

PROCIPIENT®

(Dimethyl Sulfoxide, USP, PhEur)

Technical Data Sheet

PROCIPIENT® (Dimethyl Sulfoxide USP, PhEur)

PROCIPIENT® is the only grade of DMSO suitable for healthcare and drug delivery applications. This high purity DMSO product is manufactured under current Good Manufacturing Practices (cGMP) conditions following ICH Q7 guidelines, manufactured to both the USP and PhEur monographs. PROCIPIENT® is supported by several regulatory dossiers, a Type II Drug Master File with US FDA, a Certificate of Suitability (CEP) granted by EDQM and a Type I Drug Master File with Health Canada. Our PROCIPIENT® product provides audit, traceability and inspection history.

Representative Specification

Assay, % (anhydrous basis) ≥99.99

USP Compendial	USP Spec
Identification (IR)	Compares with reference
ID (Retention Time)	Test for Organic Impurities
Acidity, (ml 0.01 N NaOH)	NMT 5.0
Water, % by KF	NMT 0.1
UV absorbance	No max 270 & 350 nm
UV absorbance @ 275 nm	NMT 0.20
A 285 / A 275	NMT 0.65
A 295 / A 275	NMT 0.45
Limit of Nonvolatile Residue	NMT 0.01%
Organic Impurities, %	Total Impurities NMT 0.1%
Assay, % (anhydrous basis)	NLT 99.9
Refractive index 25°C	1.4755 – 1.4775
Specific gravity 25°C	1.095 - 1.101

PhEur Compendial	PhEur Spec
First Identification C. (IR)	DMSO CRS
Second Identification	
A. Relative Density	1.100 – 1.104
B. Refractive Index	1.478 – 1.480
D. Nickel Chloride	Greenish yellow
Acidity (mL 0.01 NaOH)	NMT 5.0
Water, % by KF	NMT 0.2%
Freezing Point (°C)	NLT 18.3
UV absorbance	No max 270 & 350 nm
UV absorbance 275 nm	NMT 0.30
285 nm	NMT 0.20
295 nm	NMT 0.20
Related Substances, % Reporting Threshold: 0.05%	Unspecified Impurity NMT 0.10 Total Impurity: NMT 0.15

PROCIPIENT® is used in the following markets:

- Pharmaceuticals- Parenteral Drug Delivery
- Pharmaceuticals- API Synthesis
- Pharmaceuticals- Oral Dosage Form
- Pharmaceuticals- Topical & Transdermal
- Pharmaceuticals- Animal Health
- BioPharma- Cryopreservation
- BioPharma- Cell & Gene Therapy

Applications & Benefits

Excipient in Drug Delivery- PROCIPIENT® supports a wide spectrum of drug delivery formats—from early-phase R&D to commercial products.

- Parenteral (Peptide delivery, Implantable medical devices, Inter-arterial stroke rescue device)
- Topical & Transdermal (penetration enhancer)
- Oral Dosage Forms

Applications & Benefits (continued)

Cryopreservation- DMSO is well known as a cryopreservation medium. In this role, PROCIPIENT® enables the long-term storage of cells and biological tissue. It has been used to preserve a variety of cell types, including human bone marrow, ovarian tissue, pancreatic and platelet cells, and hematopoietic stem and progenitor cells

Animal Health- PROCIPIENT® is used as an excipient in Animal Health drug products. There are currently several regulated animal health products approved by US FDA which contain PROCIPIENT® (equine topical solution - 90% w/v; canine otic drug solution - 60% w/v).

Physical Properties

Density @ 25°C	1.0955	g/cm ³
Boiling Point	189	°C
Freezing Point	18.5	°C
Flash Point	87	°C
Viscosity @ 20°C	2.14	cP
Surface Tension @ 20°C	1.4785	dyne/cm
Specific Heat	5	cal/g/°C
Heat of Vaporization @ 25°C	162	cal/g
Electrical Conductivity @ 20°C	3x10 ⁻⁸	ohm/cm
Dielectric Constant @ 20°C	48	
Dipole Moment	4.3	
Vapor Pressure @ 25°C	0.6	mm Hg

Storage & Handling

Pure DMSO has a melting point of 18.5°C (64°F). As a result, frozen DMSO must be thawed before it can be transferred. When possible, it's advisable to schedule production during warmer months to simplify handling. For facilities that use DMSO year-round, implementing a few straightforward cold-weather handling guidelines can ensure smooth and efficient operations.

gChem recommends a long-term storage condition of 25°C/60% RH for PROCIPIENT® storage of 1L and 4L amber glass bottles and of 500-pound net weight HDPE drums based on ICH Q1A(R2). This is supported by formal stability protocols and data for up to 48 months in amber glass bottles and drums at the present time.

The retest date for PROCIPIENT® is four years. The retest date is not an expiration date but indicates when recertification should be performed. PROCIPIENT® should only be retested if stored under proper USP conditions.

Packaging

gChem offers the following packaging options:

- 1-liter amber glass bottles
- 4-liter amber glass bottles
- 500-lb (226.8 liter) drum

For More Information

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