**Acetaminophen for injection**

**US 8071619B2**

|  |  |  |
| --- | --- | --- |
| **N°** | **Components** | **Quantity (g/100 ml)** |
| 1 | Acetaminophen | 1 |
| 2 | Monosodium phosphate dihydrate | 0.1002 |
| 3 | Disodium phosphate dihydrate | 0.0785 |
| 4 | Sodium chloride | 0.65 |
| 5 | Water | To 100 ml |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **N°** | **Components** | **Quantity (g/100 ml)** | **Grade** | **Properties** |
| 1 | Acetaminophen | 1 |  | * Crystal form: Monoclinic type I. * Space group: P21/*n*. * pH in an aqueous solution: 5 - 6.5. * Solubility in water at 20°C: 1.4 g/100ml. |
| 2 | Monosodium phosphate dihydrate | 0.1002 | Injectable grade | * Buffering agent. |
| 3 | Disodium phosphate dihydrate | 0.0785 | Injectable grade | * Buffering agent. |
| 4 | Sodium chloride | 0.65 | Injectable grade | * Isotonic agent. * Density: 1.2 g/cm3 for a saturated aqueous solution. * Density (bulk): 0.93 g/cm3. * Density (tapped): 1.09 g/cm3. * pH : 6.7-7.3 for a saturated aqueous solution. * Solubility at 20°C in water: 1 in 2.8. * Osmolarity: iso-osmotic with serum. |
| 5 | Water | To 100 ml | Injectable grade |  |

**Process**

|  |  |  |  |
| --- | --- | --- | --- |
| **Step** | **Description** | **Apparatus** | **Parameters** |
| **1** | Mixing :   * Acetaminophen. * Ultrapurified water for injection. * Monosodium phosphate dihydrate and disodium phosphate dihydrate. * Sodium chloride. |  |  |
| **2** | Heating the mixture. |  | Temperature: 70-90°C.  t= 15 min. |
| **3** | Filling of bottles. |  | Glass bottles or polypropylene containers. |
| **4** | Sterilizing bottles by therm. |  | Temperature: 121°C.  t=15 min. |