



**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/2025-26/400006/T-001**

**11-4-2025**

**Notice inviting Email Quotaion for the supply of various raw materials- 9 Items**

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

| SI No. | ITEM CODE & DESCRIPTION                                                 | UNIT | QUANTITY | EMD            | TENDER FEES    |
|--------|-------------------------------------------------------------------------|------|----------|----------------|----------------|
| 1      | 10400101<br>Propylene Glycol IP/USP                                     | KG   | 100.000  | Not Applicable | Not Applicable |
| 2      | 10100023<br>Disodium Edetate IP/ AR                                     | KG   | 1.000    |                |                |
| 3      | 10300047<br>Sesame Oil B.P                                              | KG   | 150.000  |                |                |
| 4      | 10300048<br>SODIUM FORMALDEHYDE<br>SULPHOXYLATE I.P (LVP/SVP<br>/OPHTH) | KG   | 1.000    |                |                |
| 5      | 10600033<br>POLYETHYLENE GLYCOL 400 IP                                  | LTR  | 10.00    |                |                |
| 6      | 10300031<br>Hydrochloric Acid I.P/AR                                    | LTR  | 1.00     |                |                |
| 7      | 10300049<br>HYDROXYPROPYL<br>METHYLCELLULOSE IP                         | KG   | 10.000   |                |                |
| 8      | 10300050<br>Sorbic Acid IP                                              | KG   | 2.000    |                |                |
| 9      | 10300051<br>Monobasic sodium phosphate<br>anhydrous USP                 | KG   | 2.000    |                |                |

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

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

**Due Date/Time : 15-Apr-25 / 1.00 PM**

**Opening Date/Time: 15-Apr-25 / 2.00 PM**

*Continued...*

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

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

**Quotation received 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 01.00 PM ,15.04.2025.**


**The Quotation should be submitted through a password protected excel sheet.**

**Please share your Password to our email ksdptender@gmail.com @01.30PM, 15.04.25.**

#### **TERMS & CONDITIONS**

- 1.Payment terms :- 30 days after the receipt of material along with documents and approval from QC dept.**
- 2.Mode of payment:- E-PAYMENT**
- 3.Delivery Period:- Supply should be effected within 07 days on award of PO.**





**HOD - Purchase**

|                                                                                   |                                                                                      |  |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--|
|  | KERALA STATE DRUGS AND PHARMACEUTICALS LTD,<br>KALAVOOR PO, ALAPPUZHA, KERALA-688522 |  |
|                                                                                   | Raw Material Specification                                                           |  |


|                                                        |                 |              |                  |
|--------------------------------------------------------|-----------------|--------------|------------------|
| Name of the Material: <b>PROPYLENE GLYCOL I.P./USP</b> |                 |              |                  |
| SOP No:                                                | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/81 |
| Effective date:                                        | 05/02/2025      | Revision No: | 04               |
|                                                        |                 | Item code:   | 10400101         |

| Sl.No. | TESTS                                 | SPECIFICATION                                                                                                                                                                                                                                                                                                                   |
|--------|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Description                           | A clear, colourless, viscous liquid; hygroscopic.                                                                                                                                                                                                                                                                               |
| 2      | Identification                        | A. By IR absorption spectrophotometry.<br>B. Diethylene glycol and Ethylene glycol.<br>C. In the test for Diethylene glycol and Ethylene glycol, the retention time of propylene glycol peak obtained with the test solution corresponds to the propylene glycol peak in the chromatogram obtained with the reference solution. |
| 3      | Acidity                               | Not more than 0.2 mL of 0.1 M sodium hydroxide consumed.                                                                                                                                                                                                                                                                        |
| 4      | Relative density                      | 1.035 to 1.037                                                                                                                                                                                                                                                                                                                  |
| 5      | Diethylene glycol and ethylene glycol | Determined by gas chromatography.                                                                                                                                                                                                                                                                                               |
| 6      | Heavy metals                          | Dilute 5 mL to 25 mL with water. The resulting solution complies with the limit test for heavy metals, method D (5ppm), using 10 mL of lead standard solution (1ppm Pb).                                                                                                                                                        |
| 7      | Chlorides                             | Not more than 70 ppm.                                                                                                                                                                                                                                                                                                           |
| 8      | Sulphates                             | Not more than 60 ppm.                                                                                                                                                                                                                                                                                                           |
| 9      | Sulphated ash                         | Not more than 0.007% w/w.                                                                                                                                                                                                                                                                                                       |
| 10     | Water                                 | Not more than 0.2% determined on 5.0 g.                                                                                                                                                                                                                                                                                         |
| 11     | Assay (by HPLC)                       | Not less than 99.5% of Propylene glycol.                                                                                                                                                                                                                                                                                        |

