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| 1. **DESCRIPTION**   **Specification:** White crystalline powder.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **IDENTIFICATION** |
| * 1. **Phosphocreatine (IR spectrum)**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** Conforms to the standard.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |

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| * 1. **Creatine**   **Specification:** Red coloring should appear.  **α-Naphthol Solution.** Dissolve \_\_\_\_\_\_\_ (0.10 g) of α -naphthol in \_\_\_\_\_\_\_ (3 mL) of a 15% w/v solution of sodium hydroxide and dilute to \_\_\_\_\_\_\_ (100 mL) with water. Prepare immediately before use.  **Procedure.** \_\_\_\_\_\_\_ (2 ml) of an aqueous solution containing \_\_\_\_\_\_ (10 mg) of creatine phosphate is heated in a boiling water bath for 10 minutes, \_\_\_\_\_\_ (2 ml) of α -Naphthol and diacetyl solution are added.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| * 1. **Phosphorus**   **Specification:** Blue coloring should appear.  **Reagent A.** \_\_\_\_\_\_\_ (5g) of ammonium molybdate is placed in a \_\_\_\_\_ (100 ml) volumetric flask, dissolved in a 1 M solution of sulfuric acid and the volume in the flask is brought to the mark with the same solvent.  **Reagent B.** \_\_\_\_\_\_\_ (200 mg) of p-methylaminophenol sulfate is dissolved in \_\_\_\_\_\_\_ (100 ml) of water and \_\_\_\_\_\_\_ (20g) of sodium sulfate is added. The reagent should be stored in tightly closed containers and used for 1 month. |

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| **Procedure. \_\_\_\_\_\_\_** (10 mg) of creatine phosphate is dissolved in \_\_\_\_\_\_\_\_\_ (25 ml) of 0.5 M sulfuric acid, heated in a boiling water bath for 10 minutes, cooled and added ml of reagent A and ml of reagent B, stirred and left for a while.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply | |
| * 1. **Sodium**   **Specification:** Flame staining on yellow.  **Procedure.** When the drug is introduced into the flame of the burner, a yellow staining appears, characteristic of sodium.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply | |
| 1. **OMOGENEITY BY MASS OF VIAL CONTENTS**   **Specification:** ± 10 %.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | № | m1 | m2 | m3 | № | m1 | m2 | m3 | | 1 |  |  |  | 11 |  |  |  | | 2 |  |  |  | 12 |  |  |  | | 3 |  |  |  | 13 |  |  |  | | 4 |  |  |  | 14 |  |  |  | | 5 |  |  |  | 15 |  |  |  | | 6 |  |  |  | 16 |  |  |  | | 7 |  |  |  | 17 |  |  |  | | 8 |  |  |  | 18 |  |  |  | | 9 |  |  |  | 19 |  |  |  | | 10 |  |  |  | 20 |  |  |  | |
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| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **TRANSPARENCY**   **Specification:** The solution must be transparent (2.2.1).  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **pH value**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** 8.0 - 9.0  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |

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| 1. **PARTICULATE CONTAMINATION** |
| * 1. **Visible Particles**   **Specification:** There must be no visible particles  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| * 1. **Invisible Particles**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** NMT 10 µm 6000 per container;  NMT 25 µm 600 per container.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **SOLUBILITY**   **Specification:** The contents of one bottle should completely dissolve in a bottle with a solvent to form a transparent solution practically free of foreign particles.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **IMPURITIES**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** Sum of impurities: NMT 5 %  **0.005 M tetrabutylammonium phosphate solution.** \_\_\_\_\_\_\_ (1.7 g) of tetrabutylammonium hydrophosphate is placed in a measuring flask with a capacity of \_\_\_\_\_\_\_ (1000 ml), dissolved in 900 ml of water, adjusted pH - \_\_\_\_\_\_ (7) with a solution of sodium phosphate 20% and adjusted the volume in the flask with water to the mark.  **Standard solution A.** About \_\_\_\_\_\_ (5 mg) of creatine, about \_\_\_\_\_\_\_ (5 mg0 of creatinine and phosphate are placed in a \_\_\_\_\_\_\_ (100 ml) volumetric flask, dissolved in water and the volume in the flask is brought to the mark with the same solvent and mixed.  **Standard solution B.** Pour \_\_\_\_\_\_ (2.0 ml) of the sample solution into a \_\_\_\_\_\_\_ (100 ml) volumetric flask, bring to the volume with water.  **Test solution.** About \_\_\_\_\_\_\_\_\_ (50 mg) of the drug is placed in a measuring flask with a capacity of \_\_\_\_ (10 ml), dissolved in water and the volume in the flask is brought to the mark with the same solvent, mixed. |

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Standard** | |  | **Test** | | | Purity of Standard |  |  | Test weight |  | | Standard weight |  |  | Dilution |  | | Dilution |  |  | ***No of injection*** | ***Area*** | | ***No of injection*** | ***Area*** |  | 1 |  | | STD A (1) |  |  | 2 |  | | STD A (2) |  |  | Mean |  | | STD A (3) |  |  | Retention time | | | STD B (1) |  |  | Creatine |  | | STD B (2) |  |  | Creatinine |  | | Resolution (NLT 2.5) |  |  | Creatine phosphate |  | | RSD (NMT 15%) |  |  | Creatinine phosphate |  |   **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **WATER**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** 22.0% - 25.0%.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **QUANTITY (HPLC method)**   Instrument ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Calibration due on: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Specification:** 95.0% - 110.0%  **Test solution:** About \_\_\_\_\_\_\_ (50 mg) (exact weight) of the drug is placed in a measuring flask with a capacity of \_\_\_\_\_ (100 ml), dissolved in water and the volume in the flask is brought to the mark with the same solvent, mixed. The solution is prepared before use.  **Standard solution:** About \_\_\_\_\_\_\_ (50 mg) (exact weight) of creatine phosphate (company standard) is placed in a measuring flask with a capacity of \_\_\_\_\_\_\_\_ (100 ml), dissolved in water and the volume in the flask is brought to the mark with the same solvent and mixed. Prepare the solution before use.  **Mobile phase (0.1 % phosphoric acid solution): \_\_\_\_\_\_\_** (1.0 ml) of concentrated phosphoric acid is placed in a measuring flask with a capacity of \_\_\_\_\_\_\_\_\_ (1000 ml), dissolved in 900 ml of water, and adjusted the volume in the flask with water to the mark.3.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Standard** | |  | **Test** | | | | Purity of Standard |  |  | Test weight |  | | Standard weight |  |  | Dilution |  | | Dilution |  |  | ***No of injection*** | ***Area*** | | ***No of injection*** | ***Area*** |  | 1 |  | | 1 |  |  | 2 |  | | 2 |  |  | Mean |  | | 3 |  |  | RSD |  | | 4 |  |  |  |  | | 5 |  |  | **Bracketing standard** | | | Mean |  |  | 1 |  | | RSD |  |  | 2 |  | |
| **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **BACTERIAL ENDOTOXIN**   **Specification:** NMT 0.175 EU/mg.  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |
| 1. **STERILITY**   **Specification:** Should be sterile  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Analysed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Complies/Does not comply |

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| 1. **PACKAGING**   **Specification:** Conforms to the approved packaging artwork  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| 1. **LABELLING**   **Specification:** Conforms to the approved labelling artwork  **Observation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **Sign/ Date** |  | **Sign/ Date** |  |
| **Designation** |  | **Designation** |  |