

## **PROCIPIENT®** (Dimethyl Sulfoxide USP, PhEur) Specification

The Retention Time (RT) of the major peak in the Sensitivity soln corresponds to that of the major peak of the Sample solution in the test for Organic Impurities.  Acidity, (ml 0.01 N NaOH) Water, % by KF  UV absorbance  No absorbance maxima between 270 & 350 nm  NMT 0.20  A 285 / A 275  NMT 0.65  A 295 / A 275  NMT 0.45  Limit of Nonvolatile Residue Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis) Refractive index @ 25°C  1.4755 - 1.4775 Specific gravity @ 25°C  1.095 - 1.101  PhEur Compendial Test First Identification C. (IR) Second Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride Acidity, (ml 0.01 N NaOH) Water, % by KF  NMT 0.2% Freezing Point, (*C) UV absorbance UV absorbance 275 nm  NMT 0.20  Related Substances, % (Reporting Threshold: 0.05%)  Gavlord Chemical Company Test  The Retention Time (RT) of the major peak in the Sensitivity soln corresponds to that of the major peak in the Sensitivity soln corresponds to that of the major peak in the Sensitivity soln corresponds to the test for Organic Impurities.  NMT 0.20  The Retention Time (RT) of the major peak in the Sensitivity soln corresponds to the test for Organic Impurities.  NMT 0.10  NMT 0.20  Total Impurities. NMT 0.10  Total Impurities. NMT 0.15  Gavlord Chemical Company  The Retention Time (RT) of the major peak in the Sensitivity soln corresponds to the test for Organic Impurities.  The Retention Time (RT) of the sample solution in the test for Organic Impurities.  NMT 0.20  Total Impurities: NMT 0.10  Total Impurities: NMT 0.15  Gavlord Chemical Company	USP Compendial Test	USP Specifications	
that of the major peak of the Sample solution in the test for Organic Impurities.  Acidity, (ml 0.01 N NaOH)  Water, % by KF  UV absorbance  UV absorbance  UV absorbance @ 275 nm  A 285 / A 275  A 295 / A 275  Init of Nonvolatile Residue  Organic Impurities, %  (Reporting Threshold: 0.03%)  Assay, % (anhydrous basis)  Refractive index @ 25°C  J. 4755 - 1.4775  Specific gravity @ 25°C  B. Refractive Index @ 25°C  B. Refractive Index @ 20°C  B. Refractive Density @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  UV absorbance 275 nm  NMT 0.20  Related Substances, %  (Reporting Threshold: 0.05%)  Refractive Index @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  NMT 5.0  NMT 5.0  NMT 0.20  Related Substances, %  (Reporting Threshold: 0.05%)  Related Substances, %  (Reporting Threshold: 0.05%)  Gavlord Chemical Company Test  Gavlord Chemical Company  The substances of the sample solution in the test for Organic Impurities.  NMT 0.10  NMT 0.15  Gavlord Chemical Company  The substances of the sample solution in the test for Organic Impurities.  NMT 0.10  NMT 0.10  Total Impurities.  NMT 0.15  Gavlord Chemical Company  The substances of the sample solution in the test of the substances in the substance of the substance	Identification (IR)	Compares with reference sample	
Acidity, (ml 0.01 N NaOH) Water, % by KF  UV absorbance  UV absorbance @ 275 nm  A 285 / A 275  A 295 / A 275  Limit of Nonvolatile Residue Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis) Refractive index @ 25°C  PhEur Compendial Test First Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride Acidity, (ml 0.01 N NaOH) Water, % by KF Freezing Point, (°C) UV absorbance UV absorbance Related Substances, % (Reporting Threshold: 0.05%) Gaylord Chemical Company Test  ONA Dassay, Was an	ID (Retention Time)	The Retention Time (RT) of the major peak in the Sensitivity soln corresponds t that of the major peak of the Sample solution in the test for Organic Impurities	
