**Kerala State Drugs and Pharmaceuticals Ltd**
**(A Govt. of Kerala Enterprise)**
**KALAVOOR, ALAPPUZHA**
Phone :0477-2258184 (Extn:207) ; Email :purchase@ksdp.in
Web :http://www.ksdp.co.in

**KSDP/PS/EQ/2024-25/20000415/T-211** **30-8-2024**

## Notice Inviting Email Quotation for the Supply various Raw Materials

Quotations are invited for the supply of undermentioned goods/ services as per the attached specifications on FOR destination basis at our factory site at Kalavoor,Alapuzha, Kerala state

| Sl No. | ITEM CODE & DESCRIPTION | UNIT | QUANTITY | EMD | TENDER FEES |
|---|---|---|---|---|---|
| 1 | 10300024<br>Sodium Chloride USP | KG | 105.000 | ♦ Not Applicable | ♦ Not Applicable |
| 2 | 10300025<br>Dibasic Potassium Phosphate USP | KG | 2.000 | | |
| 3 | 10300029<br>Citric Acid IP/AR | Gm | 500.00 | | |
| 4 | 10100042<br>OFLOXACIN I.P. | KG | 7.000 | | |
| 5 | 10400018<br>PARACETAMOL IP | KG | 35.000 | | |
| 6 | 10300032<br>Di sodium hydrogen phosphate dihydrate | Gm | 500.00 | | |

**Quotations should be submitted as per the Proforma given below on your letter head.**

| Sl No. | Name of item | Make | Rate per unit (including freight, if any) | GST % | Offer validity | Remarks, if any |
|---|---|---|---|---|---|---|

**Due Date/Time : 3-Sep-24 / 1pm** **Opening Date/Time: 3-Sep-24 / 2pm**

**Note : Please provide COA along with the quotation.**

**Offer validity*: Minimum 7 days offer validity from the date of closure of bid submission.**

**Quotationreceived with offer validity less than 7 days from the date of closure of bid submission will be entirely rejected.**

**Please send your lowest offers of the item to our e-mail ksdptender@gmail.com before 12.00 PM,03/09 /2024.**

**The Quotation should be submitted through a password protected excel sheet.**
**Please share your Password to our email ksdptender@gmail.com@1.00 PM, 03.09.2024.**

**TERMS & CONDITIONS**

*Continued...*

**1.Payment terms :-** **30 days after the receipt of material with documents and QC approval.**

**2.Mode of payment:-** **E-PAYMENT**

**3.Delivery Period:-** **Within 15 days from the award of Purchase Order**

## HOD - Purchase

| | KERALA STATE DRUGS AND PHARMACEUTICALS LTD,<br>KALAVOOR PO, ALAPPUZHA, KERALA-688522 | | | |
|---|---|---|---|---|
| **Raw Material Specification** | | | | |
| Name of the Material: **SODIUM CHLORIDE USP** | | | | |
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/314 | |
| Effective date: | 19/7/24 | Revision No: | 00 | Page **1** of **2** |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | White or colorless crystals or a white crystalline powder. |
| 2. | Solubility | Freely soluble in water and slightly more soluble in boiling water; practically insoluble in ethanol. |
| 3. | Identification | |
| I. | It gives the reactions of chlorides | The precipitate dissolves easily with the possible exception of a few large particle which dissolve more slowly |
| II. | Solution (A) gives the reactions of sodium salts | A dense white precipitate is formed in the characteristic reaction |
| 4. | Appearance of solution | 20% w/v Solution is clear and colorless. |
| 5. | Acidity or alkalinity | Not more than 0.5 mL of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide is required to change the color of the solution. |
| 6. | Arsenic | After 40 min any stain produced on the mercuric chloride paper in not more intense than that obtained by treating in the same manner 1.0 ml of Arsenic standard solution (10 PPM) diluted to 50 ml of water (1 PPM) |
| 7. | Barium | Any Opalescence in test solution is not more intense than that in the reference solution |
| 8. | Bromide | NMT 100 ppm. The absorbance of test solution is not greater than that of the standard solution |
| 9. | Magnesium and Alkaline earth Metals | The volume of 0.01M Edetate di sodium consume in the second solution does not exceed 2.5 mL (Not more than 100 PPM calculated as Calcium) |
| 10. | Ferro cyanide | No blue color is produced within 10 minutes. |
| 11. | Nitrites | Absorbance at 354nm is NMT 0.01 |

