



Material No.: 7624-18

Revision No.: 0

## **Product Specification**

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

NF - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>2</sub> )         98.0 - 102.0 %           NF - Identification A         Passes Test           NF - Identification B         Passes Test           NF - Color of Solution         Passes Test           NF - Color of Solution         Passes Test           NF - Related Substances - p-Hydroxybenzoic Acid         ≤ 0.5 %           NF - Related Substances - Unspecified Impurities (each)         ≤ 0.5 %           NF - Related Substances - Total Impurities (each)         ≤ 0.1 %           EP/BP - Assay (C <sub>10</sub> -H <sub>10</sub> O <sub>1</sub> )         98.0 - 102.0 %           EP/BP - Appearance of Solution         Passes Test           EP/BP - Appearance of Solution         Passes Test           EP/BP - Identification A         Passes Test           EP/BP - Related Substances - Impurity A         ≤ 0.5 %           EP/BP - Related Substances - Impurity A         ≤ 0.5 %           EP/BP - Related Substances - Unspecified impurities (each)         ≤ 0.5 %           EP/BP - Sulfated Ash         ≤ 0.1 %           EP/BP - Sulfated Ash         ≤ 0.7 %           JP - Identification         Passes Test           JP - Identification         Passes Test           JP - Melting Point         96 - 99 °C           JP - Melting Point         92 - 99 °C           JP - Related Substances - Phydroxyb	Test	Specification
NF - Identification B NF - Color of Solution NF - Acidity NF - Acidity NF - Related Substances - p-Hydroxybenzoic Acid NF - Related Substances - p-Hydroxybenzoic Acid NF - Related Substances - Unspecified Impurities (each) NF - Related Substances - Total Impurities S1.0 % NF - Related Substances - Total Impurities S1.0 % NF - Residue on Ignition PF/BP - Assay (Coding Ob) SP/BP - Assay (Coding Ob) SP/BP - Assay (Coding Ob) SP/BP - Acidity Passes Test SP/BP - Acidity Passes Test SP/BP - Acidity Passes Test SP/BP - Related Substances - Impurity A SP/BP - Acidity SP/BP - Related Substances - Total Impurities (each) SP/BP - Sulfated Ash SP - Acidity S	NF - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )	98.0 - 102.0 %
NF - Color of Solution  NF - Acidity  NF - Related Substances - p-Hydroxybenzoic Acid  NF - Related Substances - Unspecified Impurities (each)  NF - Residue on Ignition  EP/BP - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )  EP/BP - Acidity  Passes Test  EP/BP - Acidity  Passes Test  EP/BP - Related Substances - Total Impurities  EP/BP - Acidity  Passes Test  EP/BP - Related Substances - Data Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Sulfated Ash  JP - Assay  JP - Sasay  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Melting Point  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - Total Impurities (each)  EV SW  JP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Impurities (each)  EV DP/BP - Related Substances - Total Imp	NF - Identification A	Passes Test
NF - Acidity NF - Related Substances - p-Hydroxybenzoic Acid SC - S & S NF - Related Substances - Unspecified Impurities (each) SC - Related Substances - Unspecified Impurities SC - S & S NF - Related Substances - Total Impurities SC - S & S NF - Related Substances - Total Impurities SC - S & S NF - Residue on Ignition SC - Residue on Ignition	NF - Identification B	Passes Test