UV absorbance  UV absorbance @ 275 nm  A 285 / A 275  A 295 / A 275  Limit of Nonvolatile Residue  Organic Impurities, % (Reporting Threshold: 0.03%)  Assay, % (anhydrous basis)  Refractive index @ 25°C  Specific gravity @ 25°C  PhEur Compendial Test  First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  Related Substances, % (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  PMT 0.20  NMT 0.20  Related Company Test  NMT 0.20  Gaylord Chemical Company  NMT 0.20  Gaylord Chemical Company  SMT 0.15  Sason  NMT 0.20  Gaylord Chemical Company  Each Unspecified Impurity: NMT 0.15  Gaylord Chemical Company  Test  NMT 0.15  NMT 0.15  Sagon  SMT 0.15  Saylord Chemical Company  Test  NMT 0.15  Saylord Chemical Company  Test  NMT 0.15  Saylord Chemical Company  Total Impurities: NMT 0.15  Gaylord Chemical Company	Acidity, (ml 0.01 N NaOH)		
UV absorbance @ 275 nm  A 285 / A 275  A 295 / A 275  Limit of Nonvolatile Residue  Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis)  Refractive index @ 25°C  Specific gravity @ 25°C  PhEur Compendial Test  First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  UV absorbance  Related Substances, % (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  NMT 0.15  NMT 0.15  SMMT 0.15  NMT 0.15  SMMT 0.10  SMMT 0.20  SMMT 0.15  SMMT 0.15  SMMT 0.15  SMAT 0.1	Water, % by KF	NMT 0.1	
A 285 / A 275 A 295 / A 275 Limit of Nonvolatile Residue Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis) Refractive index @ 25°C Specific gravity @ 25°C 1.4755 - 1.4775 Specific gravity @ 25°C 1.095 - 1.101  PhEur Compendial Test PhEur Specifications First Identification C. (IR) Second Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride Acidity, (ml 0.01 N NaOH) Water, % by KF Freezing Point, (°C) UV absorbance UV absorbance UV absorbance UV absorbance UV absorbance 295 nm Related Substances, % (Reporting Threshold: 0.05%) Gaylord Chemical Company Test  NMT 0.18  NMT 0.19  NMT 0.19  Compares with spectrum of Dimethyl Sulfoxide CRS  NAT 0.20  NMT 0.20  NMT 0.20  Second Identification  NMT 0.20  Total Impurities: NMT 0.15  Gaylord Chemical Company  Test	UV absorbance	No absorbance maxima between 270 & 350 nm	
A 295 / A 275 Limit of Nonvolatile Residue Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis) Refractive index @ 25°C Refractive index @ 25°C Specific gravity @ 25°C 1.095 - 1.101  PhEur Compendial Test PhEur Specifications First Identification C. (IR) Second Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride Acidity, (ml 0.01 N NaOH) Water, % by KF Freezing Point, (°C) UV absorbance UV absorbance UV absorbance UV absorbance UV absorbance UV absorbance Specific gravity (°C) D. Nickel Chloride Acidity, (ml 0.01 NaOH) Roman Specification NMT 0.20 Related Substances, % (Reporting Threshold: 0.05%) Gaylord Chemical Company Test  Rotal Impurities NMT 0.16  Rotal Impurities NMT 0.15  Rotal Impurities NMT 0.16  Rotal Impurities: NMT 0.15  Gaylord Chemical Company  Total Impurities NMT 0.16  Rotal Impurities: NMT 0.15  Gaylord Chemical Company  Total Impurities NMT 0.16  Rotal Impurities: NMT 0.15  Gaylord Chemical Company	UV absorbance @ 275 nm	NMT 0.20	
Limit of Nonvolatile Residue Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis) Refractive index @ 25°C Refractive index @ 25°C Specific gravity @ 25°C Specific gravity @ 25°C  PhEur Compendial Test First Identification C. (IR) Second Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride Acidity, (ml 0.01 N NaOH) Water, % by KF Freezing Point, (°C) UV absorbance UV absorbance 275 nm UV absorbance 275 nm Related Substances, % (Reporting Threshold: 0.05%) Gaylord Chemical Company Test  NMT 0.1%  Total Impurities NMT 0.16  Total Impurities NMT 0.15  Gaylord Chemical Company  Total Impurities NMT 0.1%  Total Impurities NMT 0.16  Total Impurities NMT 0.15  Gaylord Chemical Company	A 285 / A 275	NMT 0.65	
