 70 mL diluent and sonicate for 10 min with vigorous intermittent shaking, allow to equilibrate to room temperature and dilute to volume with diluent & mix, filter through nylon syringe filter (0.45 µ) discard first 3 mL of the filtrate.

Mobile Phase: See Below Table

Time (min)	Solution A (%)	Solution B (%)
0	95	5
1	95	5
20	70	30
30	70	30
31	95	5
40	95	5

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Chromatographic System	
Column	Stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous polymer (5 µm) (Sunfire C18 is Suitable)
Flow rate	1 mL per minute
Column Temperature	25°C
Injection volume	20 µL
Wavelength	225 nm
Mobile Phase (Gradient Technique)	Solution A: - 5.44 g/L of monobasic potassium phosphate, pH adjusted to 3.00 with phosphoric acid. Solution B: - Acetonitrile.

Calculation-

Assay-

$$\frac{\text{Area Sample}}{\text{Standard Area}} \times \frac{\text{STD. WL.}}{\text{Dilution (standard)}} \times \frac{\text{Dilution (sample)}}{\text{SPL. WL.}} \times \frac{\text{Std Potency}}{100} \times \frac{\text{Wt./mL}}{\text{Label Claim (mg/mL)}} \times 100$$

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B) Commercial Compliance Statement

Sl. No.	Features	Requirements of KAPL, Terms & conditions	Whether Agreed by the firm	Deviation, if any
1	Payment Terms	As mentioned in Sl.No.22 of Section II	Yes agreed	
2	Liquidated Damages	As mentioned in Sl.No.20 of Section II	Yes agreed	

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3	Risk Purchase	As mentioned in SI No.21 of Section II	Yes agreed	
4	No. of pages	Total number of pages in Technical Bid		

ANNEXURE –A

Any bidder from a country which shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (The Registered Committee constituted by the Department for Promotion of Industry and Internal Trade)

- I) Bidder means any person or firm or company, including any member of a consortium or joint venture (that is an association of several persons, or firms, or companies), every artificial judicial person not falling in any of the descriptions of bidders stated hereinbefore, including any agency branch or office controlled by such person participating in a procurement process.
 - II) “Bidder from a country which shares a land border with India” for the purpose of this order means:-
 - a) An entity incorporated, established or registered in such a country; or
 - b) A subsidiary controlled through entities incorporated, established or registered in such a country, or
 - c) An entity substantially controlled through entities incorporated, established or registered in such a country, or
 - d) An entity whose beneficial owner is situated in such a country; or
 - e) An India (or other) agent of such an entity; or
 - f) A natural person who is a citizen of such a country; or
 - g) A consortium or joint venture where any member of the consortium or joint venture falls under any of the above.
 - III) The beneficial owner for the purpose of (ii) above will be as under :-
 - 1) In case of a company or limited liability partnership, the beneficial owner is the natural person (s), who, whether acting alone or together, or through one or more judicial person, has a controlling ownership interest or who exercise control through other means.

Further explanation:

 - a) “Continuing ownership interest” means ownership of or entitlement to more than twenty five per cent of shares or capital or profits of the company;
 - b) “Control” shall include the right to appoint majority of the director or to control the management or policy decision including by virtue of their shareholding or management rights or shareholder agreements or voting agreements;
 - 2) In case of partnership firm, the beneficial owner is the natural person(s) who, whether acting alone

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or together, or through one or more judicial person, has ownership of entitlement to more than fifteen percent of capital or profits of the partnership;

- 3) In case of an unincorporated association or body of individuals, the beneficial owner is the natural person(s), who, whether acting alone or together, or through one or more judicial person, has ownership of or entitlement to more than fifteen percent of the property or capital or profits of such association or body of individuals;
- 4) Where no natural person is identified under (1) or (2) or (3) above, the beneficial owner is the relevant natural person who holds the position of senior managing official;
- 5) In case of a trust, the identification of beneficial owners(s) shall include identification of the author of the trust, the trustee, the beneficiaries with fifteen percent or more interest in the trust and any other natural person exercising ultimate effective control over the trust through a chain of control or ownership

IV) An agent is a person employed to do any act for any another, or to represent another in dealings with tired person.

V) The successful bidder shall not be allowed to sub contract works to any contractor from a country which shares a land border with India unless such contractor is registered with the Competent Authority.

vi) A bidder is permitted to procure raw material, components, sub-assemblies etc. from the vendors from countries which shares a land border with India. Such vendors will not be required to be registered with the competent authority, as it is not regarded as sub-contracting.

vii) However, in case a bidder has proposed to supply finished goods procured directly/indirectly from the vendors from the countries sharing land border with India, such vendor will be required to be registered with the competent authority.

VII) The registration shall be valid at the time of submission of bid and at the time of acceptance of bid.

Bidder to furnish stipulated documents is support of fulfilment of qualifying criteria. Non-submission or incomplete submission of documents may lead to rejection of offer.

