Sodium Sulfate, Anhydrous, Powder USP – GenAR® Suitable for Use in Biotechnology





Material No.: 7803-88 Revision No.: 0

## **Product Specification**

Meets U.S.P Requirements, Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, GMP Manufactured Product

USP - Assay (Na2SO4) (dried basis)≥ 99.0 %USP - Acidity or AlkalinityPasses TestUSP - Chloride (Cl)≤ 0.005 %USP - Identification APasses TestUSP - Identification BPasses TestUSP - Identification CPasses TestUSP - Insoluble Matter≤ 0.01 %USP - Insoluble Matter≤ 0.001 %USP - Loss on Drying at 105°C≤ 0.5 %Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	Test	Specification
USP - Chloride (Cl)≤ 0.005 %USP - Identification APasses TestUSP - Identification BPasses TestUSP - Identification CPasses TestUSP - Insoluble Matter≤ 0.01 %USP - Insoluble Matter≤ 0.01 %USP - Iron (Fe)≤ 0.001 %USP - Loss on Drying at 105°C≤ 0.5 %Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Assay (Na2SO4) (dried basis)	≥ 99.0 %
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USP - Identification CPasses TestUSP - Insoluble Matter≤ 0.01 %USP - Iron (Fe)≤ 0.001 %USP - Loss on Drying at 105°C≤ 0.5 %Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP - Identification A	Passes Test
USP - Insoluble Matter≤ 0.01 %USP - Iron (Fe)≤ 0.001 %USP - Loss on Drying at 105°C≤ 0.5 %Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Identification B	Passes Test
USP - Iron (Fe) $\leq 0.001 \%$ USP - Loss on Drying at 105°C $\leq 0.5 \%$ Thru U.S. No. 50 Sieve, For Information Only $\%$ Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 \%EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl) $\leq 450 \text{ ppm}$ EP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Identification C	Passes Test
USP - Loss on Drying at 105°C≤ 0.5 %Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Insoluble Matter	≤ 0.01 %
Thru U.S. No. 50 Sieve, For Information Only%Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Iron (Fe)	≤ 0.001 %
Solubility (5 in 100)Passes TestEP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	USP – Loss on Drying at 105°C	≤ 0.5 %
EP/BP - Assay (Na2SO4)98.5 - 101.0 %EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	Thru U.S. No. 50 Sieve, For Information Only	%
EP/BP - Acidity or AlkalinityPasses TestEP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	Solubility (5 in 100)	Passes Test
EP/BP - Appearance of SolutionPasses TestEP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	EP/BP – Assay (Na2SO4)	98.5 - 101.0 %
EP/BP - Chloride (Cl)≤ 450 ppmEP/BP - Identification APasses TestEP/BP - Identification BPasses Test	EP/BP - Acidity or Alkalinity	Passes Test
EP/BP - Identification APasses TestEP/BP - Identification BPasses Test	EP/BP - Appearance of Solution	Passes Test
EP/BP – Identification B Passes Test	EP/BP – Chloride (Cl)	≤ 450 ppm
	EP/BP – Identification A	Passes Test
	EP/BP – Identification B	Passes Test
EP/BP – Identification C Passes Test	EP/BP – Identification C	Passes Test
EP/BP – Loss on Drying @ 130° C $\leq 0.5$ %	EP/BP – Loss on Drying @ 130° C	$\leq$ 0.5 %

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Test

Specification

GMP Manufactured Product Bulk Pharmaceutical Chemical CAUTION: For Manufacturing, processing or repackaging No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Packaging Site: Paris Mfg Ctr & DC

James Techie

Jamie Ethier Vice President Global Quality

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