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





|                                                                                     |                                                                                     |                                                                                     |                                                                                       |                                                |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------------|
| Prepared by                                                                         | Checked by                                                                          | Reviewed by                                                                         | Approved by                                                                           | <b>MASTER COPY</b><br><b>UNCONTROLLED COPY</b> |
| Officer QA                                                                          | QC Head                                                                             | Production Head                                                                     | QA Head                                                                               |                                                |
|  |  |  |  |                                                |
| 03/02/2025                                                                          | 04/02/2025                                                                          | 05/02/2025                                                                          | 05/02/2025                                                                            |                                                |



|                                                                                   |                 |                                                                                                    |                   |
|-----------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------|-------------------|
|  |                 | <b>KERALA STATE DRUGS AND PHARMACEUTICALS LTD,</b><br><b>KALAVOOR PO, ALAPPUZHA, KERALA-688522</b> |                   |
| <b>Raw Material Specification</b>                                                 |                 |                                                                                                    |                   |
| Name of the Material: <b>DISODIUM EDTATE I.P./AR</b>                              |                 |                                                                                                    |                   |
| SOP No:                                                                           | KSDP/SOP/SPEC01 | Spec. No:                                                                                          | KSDP/R/SPEC01/312 |
| Effective date:                                                                   | 19/7/24         | Revision No:                                                                                       | 00                |

| Sl.No. | TESTS                           | SPECIFICATION                                                                                                       |
|--------|---------------------------------|---------------------------------------------------------------------------------------------------------------------|
| 1.     | Description                     | A white, crystalline powder; Odourless                                                                              |
| 2.     | Solubility                      | Soluble in water; practically insoluble in ethanol (95 %).                                                          |
| 3.     | Identification                  |                                                                                                                     |
| A)     | By IR                           | The infrared absorption spectrum of the sample is concordant with the spectrum obtained from Disodium Edetate IPRS. |
| B)     | By Chemical                     | No precipitate is produced                                                                                          |
| C)     | By Sodium Salts                 | A dense white precipitate is formed                                                                                 |
| 4.     | Appearance of solution          | 5% w/v solution should be clear and colourless.                                                                     |
| 5.     | pH                              | Between 4.0 to 5.5                                                                                                  |
| 6.     | Related substances (Impurity A) | NMT 0.1%                                                                                                            |
| 7.     | Heavy metals                    | NMT 20 ppm.                                                                                                         |
| 8.     | Iron                            | NMT 80 ppm                                                                                                          |
| 9.     | Assay                           | NLT 98.5% to NMT 101.0 %                                                                                            |

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

| Prepared by           | Checked by                                                                          | Reviewed by                                                                         | Approved by                                                                          | Authorized by                                                                         | <b>MASTER COPY</b><br><b>UNCONTROLLED COPY</b> |
|-----------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------------|
| QA Officer            | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                      | QA Head                                                                               |                                                |
| F<br>Rinny<br>15/7/24 |  |  |  |  |                                                |
|                       | 17/7/24                                                                             | 18/7/24                                                                             | 19/7/24                                                                              | 19/7/24                                                                               |                                                |




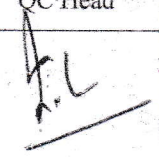

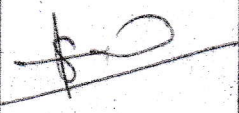



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

**Raw Material Specification**

|                                             |                 |                |                   |
|---------------------------------------------|-----------------|----------------|-------------------|
| Name of the Material: <b>SESAME OIL B.P</b> |                 | (LVP/SVP/OPTH) |                   |
| SOP No:                                     | KSDP/SOP/SPEC01 | Spec. No:      | KSDP/R/SPEC01/340 |
| Effective date:                             | 24/03/2025      | Revision No:   | 00                |
|                                             |                 | Item code:     | 10300047          |

