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Material No.: 7558-18 Revision No.: 0

Product Specification

Meets J.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets N.F. Requirements, GMP Manufactured Product

| Test | Specification |
|--|----------------|
| NF - Assay (C11H14O3) | 98.0 - 102.0 % |
| NF - Identification A | Passes Test |
| NF – Identification B | Passes Test |
| NF – Color of Solution | Passes Test |
| NF – Acidity | Passes Test |
| NF – Residue on Ignition | ≤ 0.1 % |
| NF – Related Substances – p-Hydroxybenzoic Acid | \leq 0.5 % |
| NF – Related Substances – Unspecified Impurities (each) | \leq 0.5 % |
| NF - Related Substances - Total Impurities | \leq 1.0 % |
| EP/BP - Assay (C11H14O3) | 98.0 - 102.0 % |
| EP/BP – Appearance of Solution | Passes Test |
| EP/BP - Identification A | Passes Test |
| EP/BP – Identification B | Passes Test |
| EP/BP – Acidity | Passes Test |
| EP/BP - Related Substances - Impurity A | \leq 0.5 % |
| EP/BP – Related Substances – Unspecified Impurities (each) | \leq 0.5 % |
| EP/BP - Related Substances - Total Impurities | \leq 1.0 % |
| EP/BP – Sulfated Ash | ≤ 0.1 % |
| JP – Acidity | Passes Test |
| JP – Assay | 98.0 - 102.0 % |
| JP - Clarity and Color of Solution | Passes Test |
| JP – Heavy Metals | ≤ 20 ppm |
| JP - Identification | Passes Test |
| JP – Melting Point | 68 – 71 °C |
| JP-RelatedSubstances- p-Hydroxybenzoic Acid | \leq 0.5 % |
| JP-Related Substances-Unspecified Impurities (each) | \leq 0.5 % |
| JP-Related Substances-Total Impurities | \leq 1.0 % |
| JP – Residue on Ignition | \leq 0.10 % |

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700 Avantor Performance Materials, LLC 100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700 Butylparaben NF - GenAR®





Material No.: 7558-18

Test

Specification

GMP Manufactured Product Bulk Pharmaceutical Chemical CAUTION: For Manufacturing, processing or repackaging Only the Class 3 solvent 1-butanol is present. The concentration is controlled below 0.5%. Elemental Impurities (USP 232, EP 5.20) – Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Paris Mfg Ctr & DC

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