**Acetaminophen Syrup**

**Formula :**

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| **N°** | **Constituants** | **Quantity in mg/ml** |
| 1 | Acetaminophen | 33.33 mg |
| 2 | Guaifenesin | 13.33 mg |
| 3 | Propylene glycol | 125.00 mg |
| 4 | Polyethylene glycol | 350.00 mg |
| 5 | Sucrose | 250.00 mg |
| 6 | Sorbitol | 125.00 mg |
| 7 | Sucralose | 5.00 mg |
| 8 | Citric acid | 0.70 mg |
| 9 | Sodium benzoate | 2.00 mg |
| 10 | Sodium carboxy methylcellulose | 2.00 mg |
| 11 | Natural peppermint flavor #104 | 2.00 mg |
| 12 | FD&C Blue #1 | 0.01 mg |
| 13 | Purified water | QS |

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| **N°** | **Constituants** | **Quantity in mg/ml** | **Grade** | **Properties** |
| 1 | Acetaminophen | 33.33 mg |  | * 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 | Guaifenesin | 13.33 mg |  | * Crystal form : orthorhombic. * Space group : P 212121. * Density : 1.2 ± 0.1 g/cm3. * Solubility in water: 5g/100 ml at 25°C. |
| 3 | Propylene glycol (PG) | 125.00 mg |  | * Solvant. * Density: 1.038 g/cm3 at 20°C. * Surface tension: 40.1 mN/m at 25°C. * Viscosity: 15- 20 mPa.s. |
| 4 | Polyethylene glycol (PEG) | 350.00 mg | PEG 600 | * Solubilating agent. * Average molecular weight: 570- 613 amu. * Density: 1.08 g/cm3. * Surface tension: 44mN/m. |
| 5 | Sucrose | 250.00 mg | 60/200 | * Sweetening agent. * Crystalline form. * Density (bulk): 0.93 g/cm3. * Density (tapped): 1.03 g/cm3. * Density (true): 1.6 g/cm3. * Solubility in water at 20°C: 1 in 0.5. * Median particle size: 540µm. * Moisture content: it absorbs up to 1% water. |
| 6 | Sorbitol | 125.00 mg | 70/70 | * Sweetening agent. * Liquid (non crystalling). * pH: 4.5 - 7 for a 10% w/v aqueous solution. * Density (bulk): 0.448 g/cm3. * Density (tapped): 0.400 g/cm3. * Density (true): 1.507 g/cm3. * Moisture content: >60% at 25°C. |
| 7 | Sucralose | 5.00 mg |  | * Sweetening agent. * pH: 5 – 6 for a 10% w/v aqueous solution at 20°C. * Density (bulk): 0.35 g/cm3. * Density (tapped): 0.62 g/cm3. * Density (true): 1.63 g/cm3. * Particle size distribution: 90%<12µm in size. * Viscosity: 0.6 – 3.8 mPa.s. |
| 8 | Citric acid | 0.70 mg |  | * Preservative * Density: 1.665 g/cm3. * Solubility in water 133g/100ml at 20°C. * Viscosity: 6.5 mPa.s for a 50% w/v aqueous solution at 25°C. |
| 9 | Sodium benzoate | 2.00 mg |  | * Antimicrobial preservative * Density: 1.497- 1.527 g/cm3 at 24°C. * Solubility in water at 20°C: 1 in 1.8. |
| 10 | Sodium carboxy methylcellulose | 2.00 mg |  |  |
| 11 | Natural peppermint flavor #104 | 2.00 mg |  |  |
| 12 | FD&C Blue #1 | 0.01 mg |  |  |
| 13 | Water | QS | Purified water | In accordance with the pharmacopeia. |

**Process:**

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| **Step** | **Description** | **Equipments** | **Parameters** |
| 1 | A solution of liquid excipient was prepared using Polyethylene glycol and propylene glycol. |  |  |
| 2 | Acetaminophen was dissolved in a solution of liquid excipient base under stirring. |  | Mixing time: 15 to 60 min. |
| 3 | Guaifenesin was added to the acetaminophen solution obtained previously under stirring. |  |  |
| 4 | Sodium benzoate, sucralose, citric acid and sorbitol was added successively to 20% of purified water and stirred. |  |  |
| 5 | The solution of step 4 was added to the acetaminophen solution. |  |  |
| 6 | Sodium carboxy methylcellulose soaked in 5% of purified water was prepared then added and stirred. |  | Mixing time: 10min. |
| 7 | Peppermint flavor, FD&C blue #1 was added to the mixture. |  |  |
| 8 | The volume was made with purified water and filtered. |  | 5µm filters |
|  |
| 9 | The final solution was filled in bottles. |  |  |

**Syrup caracterestics:**

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| pH of the liquid excipient base | 4.5 - 6.5 |
| Viscosity at 25±3°C  (Measured with Brookfield viscometer spindle N°1 (LV1) at 40 RPM ) | 80- 140 cPs |