| Sl.No. | TEST                         | SPECIFICATION                                                                                     |
|--------|------------------------------|---------------------------------------------------------------------------------------------------|
| 1.     | Description                  | Clear, light yellow liquid, almost colourless.                                                    |
| 2.     | Solubility                   | Practically insoluble in ethanol (96%), miscible with light petroleum.                            |
| 3.     | Relative density             | About 0.919                                                                                       |
| 4.     | Refractive index             | About 1.473.                                                                                      |
| 5.     | Identification               |                                                                                                   |
| A)     | By Chemical Reaction         | Composition of triglycerides.                                                                     |
| B)     | By Thin-layer chromatography | To meet the test.                                                                                 |
| 6.     | Acid Value                   | Maximum 0.3, determined on 10.0g; (intended for use in the manufacture of parental preparations). |
| 7.     | Peroxide value               | Maximum 5.0 (intended for use in the manufacture of parental preparations).                       |
| 8.     | Unsaponifiable matter        | Maximum 2.0 percent, determined on 5.0 g.                                                         |
| 9.     | Alkaline impurities          | It complies with the test for alkaline impurities in fatty oils.                                  |
| 10.    | Cottonseed oil               | As per BP.                                                                                        |
| 11.    | Non – volatile residue       | a) Maximum 100mg/L<br>b) The residue weighs a maximum of 1.0 mg                                   |

|                                                                                                 |                                                                                                 |                                                                                                 |                                                                                                 |                                                                                                   |                                  |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------------------------------|
| Prepared by                                                                                     | Checked by                                                                                      | Reviewed By                                                                                     | Approved By                                                                                     | Authorized By                                                                                     | MASTER COPY<br>UNCONTROLLED COPY |
| QA Officer                                                                                      | QC Head                                                                                         | Dy. Manager Production                                                                          | Production Head                                                                                 | QA Head                                                                                           |                                  |
| <br>20/03/25 | <br>22/03/25 | <br>22/03/25 | <br>24/03/25 | <br>24/03/25 |                                  |



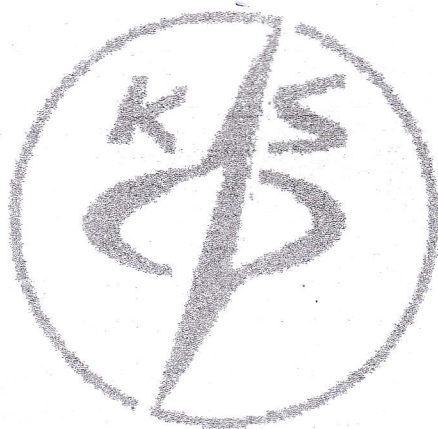
KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

### Raw Material Specification

|                                                            |                 |              |                   |
|------------------------------------------------------------|-----------------|--------------|-------------------|
| Name of the Material: <b>SESAME OIL B.P</b> (LVP/SVP/OPTH) |                 |              |                   |
| SOP No:                                                    | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/340 |
| Effective date:                                            | 24/03/2025      | Revision No: | 00                |
|                                                            |                 | Item code:   | 10300047          |

|     |            |                                                  |
|-----|------------|--------------------------------------------------|
| 12. | Water      | Maximum 0.050 per cent m/m determined on 10.0mL. |
| 13. | Impurities | As per BP.                                       |

*The product complies to current version of B.P. with respect to the above tests.*



|             |            |                        |                 |               |                                  |
|-------------|------------|------------------------|-----------------|---------------|----------------------------------|
| Prepared by | Checked by | Reviewed By            | Approved By     | Authorized By | MASTER COPY<br>UNCONTROLLED COPY |
| QA Officer  | QC Head    | Dy. Manager Production | Production Head | QA Head       |                                  |
|             |            |                        |                 |               |                                  |
| 20/03/25    | 22/03/25   | 24/03/25               | 24/03/25        | 24/03/25      |                                  |





KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

**Raw Material Specification**

Name of the Material: **SODIUM FORMALDEHYDE SULPHOXYLATE I.P**  
(LVP/SVP/OPTH)

|                 |                 |              |                   |
|-----------------|-----------------|--------------|-------------------|
| SOP No:         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/342 |
| Effective date: | 24/03/2025      | Revision No: | 00                |
|                 |                 | Item code:   | 10300048          |