Organic Impurities, % (Reporting Threshold: 0.03%) Assay, % (anhydrous basis)  Refractive index @ 25°C  Specific gravity @ 25°C  PhEur Compendial Test  First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  UV absorbance  275 nm  Related Substances, %  (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Total Impurities NMT 0.1%  Total Impurities NMT 0.1%  Total Impurities NMT 0.1%  Interval Index 0.1%  Interval Index 0.1%  Interval Impurities NMT 0.10  Interval Impurities NMT 0.16  Interval Impurities NMT 0.16  Interval Impurities NMT 0.16  Interval Impurities NMT 0.16  Interval Impurities NMT 0.15  Interval Interv	A 295 / A 275	NMT 0.45	
Reporting Threshold: 0.03%) Assay, % (anhydrous basis)  Refractive index @ 25°C  Refractive index @ 25°C  Specific gravity @ 25°C  Refractive index @ 25°C  Refractive index @ 25°C  Refractive index @ 25°C  Refractive index @ 25°C  Record Identification  A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  Description:  No absorbance maxima between 270 & 350 nm  NMT 0.30  285 nm NMT 0.20  Related Substances, %  Reporting Threshold: 0.05%)  Gaylord Chemical Company  Test  Related Company  Residence of the state of the stat	Limit of Nonvolatile Residue	NMT 0.01%	
Assay, % (anhydrous basis)  Refractive index @ 25°C  Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  Compares with spectrum of Dimethyl Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density @ 20°C  B. Relative Density @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relation Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density & Sulfoxide CRS  B. Refractive Index @ 20°C  B. Relative Density	Organic Impurities, % (Reporting Threshold: 0.03%)	Total Impurities NMT 0.1%	
Specific gravity @ 25°C  PhEur Compendial Test  PhEur Specifications  First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  UV absorbance 275 nm  UV absorbance 275 nm  Related Substances, %  Related Substances, %  Related Substances, %  Related Substances, %  Reach Unspecified Impurities: NMT 0.15  Gaylord Chemical Company Test  PhEur Specifications  PhEur Specifications  1.095 - 1.101  PhEur Specifications  PhEur Specifications  1.100 – 1.104  1.478 – 1.480  Greenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 5.0  NMT 5.0  NMT 0.2%  Freezing Point, (°C)  NLT 18.3  No absorbance maxima between 270 & 350 nm  NMT 0.30  NMT 0.20  PhEur Specifications  1.095 - 1.101  1.000 – 1.104  1.478 – 1.480  Greenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 0.2%  Freezing Point, (°C)  NLT 18.3  No absorbance maxima between 270 & 350 nm  NMT 0.30  NMT 0.20  285 nm  NMT 0.20  Total Impurities: NMT 0.10  Gaylord Chemical Company  Gaylord Chemical Company	Assay, % (anhydrous basis)	NLT 99.9	
PhEur Compendial Test  First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  285 nm  285 nm  NMT 0.20  Related Substances, %  (Reporting Threshold: 0.05%)  Gaylord Chemical Company  PhEur Specifications  1.100 – 1.104  1.478 – 1.480  Precaise place of the sulfaction of the precaise place of the pla	Refractive index @ 25°C	1.4755 – 1.4775	
First Identification C. (IR)  Second Identification  A. Relative Density @ 20°C  B. Refractive Index @ 20°C  D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance  UV absorbance 275 nm  UV absorbance 275 nm  Related Substances, %  Reporting Threshold: 0.05%)  Related Chemical Company Test  Compares with spectrum of Dimethyl Sulfoxide CRS  1.100 – 1.104  1.478 – 1.480  Greenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 5.0  NMT 5.0  NMT 0.2%  Freezing Point, (°C)  NLT 18.3  No absorbance maxima between 270 & 350 nm  NMT 0.30  285 nm  NMT 0.20  Each Unspecified Impurity: NMT 0.10  Total Impurities: NMT 0.15  Gaylord Chemical Company	Specific gravity @ 25°C	1.095 - 1.101	
Second Identification A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF Freezing Point, (°C)  UV absorbance  UV absorbance  285 nm  285 nm  295 nm  Related Substances, %  (Reporting Threshold: 0.05%)  Greenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 5.0  NMT 5.0  NMT 0.2%  NMT 0.2%  NMT 0.2%  NNT 18.3  No absorbance maxima between 270 & 350 nm  NMT 0.30  285 nm  NMT 0.20  Each Unspecified Impurity: NMT 0.10  Total Impurities: NMT 0.15  Gaylord Chemical Company Test  Gaylord Chemical Company	PhEur Compendial Test	PhEur Specifications	