All experience, past performance and capacity/ capability related/ data should be certified by the authorized signatory of the bidder firm. The credentials regarding experience and past performance to the extent required as per eligibility criteria submitted by bidder may be verified from the parties for whom work has been done.

We confirm that, we are competent and legally authorized to submit the tender and / or to enter into legally binding contract.

We (Name of the company) have submitted the required documents in support of the eligibility criteria mentioned above.

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Authorized Signature with stamp & date

ANNEXURE -A1

Tender No: KAPL/QAD/020/2125 dated 30.12.2024

(To be submitted on Company letterhead)

DECLARATION

I have read the clause regarding restrictions on procurement from a bidder of a country which shares a land border with India. I hereby certify that, M/s.....is not from such a country or, if from such a country, has been registered with the Competent Authority. I hereby certify that M/s fulfills all requirements in this regard and is eligible to be considered." (Where applicable, evidence of valid registration by the Competent Authority shall be attached.)

I, the undersigned, declare that the item originate in.....(Name of the country).

Signature _____

Name-----

Designation-----

Date-----

Stamp of the Organization-----

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ANNEXURE -B

e-Tender No: KAPL/QAD/020/ 2125 dated 30.12.2024

(To be submitted on the letterhead)

DECLARATION

I) We do hereby declare that,

1. We do hereby declare that as on the date of submission of bid against this tender we are not in the list of ineligible/ blacklisted/ banned/ debarred entity by KAPL/any Government Agency, for participating in its tenders.

Further, we agree, in case we get blacklisted/ banned/ debarred by KAPL/any Government Agency, any time prior to finalization of tender/ contract, our bid shall not be considered for further evaluation/ award of order.

2. The director/proprietor of the bidding firm are not closely related to KAPL.

In case, at any time the information furnished is found to be false, you may disqualify/ debar me/ us as deemed fit.

II) We do hereby declare that we have read and understood all terms and conditions of tender document including GIT, SIT, GCC, SCC, Technical Specification, Quality Control Criteria and confirm to abide to those conditions without any counter conditions.

Signature _____

Name-----

Designation-----

Date-----

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Stamp of the Organization-----

ANNEXURE C

e-Tender No: KAPL/QAD/020/2125 dated 30.12.2024

(To be submitted on the letterhead)

We, the undersigned, declare that we will automatically be suspended from being eligible for bidding in any tender with KAPL, Bengaluru for the period of 12 months, if we are withdrawing our Bid during the period of bid validity (or) fail / refuse to furnish the performance security / execute the contract, if awarded.

Signature _____

Name-----

Designation-----

Date-----

Stamp of the Organization-----

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SECTION V: PRICE BID FORMAT (TO BE FILLED ONLINE THROUGH E-TENDER PORTAL)

Dear Sir

Sub: PRICE BID FOR ENCLOSURES AT KAPL, BENGALURU

Ref: Tender No: KAPL/QAD/020/2125 dated 30.12.2024

We have received and understood the above tender enquiry and are pleased to submit our price bid as under:

Sch. No.	Description	UOM	Qty	HSN/SAC	Basic Unit price (INR)	P&F, Freight & Transit Insurance & any other charges (if any) per unit (INR)	Unit Price (incl. of P&F, Freight, Transit Insurance & any other charges (if any) excl. of GST) (INR)	GST (%)	GST on Unit Price (INR)	Total Unit Price (incl. of GST) (INR)	Less: Input Credit (GST) (INR)	Effective Unit Price (net of input tax credit) (F.O.R Bengaluru) (INR)	Total Effective price (net of input tax credit) (F.O.R Bengaluru) (INR)
			A		B	C	D=B+C	E	F=D*E	G=D+F	H=F	I=G-H	J=I*A
	Supply of Polycarbonate		15	TO BE SUBMITTED IN E-TENDER PORTAL ONLY									
1.	25MMX4.6MM X5um, ODS PORUS SILICA	Nos	01	<div style="position: relative; width: 100%; height: 100%;"> X </div>									
2.	HPLC COLUMN 30CMX3.9MM, 1010MIC, C 18 BONDED TO SILICA	Nos	01										
3.	SUNFIRE C18 COLUMN, 100A, 5Um, 4. MMX25CM	Nos	01										
												Page 14 of 14	
Total effective price (net of input tax credit) for Supply of Polycarbonate Enclosures with freight, P&F, Transit Insurance and any other charges (F.O.R – KAPL, Bengaluru site) in Figures (INR)													
Total effective price (net of input tax credit) for Supply of Polycarbonate Enclosures with freight, P&F, Transit Insurance and any other charges (F.O.R – KAPL, Bengaluru site) (in words) (INR)													

Note: Prices quoted above shall be FOR KAPL, Bengaluru site basis inclusive of GST, Packing & Forwarding charges, freight, transit insurance and all other charges if applicable less input GST. Evaluation shall be carried out based on overall lowest effective price.