| MASTER COPY                                    |   |                                    | Annexe                             |
|--|---|------------------------------------|------------------------------------|
|  | Plot no. 1116/P, La<br>Manjusar -<br><u>Ta- Savli, Dist. Vadoc</u><br>Quality ( | - 391 775,<br>lara, Gujarat, India | GHEM PVI. LID.                     |
|  | Standard Test   |                                    |                                    |
| Title: Sodium Dihydrogen Phos                  |   | -                                  | <b>Page No.:</b> 1 of 3            |
| Specification No.:<br>ACPL/FP/SP/044           | <b>Revision No.:</b><br>00  | <b>Effective Date</b> 04/09/2021   | e <b>Review Date</b><br>03/09/2024 |
| Change Control No. NA                          | A   |                                    |                                    |
| Prepared By:<br>Name : <u>Pankaj</u><br>(QC Of | Patel<br>Ficer / Designee)  | Date: <u>(</u>                     | 0 <u>1/09/2021</u>                 |
| Reviewed By:<br>Name : <u>Niles</u><br>(Unit F | h Shah<br>Head / Designee)  | Date: <u>(</u>                     | ) <u>2/09/2021</u>                 |
|  | n <u>Solanki</u><br>C In Charge / Designee                                      |                                    | <u>)3/09/2021</u>                  |
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| Format No. QC/017/F/01-00                      |   | Certified By (Sign                 | / <b>Date):</b> 04/09/2021         |

| MASTER COPY   | 7   |                                  | Annexe                           |
|---|---|----------------------------------|----------------------------------|
|   | Plot no. 1116/P, Lam  | -                                | CHEM PVT. LTD.                   |
|   | Manjusar – 3<br>Ta- Savli, Dist. Vadoda                             |                                  |                                  |
|   | Quality Co  |                                  |                                  |
| Title: Sodium Dihydrogen Ph   | Standard Test Sp  |                                  | <b>Page No.:</b> 2 of 3          |
| The. Soulum Dinyurogen Th   | ospilate Mononyul'ate 03  | 1                                | 1 age 110 2 01 5                 |
| Specification No.:<br>ACPL/FP/SP/044                                      | Revision No.:<br>00   | <b>Effective Date</b> 04/09/2021 | <b>Review Date</b><br>03/09/2024 |
| Change Control No.  | NA  |                                  |                                  |
|   | <b>'EL</b> :<br>"Sampling procedure" SO<br><b>HOD TO BE FOLLOWE</b> |                                  |                                  |
| 100% sampling to b  | e done from each container  | ·.                               |                                  |
| <b>3.0 TOTAL COMPOS</b><br>100 gm   | TTE SAMPLE TO BE C  | OLLECTED :                       |                                  |
| <b>4.0 EXPIRY :</b><br>Five years from the                                | Date of Manufacturing.  |                                  |                                  |
| <b>5.0 CAS No:</b> 10049-21   | -5  |                                  |                                  |
| 6.0 MOLECULAR FORMULA: NaH <sub>2</sub> P0 <sub>4</sub> ,H <sub>2</sub> O |   |                                  |                                  |
| 7.0 MOLECULAR WEIGHT: 137.99 gm/mol.                                      |   |                                  |                                  |
| 8.0 CATEGORY: Exc.  | 8.0 CATEGORY: Excipient.  |                                  |                                  |
| 9.0 STORAGE: Preser   | ve in well-closed container   | s.                               |                                  |
| 10.0 SAFETY PRECA   | UTIONS TO BE TAKE   | N WHILE SAMPLIN                  | G AND HANDLING :                 |
| Use hand gloves, goggles and apron during Handling.                       |   |                                  |                                  |
| 11.0 CONTROL SAMPLE: 3 X 100gm.   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
|   |   |                                  |                                  |
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|--|--|------------------------|---------------------------|--------------------------|--|
|  |  | Plot no. 1116/P, Lam   | - /                       | CHEM PVT. LTD.           |  |
|  | Manjusar – 391 775,<br>Ta- Savli, Dist. Vadodara, Gujarat, India |                        |                           |                          |  |
|  |  | Quality Co             |                           |                          |  |
|  |  | Standard Test Sp       |                           |                          |  |
| Title: Sodiur                              | n Dihydrogen Ph  | osphate Monohydrate US | SP                        | <b>Page No.:</b> 3 of 3  |  |
| Specifica                                  | ation No.:   | <b>Revision No.:</b>   | Effective Date            | Review Date              |  |
|  | FP/SP/044  | 00                     | 04/09/2021                | 03/09/2024               |  |
| Change (                                   | Control No.  | NA                     |                           |                          |  |
|  | TEST PARAMETERS AND SPECIFICATIONS<br>REF: USP                   |                        |                           |                          |  |
| Sr. No.                                    | TEST   | PARAMETER              | SPE                       | CIFICATION               |  |
| 1. A                                       | Appearance   |                        | White, slightly granules. | deliquescent crystals or |  |
| Identification A                           |  | To Pass test           |                           |                          |  |
| 2. Test for Sodium                         |  |                        |                           |                          |  |
| Identification B                           |  | To Pass test           |                           |                          |  |
| Test for Phosphate                         |  |                        |                           |                          |  |
| 3. Assay (dried basis)                     |  | 98.0 % - 103.0 %       |                           |                          |  |
| 4. Insoluble Substances                    |  | Max. 0.2 %             |                           |                          |  |
| 5. Chlorides                               |  | Max. 140 ppm           |                           |                          |  |
| 6. Sulfates                                |  | Max. 1500 ppm          |                           |                          |  |
| 7. Aluminum, Calcium, And Related Elements |  | To Pass test           |                           |                          |  |
| 8. Arsenic                                 |  | Max. 8 ppm             |                           |                          |  |
| 9. pH (5 % Solution)                       |  | 4.1 to 4.5.            |                           |                          |  |
| 10. Water Determination                    |  | 10.0 % to 15.0 %       |                           |                          |  |
| <u> </u>                                   |  |                        |                           |                          |  |

## **REVISION HISTORY:**

| Revision No. | Effective Date | <b>Revision Description</b> | Change Control No. |
|--------------|----------------|-----------------------------|--------------------|
| 00           | 04/09/2021     | First Issuance              | N A                |

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Certified By (Sign/Date) : 04/09/2021