A. Relative Density @ 20°C B. Refractive Index @ 20°C D. Nickel Chloride  Acidity, (ml 0.01 N NaOH)  Water, % by KF  Freezing Point, (°C)  UV absorbance  UV absorbance 275 nm  285 nm  295 nm  Related Substances, %  (Reporting Threshold: 0.05%)  Greenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 5.0  NMT 5.0  NMT 5.0  NMT 0.2%  NLT 18.3  No absorbance maxima between 270 & 350 nm  NMT 0.30  285 nm  NMT 0.20  295 nm  Related Substances, %  (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Gaylord Chemical Company  Gaylord Chemical Company  Interval 1.100 – 1.104  1.478 – 1.480  Serenish yellow changing to bluish green at 50°C. Color changes back to greenish yellow on cooling NMT 5.0  NMT 5.0  NMT 0.2%  Freezing Point, (°C)  NLT 18.3  NMT 0.30  Each Unspecified Impurity: NMT 0.10  Total Impurities: NMT 0.15  Gaylord Chemical Company	First Identification C. (IR)	Compares with spectrum of Dimethyl Sulfoxide CRS	
Acidity, (ml 0.01 N NaOH) Water, % by KF NMT 0.2% Freezing Point, (°C) NLT 18.3  UV absorbance No absorbance maxima between 270 & 350 nm UV absorbance 275 nm NMT 0.30 285 nm NMT 0.20 295 nm Related Substances, % Each Unspecified Impurity: NMT 0.10 (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Gaylord Chemical Company  MT 0.28  Gaylord Chemical Company  Gaylord Chemical Company	B. Refractive Index @ 20°C		
Freezing Point, (°C)  UV absorbance  No absorbance maxima between 270 & 350 nm  NMT 0.30  285 nm  NMT 0.20  295 nm  Related Substances, %  (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  NLT 18.3  NMT 0.30  NMT 0.30  Each Unspecified Impurity: NMT 0.10  Total Impurities: NMT 0.15  Gaylord Chemical Company	Acidity, (ml 0.01 N NaOH)	NMT 5.0	
UV absorbance No absorbance maxima between 270 & 350 nm  UV absorbance 275 nm NMT 0.30  285 nm NMT 0.20  295 nm NMT 0.20  Related Substances, % Each Unspecified Impurity: NMT 0.10 (Reporting Threshold: 0.05%) Total Impurities: NMT 0.15  Gaylord Chemical Company Test Gaylord Chemical Company	Water, % by KF	NMT 0.2%	
UV absorbance 275 nm  285 nm  NMT 0.20  295 nm  NMT 0.20  Related Substances, %  (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Substances of the substance of the	Freezing Point, (°C)		
285 nm NMT 0.20 295 nm NMT 0.20  Related Substances, % Each Unspecified Impurity: NMT 0.10 (Reporting Threshold: 0.05%) Total Impurities: NMT 0.15  Gaylord Chemical Company Test Gaylord Chemical Company		No absorbance maxima between 270 & 350 nm	
295 nm NMT 0.20  Related Substances, % Each Unspecified Impurity: NMT 0.10 (Reporting Threshold: 0.05%) Total Impurities: NMT 0.15  Gaylord Chemical Company Test Gaylord Chemical Company			
Related Substances, % (Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Each Unspecified Impurity: NMT 0.10  Total Impurities: NMT 0.15  Gaylord Chemical Company  Gaylord Chemical Company			
(Reporting Threshold: 0.05%)  Gaylord Chemical Company Test  Gaylord Chemical Company  Gaylord Chemical Company			
	Related Substances, % (Reporting Threshold: 0.05%)		
Assay, % (anhydrous basis) ≥ 99.99	Gaylord Chemical Company Test	Gaylord Chemical Company	
	Assay, % (anhydrous basis)	≥ 99.99	

Approved by:	<u>Function</u>	Signature / Date / /
Steve Barber	Operations	Din Jahan 1/6/25
Natalie Herd	<b>Quality Control</b>	N. Hod 1/6/25
Mary Posey	Quality Assurance	Many M. Dogen 06 JAN 2025

Gaylord Chemical Company, LLC certifies that the lot was fabricated, packaged, labeled, and tested in accordance with the Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients and that the US Food and Drug Administration has recognized those facilities as meeting its GMP guidances.

## **Contact Information:**

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