| Sl.No. | TEST                   | SPECIFICATION                                                                                                                     |
|--------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| 1.     | Description            | White crystals or hard white masses.                                                                                              |
| 2.     | Solubility             | Freely soluble in water, slightly soluble in chloroform, in ethanol (95%) and in ether.                                           |
| 3.     | Identification         |                                                                                                                                   |
| A)     | By Chemical Reaction   | To meet the test.                                                                                                                 |
| B)     | By Colour Reaction     | A permanent deep red colour develops.                                                                                             |
| 4.     | Appearance of solution | A 5.0 %w/v solution in carbon dioxide-free water is clear and colourless.                                                         |
| 5.     | Alkalinity             | NMT 3.5ml of 0.05M Sulphuric acid is required to change the colour of the solution.                                               |
| 6.     | pH                     | 9.5 to 10.5, determined in a 2.0 %w/v solution of carbon dioxide-free water.                                                      |
| 7.     | Iron                   | The red colour of the solution is not more intense than that 1.0 ml of iron standard solution (10ppm) treated in the same manner. |
| 8.     | Sulphides              | No discolouration is evident within 5 minutes.                                                                                    |

| Prepared by | Checked by | Reviewed By            | Approved By     | Authorized By | MASTER COPY<br>UNCONTROLLED COPY |
|-------------|------------|------------------------|-----------------|---------------|----------------------------------|
| QA Officer  | QC Head    | Dy. Manager Production | Production Head | QA Head       |                                  |
|             |            |                        |                 |               |                                  |
| 20/03/25    | 22/03/25   | 22/03/25               | 24/03/25        | 24/03/25      |                                  |





KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

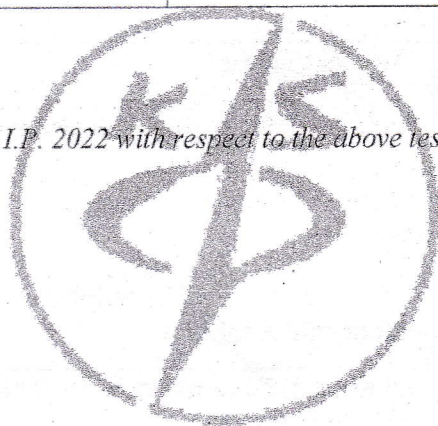
**Raw Material Specification**



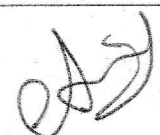

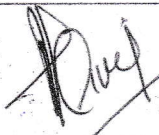
Name of the Material: **SODIUM FORMALDEHYDE SULPHOXYLATE I.P**  
(LVP/SVP/OPTH)

|                 |                 |              |                   |
|-----------------|-----------------|--------------|-------------------|
| SOP No:         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/342 |
| Effective date: | 24/03/2025      | Revision No: | 00                |
|                 |                 | Item code:   | 10300048          |

|     |                 |                                                                                                |
|-----|-----------------|------------------------------------------------------------------------------------------------|
| 9.  | Sodium sulphite | NMT 5.0 per cent, calculated as $\text{Na}_2\text{SO}_3$ , determined by the method as per IP. |
| 10. | Loss on drying  | NMT 27.0 per cent, determined on 0.5g by drying in an oven at $105^\circ$ for 3 hours.         |
| 11. | Assay           | NLT 45.0 % and NMT 55.0 % of $\text{SO}_2$ , calculated on the dried basis.                    |

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



| Prepared by                                                                         | Checked by                                                                          | Reviewed By                                                                         | Approved By                                                                          | Authorized By                                                                         | MASTER COPY<br>UNCONTROLLED COPY |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------|
| QA Officer                                                                          | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                      | QA Head                                                                               |                                  |
|  |  |  |  |  |                                  |
| 20/03/25                                                                            | 22/03/25                                                                            | 22/03/25                                                                            | 24/03/25                                                                             | 24/03/25                                                                              |                                  |



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522


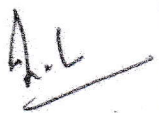



**Raw Material Specification**

Name of the Material: **POLYETHYLENE GLYCOL 400 IP** (LVP/SVP/OPTH)


|                 |                 |              |                   |
|-----------------|-----------------|--------------|-------------------|
| SOP No:         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/349 |
| Effective date: | 09/04/25        | Revision No: | 00                |
|                 |                 | Item code:   | 10600033          |

| SLNo. | TEST            | SPECIFICATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.    | Description     | A clear, viscous, colorless and hygroscopic liquid.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.    | Identification  | A. Polyethylene Glycol is an addition polymer of ethylene oxide and water, represented by the formula $H(OCH_2CH_2)_n OH$ , in which n represents the average number of oxyethylene groups. The average molecular weight is NLT 95.0% and NMT 105.0% of the labeled nominal value if the labeled nominal value is less than 1000; it is NLT 90.0% and NMT 110.0% of the labeled nominal value if the labeled nominal value is between 1000 and 7000; and it is NLT 87.5% and NMT 112.5% of the labeled nominal value if the labeled nominal value is more than 7000. It may contain a suitable antioxidant. |
| 3.    | Viscosity Range | 6.8 to 8.0 centistokes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4.    | pH              | 4.5 to 7.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 5.    | Density         | 1.127 g/cm <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6.    | Melting Point   | 4-8 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 7.    | Wt. per ml      | About 1.13g                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 8.    | Freezing Point  | About 6°                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