NF - Related Substances - p-Hydroxybenzoic Acid  NF - Related Substances - Unspecified Impurities (each)  NF - Related Substances - Total Impurities  \$ 1.0 %  NF - Residue on Ignition  \$ 20.1 %  EP/BP - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )  \$ 98.0 - 102.0 %  EP/BP - Aleditification A  Passes Test  EP/BP - Identification B  EP/BP - Related Substances - Impurity A  \$ 20.5 %  EP/BP - Related Substances - Unspecified Impurities (each)  \$ 20.5 %  EP/BP - Related Substances - Unspecified Impurities (each)  \$ 20.5 %  EP/BP - Related Substances - Total Impurities  \$ 1.0 %  EP/BP - Related Substances - Total Impurities  \$ 20.1 %  IP - Assay  IP - Assay  IP - Assay  IP - Assay  IP - Identification  Passes Test  IP - Identification  IP - Related Substances - Impurity A  Solon - 102.0  IP - Identification  IP - Related Substances - Total Impurities  IP - Related Substances - Solution  Passes Test  IP - Related Substances - Total Impurities  \$ 20 ppm  IP - Related Substances - PHydroxybenzoic Acid  IP - Related Substances - PHydroxybenzoic Acid  IP - Related Substances - PHydroxybenzoic Acid  IP - Related Substances - Data Impurities  \$ 1.0 %	NF - Color of Solution	Passes Test
NF - Related Substances - Unspecified Impurities (each)  NF - Related Substances - Total Impurities  \$ 1.0 %  NF - Residue on Ignition  EP/BP - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )  98.0 - 102.0 %  EP/BP - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )  98.0 - 102.0 %  EP/BP - Appearance of Solution  Passes Test  EP/BP - Identification A  Passes Test  EP/BP - Acidity  Passes Test  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  JP - Assay  JP - Identification  Passes Test  EP/BP - Sulfated Ash  JP - Addity  Passes Test  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - Total Impurities (each)  JP - Related Substances - Total Impurities (each)  S 0.5 %  JP - Related Substances - Total Impurities (each)  S 0.5 %  JP - Related Substances - Total Impurities (each)  S 0.5 %  JP - Related Substances - Total Impurities  \$ 1.0 %	NF - Acidity	Passes Test
NF - Related Substances - Total Impurities  NF - Residue on Ignition  EP/BP - Assay (C <sub>10</sub> H <sub>10</sub> O <sub>3</sub> )  EP/BP - Assay (C <sub>10</sub> H <sub>10</sub> O <sub>3</sub> )  EP/BP - Appearance of Solution  Passes Test  EP/BP - Identification A  Passes Test  EP/BP - Identification B  Passes Test  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  JP - Assay  JP - Identification  Passes Test  EP/BP - Sulfated Ash  JP - Identification  Passes Test  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - Inspecified Impurities (each)  JP - Related Substances - Total Impurities  ≤ 1.0 %  JP - Related Substances - Total Impurities (each)  S - 0.5 %  JP - Related Substances - Total Impurities  ≤ 1.0 %	NF - Related Substances - p-Hydroxybenzoic Acid	≤ 0.5 %
NF - Residue on Ignition  EP/BP - Assay (CnoHn2Os)  EP/BP - Appearance of Solution  EP/BP - Appearance of Solution  EP/BP - Identification A  EP/BP - Identification B  EP/BP - Acidity  Passes Test  EP/BP - Acidity  Passes Test  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  ≤ 0.5 %  EP/BP - Related Substances - Total Impurities  ≤ 1.0 %  EP/BP - Sulfated Ash  JP - Assay  JP - Alentification  JP - Melting Point  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - D-Hydroxybenzoic Acid  JP - Related Substances - Total Impurities  ≤ 1.0 %  ≤ 0.5 %  JP - Related Substances - Total Impurities  ≤ 1.0 %	NF - Related Substances - Unspecified Impurities (each)	≤ 0.5 %
EP/BP - Assay (CnoHn2O3)  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  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  JP - Assay  BR - 102.0  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances- Unspecified Impurities (each)  EV - Related Substances - Unspecified Impurities (each)  EV - Related Substances - Unspecified Impurities (each)  EV - Related Substances - Total Impurities	NF - Related Substances - Total Impurities	≤ 1.0 %
