

Material No.: 6215-18  
Batch No.: 23K1061009  
Manufactured Date: 2023-02-24  
Retest Date: 2028-02-23  
Release Date: 2024-03-13  
Revision No.: 0

## Certificate of Analysis

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

| Test  | Specification  | Result      |
|---|----------------|-------------|
| NF – Identification A   | Passes Test    | Passes Test |
| NF – Identification B   | Passes Test    | Passes Test |
| NF – Color of Solution  | Passes Test    | Passes Test |
| NF – Acidity  | Passes Test    | Passes Test |
| NF – Related Substances – p-Hydroxybenzoic Acid               | ≤ 0.5 %        | < 0.5 %     |
| NF – Related Substances – Unspecified Impurities (each)       | ≤ 0.5 %        | < 0.5 %     |
| NF – Related Substances – Total Impurities                    | ≤ 1.0 %        | < 1.0 %     |
| NF – Residue on Ignition                                      | ≤ 0.1 %        | < 0.1 %     |
| Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> )(NF)     | 98.0 – 102.0 % | 100.1 %     |
| JP – Identification   | Passes Test    | Passes Test |
| JP – Melting Point  | 125 – 128 °C   | 127 °C      |
| JP – Clarity and Color of Solution                            | Passes Test    | Passes Test |
| JP – Acidity (JP)   | Passes Test    | Passes Test |
| JP – Heavy Metals   | ≤ 20 ppm       | < 20 ppm    |
| JP-RelatedSubstances– p-Hydroxybenzoic Acid                   | ≤ 0.5 %        | < 0.5 %     |
| JP-Related Substances–Unspecified Impurities (each)           | ≤ 0.5 %        | < 0.5 %     |
| JP-Related Substances–Total Impurities                        | ≤ 1.0 %        | < 1.0 %     |
| JP – Residue on Ignition                                      | ≤ 0.10 %       | < 0.10 %    |
| JP – Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> )    | 98.0 – 102.0 % | 100.1 %     |
| EP/BP – Assay (C <sub>8</sub> H <sub>8</sub> O <sub>3</sub> ) | 98.0 – 102.0 % | 100.1 %     |
| EP/BP – Appearance of Solution                                | Passes Test    | Passes Test |
| EP/BP – Identification A                                      | Passes Test    | Passes Test |
| EP/BP – Identification B                                      | Passes Test    | Passes Test |
| EP/BP – Acidity   | Passes Test    | Passes Test |
| EP/BP – Related Substances – Impurity A                       | ≤ 0.5 %        | < 0.5 %     |
| EP/BP – Related Substances – Unspecified Impurities (each)    | ≤ 0.5 %        | < 0.5 %     |
| EP/BP – Related Substances – Total Impurities                 | ≤ 1.0 %        | < 1.0 %     |
| EP/BP – Sulfated Ash  | ≤ 0.1 %        | < 0.1 %     |

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Methylparaben  
NF – GenAR®



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| Test   | Specification | Result   |
|--|---------------|----------|
| Methanol (CH <sub>3</sub> OH)(by GC), For Information Only |               | < 10 ppm |

GMP Manufactured Product  
Bulk Pharmaceutical Chemical  
CAUTION: For Manufacturing, processing or repackaging  
Only the Class 2 solvent Methanol is present. Residual concentration is <3000 ppm.  
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.

Country of Origin: Japan  
Packaging Site: Paris Mfg Ctr & DC  
Manufacturer: P0151001  
Manufacturer source batch: 23K1061009

Michelle Bales  
Sr. Manager, Quality Assurance

For questions on this Certificate of Analysis 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