Grade:-IP, BP, USP and In-House.

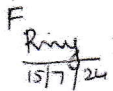

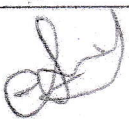

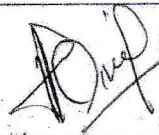
| Prepared by                                                                                     | Checked by                                                                                      | Reviewed By                                                                                     | Approved By                                                                                      | Authorized By                                                                                     | MASTER COPY<br><br>UNCONTROLLED COPY |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------|
| QA Officer                                                                                      | QC Head                                                                                         | Dy. Manager Production                                                                          | Production Head                                                                                  | QA Head                                                                                           |                                      |
| <br>03/04/25 | <br>05/04/25 | <br>07/04/25 | <br>09/04/25 | <br>09/04/25 |                                      |



|                                                                                   |                 |                                                                                                    |                   |
|-----------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------|-------------------|
|  |                 | <b>KERALA STATE DRUGS AND PHARMACEUTICALS LTD,</b><br><b>KALAVOOR PO, ALAPPUZHA, KERALA-688522</b> |                   |
| <b>Raw Material Specification</b>                                                 |                 |                                                                                                    |                   |
| Name of the Material: <b>HYDROCHLORIC ACID I.P./AR</b>                            |                 |                                                                                                    |                   |
| SOP No:                                                                           | KSDP/SOP/SPEC01 | Spec. No:                                                                                          | KSDP/R/SPEC01/310 |
| Effective date:                                                                   | 19/7/24         | Revision No:                                                                                       | 00                |

| Sl.No. | TESTS                  | SPECIFICATION                                                                            |
|--------|------------------------|------------------------------------------------------------------------------------------|
| 1.     | Description            | A Clear, colourless, fuming liquid                                                       |
| 2.     | Identification         |                                                                                          |
| A)     | Chemical test          | When added to potassium permanganate, chlorine is evolved                                |
| B)     | Chlorides              | A curdy white precipitate is formed                                                      |
| 3.     | Arsenic                | 1 PPM                                                                                    |
| 4.     | Heavy metals           | 5 PPM                                                                                    |
| 5.     | Bromide and iodide     | Chloroform layer does not become brown or violet                                         |
| 6.     | Free chlorine          | Any blue colour produced disappears on the colour of 0.2ml of 0.01m sodium thiosulphate. |
| 7.     | Sulphite               | The colour of the iodine is not completely discharged.                                   |
| 8.     | Sulphates              | 20ppm                                                                                    |
| 9.     | Residue on evaporation | Not more than 0.01% determined on 100g.                                                  |
| 10.    | Assay                  | Not less than 35.0 % w/w and not more than 38.0% w/w.                                    |

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

| Prepared by                                                                                              | Checked by                                                                          | Reviewed by                                                                         | Approved by                                                                         | Authorized by                                                                         |                                                |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------------|
| QA Officer                                                                                               | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                     | QA Head                                                                               |                                                |
| <br>F. Riny<br>15/7/24 |  |  |  |  | <b>MASTER COPY</b><br><b>UNCONTROLLED COPY</b> |
|                                                                                                          | 17/7/24                                                                             | 18/7/24                                                                             | 19/7/24                                                                             | 19/7/24                                                                               |                                                |





**KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522**

**Raw Material Specification**


Name of the Material: **HYDROXYPROPYL METHYLCELLULOSE IP**  
(LVP/SVP/OPTH)

|                 |                 |              |                   |
|-----------------|-----------------|--------------|-------------------|
| SOP No:         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/348 |
| Effective date: | 09/04/25        | Revision No: | 00                |
|                 |                 | Item code:   | 10300049          |

| Sl.No. | TEST                   | SPECIFICATION                                                                                                                                               |
|--------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.     | Description            | A white or yellowish white, fibrous or granular powder; hygroscopic after drying.                                                                           |
| 2.     | Identification         |                                                                                                                                                             |
| A)     | By Chemical Reaction   | At temperatures above 50° the solution becomes cloudy or a flocculent precipitate is formed. On cooling, the solution becomes clear or slightly opalescent. |
| B)     | By Chemical Reaction   | To meet the test                                                                                                                                            |
| C)     | By Chemical Reaction   | A yellowish white, flocculent precipitate is produced which dissolves in 6 M ammonia.                                                                       |
| D)     | By Chemical Reaction   | A pink colour is produced immediately which becomes violet within 100 minutes.                                                                              |
| E)     | By Chemical Reaction   | After evaporation of the water a thin film is produced.                                                                                                     |
| 3.     | pH                     | 5.5 to 8.0, determined in solution A.                                                                                                                       |
| 4.     | Appearance of solution | Solution A is not more opalescent than opalescence standard OS3 and not more intensely coloured than reference solution YS6.                                |

|             |            |                        |                 |               |                                                |
|-------------|------------|------------------------|-----------------|---------------|------------------------------------------------|
| Prepared by | Checked by | Reviewed By            | Approved By     | Authorized By | <b>MASTER COPY</b><br><b>UNCONTROLLED COPY</b> |
| QA Officer  | QC Head    | Dy. Manager Production | Production Head | QA Head       |                                                |
|             |            |                        |                 |               |                                                |
| 03/04/25    | 05/04/25   | 07/04/25               | 09/04/25        | 09/04/25      |                                                |


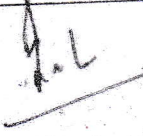
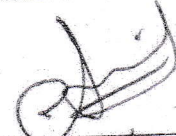

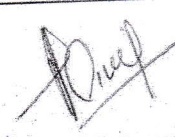


|                                                                                   |                                                                                      |  |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--|
|  | KERALA STATE DRUGS AND PHARMACEUTICALS LTD,<br>KALAVOOR PO, ALAPPUZHA, KERALA-688522 |  |
|                                                                                   | Raw Material Specification                                                           |  |

|                                                                                 |                 |              |                   |
|---------------------------------------------------------------------------------|-----------------|--------------|-------------------|
| Name of the Material: <b>HYDROXYPROPYL METHYLCELLULOSE IP</b><br>(LVP/SVP/OPTH) |                 |              |                   |
| SOP No:                                                                         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/348 |
| Effective date:                                                                 | 09/04/25        | Revision No: | 00                |
|                                                                                 |                 | Item code:   | 10300049          |

|    |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5. | Apparent Viscosity | 75 to 140 per cent of the stated value, determined by the following method. Weigh a quantity equivalent to 2.0 g of the dried substance and add, with constant stirring, to 50 ml of water previously heated to 90°. Allow to cool, dilute to 100.0 ml with water and continue stirring until solution is complete. Adjust the weight of the solution to 100 g and centrifuge the solution to expel any trapped air. Determine the viscosity, Method C, at 20° using a shear rate of 10 s <sup>-1</sup> . |
| 6. | Heavy Metals       | 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 7. | Chlorides          | Dilute 5.0 ml of solution A to 15 ml with water. The resulting solution complies with the limit test for chlorides (0.5 per cent).                                                                                                                                                                                                                                                                                                                                                                        |
| 8. | Sulphated ash      | Not more than 3.0 per cent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 9. | Loss on drying     | Not more than 10.0 per cent, determined on 0.5 g by drying in an oven at 105°.                                                                                                                                                                                                                                                                                                                                                                                                                            |

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

| Prepared by                                                                         | Checked by                                                                          | Reviewed By                                                                         | Approved By                                                                          | Authorized By                                                                         | <b>MASTER COPY</b><br><br><b>UNCONTROLLED COPY</b> |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------------------------|
| QA Officer                                                                          | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                      | QA Head                                                                               |                                                    |
|  |  |  |  |  |                                                    |
| 03/04/25                                                                            | 05/04/25                                                                            | 07/04/25                                                                            | 09/04/25                                                                             | 09/04/25                                                                              |                                                    |