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 \$0.5 % EP/BP - Related Substances - Unspecified Impurities (each) \$0.5 % EP/BP - Related Substances - Total Impurities \$1.0 % EP/BP - Sulfated Ash \$0.1 % JP - Assay \$98.0 - 102.0 JP - Identification Passes Test JP - Melting Point \$96 - 99 °C JP - Acidity Passes Test JP - Clarity and Color of Solution Passes Test JP - Heavy Metals JP - Heavy Metals JP - Related Substances - p-Hydroxybenzoic Acid JP - Related Substances-Unspecified Impurities (each) \$0.5 % JP - Related Substances - D-Hydroxybenzoic Acid JP - Related Substances - Total Impurities (each) \$0.5 % JP - Related Substances - Total Impurities (each) \$0.5 % JP - Related Substances - Total Impurities (each) \$0.5 %	NF - Residue on Ignition	≤ 0.1 %
EP/BP - Identification A  EP/BP - Identification B  EP/BP - Acidity  Passes Test  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  JP - Assay  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  JP - Heavy Metals  JP - Related Substances - P-Hydroxybenzoic Acid  JP - Related Substances - D-Hydroxybenzoic Acid  JP - Related Substances - D-Hydroxybenzoic Acid  JP - Related Substances - Unspecified Impurities  \$ 1.0 %  1 - 1.0 %  1 - 1.0 %  1 - 1.0 %  1 - 1.0 %  1 - 1.0 %	EP/BP - Assay (C <sub>10</sub> H <sub>12</sub> O <sub>3</sub> )	98.0 - 102.0 %
EP/BP - Identification B EP/BP - Acidity Passes Test EP/BP - Related Substances - Impurity A EP/BP - Related Substances - Unspecified Impurities (each) EP/BP - Related Substances - Total Impurities EP/BP - Sulfated Ash IP - Assay JP - Identification JP - Identification JP - Melting Point JP - Acidity JP - Acidity JP - Clarity and Color of Solution JP - Clarity and Color of Solution JP - Heavy Metals JP - Related Substances - p-Hydroxybenzoic Acid JP - Related Substances - p-Hydroxybenzoic Acid JP - Related Substances - Unspecified Impurities (each) JP - Related Substances - Unspecified Impurities EP/BP - Sulfated Substances - Unspecified Impurities EP/BP - Related Substances - Total Impurities EP/BP - R	EP/BP - Appearance of Solution	Passes Test
EP/BP - Acidity  EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  EP/BP - Sulfated Ash  JP - Assay  JP - Identification  JP - Identification  JP - Melting Point  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  JP - Clarity and Color of Solution  JP - Heavy Metals  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - Unspecified Impurities (each)  JP - Related Substances - Total Impurities  \$ 0.5 %  JP - Related Substances - Total Impurities  \$ 1.0 %	EP/BP - Identification A	Passes Test
EP/BP - Related Substances - Impurity A  EP/BP - Related Substances - Unspecified Impurities (each)  EP/BP - Related Substances - Total Impurities  EP/BP - Related Substances - Total Impurities  EP/BP - Sulfated Ash  JP - Assay  JP - Assay  JP - Identification  JP - Melting Point  JP - Acidity  JP - Acidity  JP - Clarity and Color of Solution  JP - Heavy Metals  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - Unspecified Impurities (each)  JP - Related Substances - Total Impurities  \$ 1.0 %	EP/BP - Identification B	Passes Test
EP/BP - Related Substances - Unspecified Impurities (each) ≤ 0.5 %  EP/BP - Related Substances - Total Impurities ≤ 1.0 %  EP/BP - Sulfated Ash ≤ 0.1 %  JP - Assay 98.0 - 102.0  JP - Identification Passes Test  JP - Melting Point 96 - 99 °C  JP - Acidity Passes Test  JP - Clarity and Color of Solution Passes Test  JP - Heavy Metals ≤ 20 ppm  JP-Related Substances - p-Hydroxybenzoic Acid ≤ 0.5 %  JP-Related Substances-Unspecified Impurities (each) ≤ 0.5 %  JP-Related Substances-Total Impurities (each) ≤ 1.0 %	EP/BP - Acidity	Passes Test