| Prepared by | Checked by | Reviewed by | Approved by | Authorized by | |
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| | | |
|---|---|---|
| 12. | Iodides | Examine the mixture in day light, The substance shows no blue color after 5 minutes. |
| 13. | Iron | After 5 min. pink color produced is not more intense than that treating in the same manner 2.0 ml of Iron standard solution (20 PPM Fe) in place of the solution (2PPM) |
| 14. | Sulphates | Any Opalescence produce in the sample solution after 5 min standing is NMT thatproduced in the standard solution (200 PPM) |
| 15. | Loss on drying | NMT 0.5 % |
| 16. | Potassium | NMT 500 PPM |
| 17. | Bacterial endotoxins | NMT 0.5 USP Endotoxin units / mL |
| 18. | Assay | NLT 99.0 % and NMT 100.5 %, calculated on the dried basis. |
| 19. | Microbial Enumeration Tests*<br>i. Total aerobic microbial count (TAMC)<br>ii.Total Combined Yeasts and Molds count (TYMC) | ≤ 100 CFU/g<br><br>≤ 50CFU/g |

*In house specification

*The product complies USP 2016 with respect to above tests.*

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|---|---|---|---|
| **Raw Material Specification** | | | |
| Name of the Material: **PARACETAMOL I.P.** | | | |
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/306 |
| Effective date: | 19/7/24 | Revision No: | 00 |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | White crystals or a white, crystalline powder |
| 2. | Solubility | Freely soluble in ethanol; sparingly soluble in water; very slightly soluble in dichloromethane. |
| 3. | Identification | |
| A) | By IR | The spectrum obtained with the sample shall be concordant to the spectrum obtained with paracetamol IPRS/WS or with the reference spectrum of paracetamol. |
| B) | By UV | Absorbance at 249 nm, about 0.44. |
| C) | Colour reaction | A violet color develops which does not turn red. |
| D) | It gives the reaction of acetyl groups | A blue color is produced at the junction of the two drops and the color intensifies and persists for a short time. |
| 4. | Related substances | a) Chloroacetanilide – NMT 10 ppm.<br>b) 4 – aminophenol – NMT 50 ppm.<br>c) 4 – nitrophenol – NMT 0.05 %.<br>d) Any other secondary peak – NMT 0.05 %.<br>e) Sum of other secondary peaks – NMT 0.1 %.<br>f) Ignore any peak less than 0.01 %. |
| 5. | Heavy metals | NMT 10 ppm |
| 6. | Sulphated ash | NMT 0.1 %. |
| 7. | Loss on drying | NMT 0.5 %, determined on 1 g. |
| 8. | Assay | NLT 99.0 % and NMT 101.0 %, calculate on the dried basis. |
| 9. | Microbial Enumeration Tests*<br>i. Total aerobic microbial count (TAMC)<br>ii. Total Combined Yeasts and Molds count (TYMC) | <br>≤ 100 CFU/g<br><br>≤ 50CFU/g |

*In house specification

*The product complies to I.P. 2022 with respect to above tests.*

| Prepared by | Checked by | Reviewed by | Approved by | Authorized by | |
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| **Raw Material Specification** | | | |
| Name of the Material: **OFLOXACIN I.P.** | | | |
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/304 |
| Effective date: | 19/7/24 | Revision No: | 00 |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | A pale yellow or bright yellow, crystalline powder. |
| 2. | Solubility | Soluble in glacial acetic acid; slightly soluble in water, dichloromethane and methanol. |
| 3. | Identification | |
| A) | By IR | The spectrum obtained with the sample shall be concordant to the spectrum obtained with ofloxacin IPRS/WS or with the reference spectrum of ofloxacin. |
| 4. | Light absorption | Absorbance at 440 nm is not more than 0.25. |
| 5. | Related substances | a) Any secondary peak – NMT 0.5 %.<br>b) The sum of all the secondary peaks – NMT 1.0 %. |
| 6. | Heavy metals | NMT 10 ppm. |
| 7. | Sulphated ash | NMT 0.1 %. |
| 8. | Loss on drying | NMT 0.2 %, determined on 1 g. |
| 9. | Assay | NLT 98.5 % and NMT 101.5 %, calculate on the dried basis. |
| 10. | IicrobialEnumeration Tests*<br>i. Total aerobic microbial count (TAMC)<br>ii.Total Combined Yeasts and Moldscount (TYMC) | <br>≤ 100 CFU/g<br><br>≤ 50CFU/g |

