Dow PuraGuard™ Propylene Glycol USP/EP for Pharmaceuticals

Purity is essential...
in pharmaceutical applications. Dow PuraGuard™ Propylene Glycol USP/EP[1] 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[2] 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.[3] Think of it as *your security for purity*.

Dow PuraGuard PG USP/EP offers excellent versatility and functionality in pharmaceutical applications[4]:

- 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[5]
- 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.

[1]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.

[2]Monoethylene Glycol/Diethylene Glycol.

[3]Reference Dow Safety Data Sheet.

[4]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.

[5]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).

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.

Robust Supply Chain for Global Reach

With nearly 60 years of experience as a leading propylene glycol (PG) manufacturer and supplier, Dow has built a robust supply chain network that provides:

- **Reliable Global Supply** from strategically located manufacturing sites in the U.S., Brazil, Germany, Thailand and Australia.
- **The Largest Production Capacity in North America**, including plants in two different states.
- **Inventory Management Solutions** from strategically located terminals around the world to help meet changing customer needs.

Ingredient Solubility

Material	% Solubility	Material	% Solubility
Drugs and Medicinals		**Antiseptics**	
Acetanilide	2.09	Camphor	9.80
Acetarsone	0.52	Calcium Sulfocarbolate	>30.00*
Acethophenitidine	2.10	Chlorothymol	70.00
Alion	4.37	Hexylesorcinol	>80.00*
Antipyrine	>55.0	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		
Pepsin	<0.08	**Vitamins and Hormones**	
Phenobarbital	>49.00	Estradiol (mg per cc)	0.50
(Luminal Sodium)		Ascorbic Acid	8.16
Resorcinol	55.70	Calcium Pantothenate	2.04
Sodium Bismuth Thioglycolate	9.40	Nicotinic Acid	0.88
Sodium Iodobismuthite	6.00	Pyridoxine Hydrochloric	2.73
Sulfadiazine	0.30	Riboflavin	<0.006
Sulfanilamide	7.25	Thiamine Hydrochloride	5.14
Sulfapyridine	0.50	Vitamin A (12% in oil)	Insol.
Sulfathiazole	1.71		
Terpin Hydrate	18.20	**Organic Substances**	
Urea	22.20	Acacia Gum	<0.16
		Calcium	<0.07
		Glycerophosphate	

Material	% Solubility	Material	% Solubility
Local Anesthetics			
		Cetyle Alcohol	0.23
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

Innovating For You

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

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