EP/BP - Related Substances - Total Impurities \$\leq 1.0 \%\$  EP/BP - Sulfated Ash \$\leq 0.1 \%\$  JP - Assay \$\leq 98.0 - 102.0  JP - Identification \$\leq 26.99 \cdot C\$  JP - Melting Point \$\leq 6-99 \cdot C\$  JP - Acidity \$\leq 20 \text{pm}\$  Passes Test \$\leq 19 - Clarity and Color of Solution \$\leq 20 \text{pm}\$  JP - Heavy Metals \$\leq 20 \text{pm}\$  JP-Related Substances- p-Hydroxybenzoic Acid \$\leq 0.5 \%\$  JP-Related Substances-Unspecified Impurities (each) \$\leq 0.5 \%\$  JP-Related Substances-Total Impurities \$\leq 1.0 \%\$	EP/BP - Related Substances - Impurity A	≤ 0.5 %
EP/BP - Sulfated Ash  JP - Assay  JP - Identification  JP - Identification  JP - Melting Point  JP - Acidity  JP - Acidity  JP - Clarity and Color of Solution  JP - Heavy Metals  JP - Related Substances - p-Hydroxybenzoic Acid  JP - Related Substances - Unspecified Impurities (each)  JP - Related Substances - Total Impurities  ≤ 0.5 %  JP - Related Substances - Total Impurities	EP/BP - Related Substances - Unspecified Impurities (each)	≤ 0.5 %
JP - Assay  JP - Identification  Passes Test  JP - Melting Point  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  JP - Heavy Metals  JP-Related Substances- p-Hydroxybenzoic Acid  JP-Related Substances- Unspecified Impurities (each)  JP-Related Substances-Total Impurities  ≤ 1.0 %	EP/BP - Related Substances - Total Impurities	≤ 1.0 %
JP - Identification  JP - Melting Point  JP - Acidity  Passes Test  JP - Clarity and Color of Solution  JP - Heavy Metals  JP - Related Substances- p-Hydroxybenzoic Acid  JP-Related Substances- Unspecified Impurities (each)  JP-Related Substances-Total Impurities  ≤ 1.0 %	EP/BP - Sulfated Ash	≤ 0.1 %
JP - Melting Point       96 - 99 °C         JP - Acidity       Passes Test         JP - Clarity and Color of Solution       Passes Test         JP - Heavy Metals       ≤ 20 ppm         JP-Related Substances - p-Hydroxybenzoic Acid       ≤ 0.5 %         JP-Related Substances-Unspecified Impurities (each)       ≤ 0.5 %         JP-Related Substances-Total Impurities       ≤ 1.0 %	JP - Assay	98.0 - 102.0
JP - Acidity  JP - Clarity and Color of Solution  JP - Heavy Metals  JP-RelatedSubstances- p-Hydroxybenzoic Acid  JP-Related Substances-Unspecified Impurities (each)  JP-Related Substances-Total Impurities  ≤ 1.0 %	JP - Identification	Passes Test
JP - Clarity and Color of Solution  Passes Test  JP - Heavy Metals  ≤ 20 ppm  JP-RelatedSubstances- p-Hydroxybenzoic Acid  ≤ 0.5 %  JP-Related Substances-Unspecified Impurities (each)  JP-Related Substances-Total Impurities  ≤ 1.0 %	JP - Melting Point	96 - 99 °C
JP - Heavy Metals       ≤ 20 ppm         JP-RelatedSubstances- p-Hydroxybenzoic Acid       ≤ 0.5 %         JP-Related Substances-Unspecified Impurities (each)       ≤ 0.5 %         JP-Related Substances-Total Impurities       ≤ 1.0 %	JP - Acidity	Passes Test
JP-Related Substances- p-Hydroxybenzoic Acid ≤ 0.5 %  JP-Related Substances-Unspecified Impurities (each) ≤ 0.5 %  JP-Related Substances-Total Impurities ≤ 1.0 %	JP - Clarity and Color of Solution	Passes Test
JP-Related Substances-Total Impurities (each) ≤ 0.5 %  JP-Related Substances-Total Impurities ≤ 1.0 %	JP - Heavy Metals	≤ 20 ppm
JP-Related Substances-Total Impurities ≤ 1.0 %	JP-RelatedSubstances- p-Hydroxybenzoic Acid	≤ 0.5 %
	JP-Related Substances-Unspecified Impurities (each)	≤ 0.5 %
JP - Residue on Ignition $\leq 0.10 \%$	JP-Related Substances-Total Impurities	≤ 1.0 %
	JP - Residue on Ignition	≤ 0.10 %

Propylparaben NF - GenAR®





Material No.: 7624-18

Test Specification

GMP Manufactured Product Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only the Class 3 solvent 1-propanol 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.

Storage Condition: Store in a tightly closed container.

Packaging Site: Paris Mfg Ctr & DC

