

# Dow PuraGuard™ Propylene Glycol USP/EP for Pharmaceuticals

## Purity is essential...

in pharmaceutical applications as excipients. Dow PuraGuard™ Propylene Glycol USP/EP<sup>1</sup> offers one of the highest purity propylene glycols available in the marketplace — with a specified purity of 99.8 percent or greater, non-detectable MEG/DEG<sup>2</sup> contents, adherence to NSF/IPEC/ANSI 363 Good Manufacturing Practices for Pharmaceutical Excipients, and a two-year shelf life when stored according to Dow's recommendations. Think of it as your *security for purity*.



Dow PuraGuard™ PG USP/EP offers excellent versatility and functionality in pharmaceutical excipient applications<sup>4</sup>

- Solvent and extractant for a wide range of active ingredients, such as corticosteroids, phenol derivatives, barbiturates, vitamins A and D, most alkaloids and many local anesthetics<sup>5</sup>
- Humectant for promoting moisture retention in topical ointments
- Coupling agent
- Plasticizer in aqueous film coating formulations
- Emulsion stabilizer
- Dispersant
- Viscosity modifier

In addition to consistent purity and excellent quality, Dow PuraGuard™ PG USP/EP is backed by comprehensive technical support and customer service, as well as global manufacturing and supply chain capabilities.

## Excellent quality for pure confidence

Dow PuraGuard™ Propylene Glycol USP/EP offers high quality and consistency, according to the industry's most stringent quality control processes, including adherence to Good Manufacturing Practices (GMP) with third party certification to NSF/IPEC/ANSI 363 Good Manufacturing Practices for Pharmaceutical Excipients. Dow's commitment to GMP throughout the supply chain enables Dow PuraGuard™ PG USP/EP to be handled according to stringent requirements for consistent purity.

Dow PuraGuard™ PG USP/EP is tested against and certified according to the requirements for the following standards:

- United States Pharmacopeia (USP)
- European Pharmacopeia (PhEur or EP)
- Japanese Pharmacopeia (JP)
- Food Chemicals Codex (FCC)

All requirements of these monographs are included on Dow's globally applied Sales Specification and Certificate of Analysis (CoA) for Dow PG USP/EP.

Dow PuraGuard™ PG USP/EP meets the requirements and standards of the U.S. Food and Drug Administration (FDA) and is approved for use in many other jurisdictions around the world as a non-active ingredient in pharmaceuticals. It is Generally Recognized as Safe (GRAS) due to its extremely low toxicity and long history of safe use, and is included in the FDA Inactive Ingredient Guide in a variety of different dosage forms and routes of administration.

Dow PuraGuard™ PG USP/EP also complies with the requirements for Residual Solvents per the U.S. Pharmacopeia/ National Formulary (USP/NF) General Chapter ,467. and the International Committee on Harmonization (ICH) Guideline Q3C, "Impurities: Guideline for Residual Solvents." It is manufactured from hydrocarbon raw materials without the use of any solvents or additives. There are no Class 1, Class 2, Class 3 or any other solvents used or produced in making Dow PuraGuard PG USP/EP.

<sup>1</sup> Dow PuraGuard™ PG USP/EP is tested against and complies with the specific requirements of current USP, EP and JP. The Dow PuraGuard™ trade name is currently commercially available only in North America.

<sup>2</sup> Monoethylene Glycol/Diethylene Glycol.

<sup>3</sup> Reference Dow Safety Data Sheet.

<sup>4</sup> An overview of typical uses of propylene glycol in pharmaceutical formulations is published in the Handbook of Pharmaceutical Excipients, fourth edition, edited by Raymond C. Rowe, Paul J. Sheskey and Paul J. Weller, Pharmaceutical Press and American Pharmaceutical Association, 2003.

<sup>5</sup> The Inactive Ingredient Guide, U.S. Food and Drug Administration, current version lists various different dosage forms, routes of administration and maximum potency (concentration) of propylene glycol in approved drug products. ([www.fda.gov/cder/drug/iig/default.htm](http://www.fda.gov/cder/drug/iig/default.htm)).

## Ingredient solubility

Material	% Solubility	Material	% Solubility
Drugs and medicinals		Antiseptics	
Acetanilide	2.09	Camphor	9.80
Acetarsona	0.52	Calcium Sulfocarbolate	>30.00*
Acethophenitidine	2.10	Chlorothymol	70.00
Alion	4.37	Hexylesorcinol	>80.00*
Antipyrine	>55.00	Menthol	>50.00
Caffeine	0.77	Merthiolate	>29.00
Chloral Hydrate	>89.00	Metaphen	<0.27
Ethyl Carbamate	>57.00	Salol	10.50
Glycine	<0.45	Thymol	>50.00
Hexamethylenetetramine	11.22	Trichloro-tert-butanol	>60.00
o-Hydroxybenzyl Alcohol	44.10	Zinc Sulfocarbolate	>39.00
Paraldehyde	x	Vitamins and hormones	
Pepsin	<0.08	Estradiol (mg per cc)	0.50
Phenobarbital	>49.00	Ascorbic Acid	8.16
(Luminal Sodium)		Calcium Pantothenate	2.04
Resorcinol	55.70	Nicotinic Acid	0.88
Sodium Bismuth Thioglycolate	9.40	Pyridoxine Hydrochloric	2.73
Sodium Iodobismuthite	6.00	Riboflavin	<0.006
Sulfadiazine	0.30	Thiamine Hydrochloride	5.14
Sulfanilamide	7.25	Vitamin A (12% in oil)	Insol.
Sulfapyridine	0.50	Organic substances	
Sulfathiazole	1.71	Acacia Gum	<0.16
Terpin Hydrate	18.20	Calcium	<0.07
Urea	22.20	Cetyle Alcohol	0.23
Local anesthetics		Glycerophosphate	
Benzocaine	12.20	Pectin	Insol.
Benzyl Alcohol	x	Phenothiazine (Purified)	<1.15
Diothane	5.00	Sodium Citrate	0.23
Salicyl Alcohol (Saligenin)	4.00	Tannic Acid	>45.20
Inorganic substances			
Cupric Oxide	Insol.		
Ferric Oxide	Insol.		

\*Viscosity of solutions prevented further additions of solid; > = Greater Than; Insol. = Not soluble; x = Miscible or soluble in all proportions; < = Less Than

**For more information and product samples,  
contact us at your convenience:**

### Dow CIG

Toll-Free +1 (800) 441-4369

Toll +1 (989) 832-1426

### The Dow Chemical Company

2030 Dow Center

Midland, MI 48674



[www.dow.com/propyleneglycol](http://www.dow.com/propyleneglycol)

Image: dow\_73771832726

NOTICE: No freedom from infringement of any patent owned by Dow or others is to be inferred. Because use conditions and applicable laws may differ from one location to another and may change with time, Customer is responsible for determining whether products and the information in this document are appropriate for Customer's use and for ensuring that Customer's workplace and disposal practices are in compliance with applicable laws and other government enactments. The product shown in this literature may not be available for sale and/or available in all geographies where Dow is represented. The claims made may not have been approved for use in all countries. Dow assumes no obligation or liability for the information in this document. References to "Dow" or the "Company" mean the Dow legal entity selling the products to Customer unless otherwise expressly noted. NO WARRANTIES ARE GIVEN; ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED.

®™ Trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow

© 2025 The Dow Chemical Company. All rights reserved.

2000024564-174600

Form No. 117-01824-01-0525 S2D