*In house specification

*The product complies to I.P. 2022 with respect to above tests.*

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## Raw Material Specification

| Name of the Material: **DIBASIC POTASSIUM PHOSPHATE USP** | | | |
|---|---|---|---|
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/308 |
| Effective date: | 19/7/24 | Revision No: | 00 |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | A white, crystalline powder or fragments or granules; hygroscopic. |
| 2. | Identification | |
| I. | Potassium | Small amount of glacial acetic acid or alcohol also promotes the precipitation. |
| II. | Phosphate | Yellow precipitate that is soluble in 6 N ammonium hydroxide is formed. |
| 3. | pH | 8.5 to 9.6 |
| 4. | LOD | Not more than 1.0% |
| 5. | Insoluble Substance | The weight of the residue so obtained does not exceed 20mg (2.0%). |
| 6. | Carbonate | Not more than a few bubbles are evolved. |
| 7. | Chloride | 1.0g portion shows no, ore chloride than corresponds to 0.40mL of 0.020 N hydrochloric acid (0.03%) |
| 8. | Sulfate | 0.20g portion shows no more sulfate than corresponds to 0.20ml of 0.020 N sulfuric acid (0.1%) |
| 9. | Arsenic | 3 ppm. |
| 10. | Iron | 0.003 % |
| 11. | Sodium | A solution tested on a platinum wire imparts no pronounced yellow color to a nonluminous flame. |
| 12. | Heavy metals | 0.001% |
| 13. | Limit of fluoride | 0.001% |
| 14. | Limit of monobasic or tribasic salt | A blue color is produced |
| 15. | Residual Solvents | Meets the requirements. |
| 16. | Assay | 98.0 to 100.5% |

*The product complies USP2016 with respect to above tests.*

| Prepared by | Checked by | Reviewed by | Approved by | Authorized by | |
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|---|---|---|---|
| **Raw Material Specification** | | | |
| Name of the Material: **CITRIC ACID I.P./AR** | | | |
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/309 |
| Effective date: | 19/7/24 | Revision No: | 00 |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | Colourless crystals or a white powder, slightly hygroscope in moist air. |
| 2. | Identification | |
| A) | Infrared Absorption Spectrophotometry | Compare the spectrum with that obtained with citric acid IPRS or with the reference spectrum of citric acid. |
| B) | Citrates | A white precipitate soluble in 6 M acetic acid is produced. |
| C) | pH | A 10 % w/v solution is strongly acidic |
| 3. | Appearance of solution | This solution is clear, and not more intensely colored than reference solution YS7, BYS7 or GYS7 |
| 4. | Arsenic | 1 PPM |
| 5. | Barium | Any opalescence produced is not more intense than that of a mixture. |
| 6. | Calcium | Any opalescence produced is not more intense than that of a standard prepared in the same manner using mixture of 10 mL of calcium standard solution of 5 mL of water in place of solution A. |
| 7. | Heavy metals | 10 PPM |
| 8. | Iron | 50 PPM |
| 9. | Chlorides | 50 PPM |
| 10. | Sulphates | 150 PPM |
| 11. | Oxalic acid | Any pink colour produced is not more intense than produced. |
| 12. | Readily carbonisable substances. | Any colour produced is not more intense than that of a mixture of 1.0 mL of CCS and 9.0 mL of FCS |
| 13. | Sulphated ash | Not more than 0.1% |
| 14. | Water | Not more than 1.0% determined on 2.0g |
| 15. | Assay | Not less than 99.0% and not more than 101.0% of citric acid calculated on the anhydrous basis. |

*The product complies to I.P. 2022 with respect to above tests.*

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|---|---|---|---|
| **Raw Material Specification** | | | |
| Name of the Material: **DISODIUM HYDROGEN PHOSPHATE DIHYDRATE** | | | |
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/307 |
| Effective date: | 19/7/24 | Revision No: | 00 |

| Sl.No. | TESTS | SPECIFICATION |
|---|---|---|
| 1. | Description | Colourless, transparent crystals; very efflorescent. |
| 2. | Solubility | Very soluble in water; practically insoluble in ethanol (95 %). |
| 3. | Identification | |
| A) | Gives the reactions of sodium salts and phosphates | When heated, it melts, swells up and burns, and an odor of burnt sugar is perceptible. |
| 4. | Appearance of solution | Solution A is clear and colorless. |
| 5. | Arsenic | NMT 2 ppm. |
| 6. | Heavy metals | NMT 10 ppm. |
| 7. | Iron | NMT 20 ppm. |
| 8. | Chlorides | NMT 250 ppm. |
| 9. | Sulphates | NMT 600 ppm. |
| 10. | Reducing substances | The red color is not completely discharged. |
| 11. | Sodium dihydrogen phosphate | $n1$ and $n2$ are the titres of 1 M sodium hydroxide obtained in the Assay, does not exceed 0.025. |
| 12. | Loss on drying | 1.0 %, determined on 0.5 g. |
| 13. | Assay | NLT 98.5 % and NMT 102.5 %. |
| 14. | Microbial Enumeration Tests*<br>i. Total aerobic microbial count (TAMC)<br>ii.Total Combined Yeasts and Molds count (TYMC) | <br>≤ 100 CFU/g<br>≤ 50CFU/g |

*In house specification

*The product complies to I.P. 2022 with respect to above tests.*

| Prepared by | Checked by | Reviewed by | Approved by | Authorized by | |
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