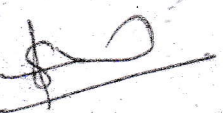



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

**Raw Material Specification**

|                                              |                 |                |                   |
|----------------------------------------------|-----------------|----------------|-------------------|
| Name of the Material: <b>SORBIC ACID I.P</b> |                 | (LVP/SVP/OPTH) |                   |
| SOP No:                                      | KSDP/SOP/SPEC01 | Spec. No:      | KSDP/R/SPEC01/345 |
| Effective date:                              | 24/03/2025      | Revision No:   | 00                |
|                                              |                 | Item code:     | 10300050          |

| Sl.No. | TEST                                                       | SPECIFICATION                                                                                                                                                                |
|--------|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.     | Description                                                | A white or almost white crystalline powder.                                                                                                                                  |
| 2.     | Solubility                                                 | Freely soluble in ethanol (95%) and in ether, slightly soluble in water.                                                                                                     |
| 2.     | Identification                                             |                                                                                                                                                                              |
|        | i. Test A may be omitted if tests B and C are carried out. |                                                                                                                                                                              |
|        | ii. Test B and C may be omitted if test A is carried out.  |                                                                                                                                                                              |
| A)     | By IR                                                      | Compare the spectrum with that obtained with sorbic acid IPRS or with the reference spectrum of sorbic acid.                                                                 |
| B)     | By UV                                                      | To meet the test.                                                                                                                                                            |
| C)     | By Chemical Reaction                                       | The solution is decolorized.                                                                                                                                                 |
| 3.     | Appearance of solution                                     | A 5.0 per cent w/v solution in ethanol (95%) is clear and colourless.                                                                                                        |
| 5.     | Heavy Metals                                               | 12 ml of 5 %w/v solution in ethanol (95%) complies with the test for heavy metals, Method D (10ppm), using 5ml of lead standard solution (1ppm Pb) and 5 ml of ethanol(95%). |
| 6.     | Aldehydes                                                  | NMT 0.15 %, determined by the method as per IP.                                                                                                                              |
| 7.     | Sulphated Ash                                              | NMT 0.2 %.                                                                                                                                                                   |
| 8.     | Water                                                      | NMT 1.0%, determined on 2.0g.                                                                                                                                                |

| Prepared by                                                                         | Checked by                                                                          | Reviewed By                                                                         | Approved By                                                                         | Authorized By                                                                         | MASTER COPY<br>UNCONTROLLED COPY |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------|
| QA Officer                                                                          | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                     | QA Head                                                                               |                                  |
|  |  |  |  |  |                                  |
| 20/03/25                                                                            | 22/03/25                                                                            | 22/03/25                                                                            | 24/03/25                                                                            | 24/03/25                                                                              |                                  |





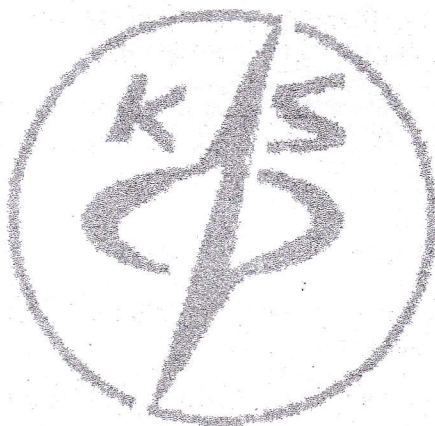
KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

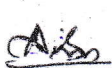




**Raw Material Specification**


|                                              |                 |                 |                   |
|----------------------------------------------|-----------------|-----------------|-------------------|
| Name of the Material: <b>SORBIC ACID I.P</b> |                 | (LVP/SVP/OPHTH) |                   |
| SOP No:                                      | KSDP/SOP/SPEC01 | Spec. No:       | KSDP/R/SPEC01/345 |
| Effective date:                              | 24/03/2025      | Revision No:    | 00                |
|                                              |                 | Item code:      | 10300050          |

|    |       |                                                                               |
|----|-------|-------------------------------------------------------------------------------|
| 9. | Assay | NLT 99.0 % and NMT 101.0% of $C_6H_8O_2$ , calculated on the anhydrous basis. |
|----|-------|-------------------------------------------------------------------------------|

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


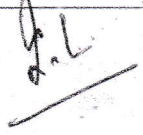
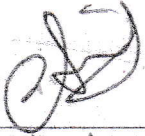




| Prepared by                                                                                     | Checked by                                                                                      | Reviewed By                                                                                     | Approved By                                                                                      | Authorized By                                                                                     | MASTER COPY<br>UNCONTROLLED COPY |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------------------------------|
| QA Officer                                                                                      | QC Head                                                                                         | Dy. Manager Production                                                                          | Production Head                                                                                  | QA Head                                                                                           |                                  |
| <br>20/03/25 | <br>22/03/25 | <br>22/03/25 | <br>24/03/25 | <br>24/03/25 |                                  |

|                                                                                   |                                                                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
|  | <b>KERALA STATE DRUGS AND PHARMACEUTICALS LTD,<br/>KALAVOOR PO, ALAPPUZHA, KERALA-688522</b> |
| <b>Raw Material Specification</b>                                                 |                                                                                              |

|                                                                                         |                 |              |                   |
|-----------------------------------------------------------------------------------------|-----------------|--------------|-------------------|
| Name of the Material: <b>MONOBASIC SODIUM PHOSPHATE ANHYDROUS USP</b><br>(LVP/SVP/OPTH) |                 |              |                   |
| SOP No:                                                                                 | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/338 |
| Effective date:                                                                         | 24/03/2025      | Revision No: | 00                |
|                                                                                         |                 | Item code:   | 10300051          |

| Sl.No. | TEST                                    | SPECIFICATION                                                                                                          |
|--------|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| 1.     | Description                             | Colorless crystals or white, crystalline powder. Is odorless and is slightly deliquescent.                             |
| 2.     | Solubility                              | Freely soluble in water; practically insoluble in alcohol.                                                             |
| 3.     | Identification                          |                                                                                                                        |
| A)     | By Chemical Reaction                    | To meet the requirements.                                                                                              |
| B)     | By Chemical Reaction                    | To meet the requirements.                                                                                              |
| 4.     | Insoluble substances                    | NMT 20mg (0.2%).                                                                                                       |
| 5.     | Chloride and sulfate                    | NMT 0.014%; the sample shows no more chloride than the control.                                                        |
| 6.     | Chloride and sulfate                    | NMT 0.15%; the sample shows no more sulfate than the control.                                                          |
| 7.     | Aluminum, calcium, and related elements | The sample solution does not become turbid when rendered slightly alkaline to litmus paper with 6N ammonium hydroxide. |
| 8.     | Arsenic                                 | NMT 8ppm                                                                                                               |
| 9.     | pH                                      | 4.1-4.5                                                                                                                |
| 10.    | Water                                   | <2.0%                                                                                                                  |

| Prepared by                                                                         | Checked by                                                                          | Reviewed By                                                                         | Approved By                                                                          | Authorized By                                                                         | <b>MASTER COPY</b><br><b>UNCONTROLLED COPY</b> |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------------|
| QA Officer                                                                          | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                      | QA Head                                                                               |                                                |
|  |  |  |  |  |                                                |
| 20/03/25                                                                            | 22/03/25                                                                            | 22/03/25                                                                            | 24/03/25                                                                             | 24/03/25                                                                              |                                                |





KERALA STATE DRUGS AND PHARMACEUTICALS LTD,  
KALAVOOR PO, ALAPPUZHA, KERALA-688522

**Raw Material Specification**

Name of the Material: **MONOBASIC SODIUM PHOSPHATE ANHYDROUS USP**  
(LVP/SVP/OPTH)

SOP No: KSDP/SOP/SPEC01 Spec. No: KSDP/R/SPEC01/338


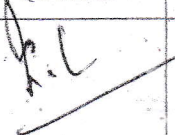



Effective date: 24/03/2025 Revision No: 00

Item code: 10300051

|     |       |                                                                                                                                  |
|-----|-------|----------------------------------------------------------------------------------------------------------------------------------|
| 11. | Assay | NLT 98.0 %w/w and NMT 103.0% w/w of monobasic sodium phosphate ( $\text{NaH}_2\text{PO}_4$ ), calculated on the anhydrous basis. |
|-----|-------|----------------------------------------------------------------------------------------------------------------------------------|

*The product complies to U.S.P. 2024 with respect to the above tests.*



| Prepared by                                                                         | Checked by                                                                          | Reviewed By                                                                         | Approved By                                                                          | Authorized By                                                                         | MASTER COPY<br>UNCONTROLLED COPY |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------|
| QA Officer                                                                          | QC Head                                                                             | Dy. Manager Production                                                              | Production Head                                                                      | QA Head                                                                               |                                  |
|  |  |  |  |  |                                  |
| 20/03/25                                                                            | 22/03/25                                                                            | 22/03/25                                                                            | 24/03/25                                                                             | 24/03/25                                                                              |                                  |