



# Topical Drug Delivery

## Excipients for creams, gels, and lotions

Stable and efficient semisolid preparations with optimal skin-feel have become the desirable standard in topical and transdermal drug delivery. Lubrizol Life Science Health (LLS Health) has long-standing experience with semisolids, offering rheology-modifying, emulsifying and bioadhesive excipients.

Our **Carbopol® polymers**, **Pemulen™ polymers**, and **Noveon® polycarbophil** have been used extensively for more than fifty years in both prescription and over-the-counter topical drug products.

**Topical Applications** - All polymers listed in the chart below are suitable for use in topical applications and are present in commercialized topical products. Topical applications can include creams, lotions, gels, and ointments for dermal, vaginal, and rectal use, among others.

Pharmacopeia Monograph Compendial Name						Application Type				Viscosity Specification Ranges		
Product Trade Name	Polymerization Solvent	United States (USP/NF)	Europe (Ph.Eur./India (I.P.))	Japan (JPE) <sup>1</sup>	China (Ch.P.)	Lotions	Creams	Gels	Bio-adhesives	% w/w	Minimum (Cp)	Maximum (Cp)
<b>Carbopol® polymers</b>												
971P NF	Ethyl Acetate	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	-	•	0.5	4,000	11,000
974P NF	Ethyl Acetate	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	•	•	0.5	29,400	39,400
980 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type C	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	-	•	•	•	0.5	40,000	60,000
981 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	-	•	0.5	4,000	10,000
5984 EP	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	•	•	0.5	30,500	39,400
ETD 2020 NF	Cosolvent <sup>2</sup>	Carbomer Interpolymer Type B				•	•	•	•	1.0	47,000	77,000
Ultrez 10 NF	Cosolvent <sup>2</sup>	Carbomer Interpolymer Type A				•	•	•	•	0.5	45,000	65,000
<b>Pemulen™ polymers</b>												
TR-1 NF	Cosolvent <sup>2</sup>	Carbomer Copolymer Type B				•	•	•	•	1.0	14,000	26,500
TR-2 NF	Cosolvent <sup>2</sup>	Carbomer Copolymer Type A				•	•	•	•	1.0	4,500	13,500
<b>Noveon® polycarbophil USP</b>												
AA-1 USP	Ethyl Acetate	Polycarbophil				-	•	•	•	0.2	2,000	12,000

<sup>1</sup>Based on customer request, Lubrizol certifies select lots of product against the JPE Carboxyvinyl Polymer monograph.

<sup>2</sup>Cosolvent = mixture of Ethylacetate (class III solvent) and Cyclohexane (class II solvent).

**Enabling innovation through our multifunctional excipients, which are:**

- Ideal for imparting **rheology control** in topical formulations
- **Highly efficient thickeners** and gel formers at low usage levels in aqueous, hydroalcoholic, and anhydrous systems

**Typical Usage Levels of LLS Health Polymers in Topical Applications**

Application	Usage Level (wt. %)
Topical gels (aqueous, anhydrous, hydroalcoholic)	0.5 - 3.0
Lotions, creams	0.2 - 1.0
Topical emulsions	0.2 - 0.4

- Able to provide **stable, uniform** emulsions and suspensions
- Excellent **bioadhesive polymers** for improving the bioavailability of some active ingredients
- **Compatible** with acidic, basic, and neutral drugs
- **Thermally stable**, allowing for versatility in manufacturing and final product sterilization
- Optimal for providing **enhanced aesthetics** and feel for the creation of non-greasy creams, exceptionally clear gels, and other semisolid formulations



**Additional FDA IID Ingredients** - LLS Health also offers an array of additional inactive ingredients for semi-solid topicals, such as humectants, emollients, emulsifiers, and surfactant thickeners. The below ingredients are featured on the FDA’s Inactive Ingredient Database (IID). Please visit our website for more information.

Additional FDA IID Ingredients* Recommended for Topical Applications				
Trade Name	Chemical Name	IID Maximum Potency - Topical**	Typical Use Level	Functionality
<b>Emollients</b>				
Schercemol™ DIA ester	Diisopropyl Adipate	20%	1-10%	Light emollient Solubilization, dermal penetration Hydroalcoholic, alcohol dispersible
Schercemol™ 318 ester	Isopropyl Isostearate	3%	1-10%	Medium emollient Derived-natural***
Schercemol™ OHS ester	Ethylhexyl Hydroxystearate	12%	1-10%	Medium emollient Derived-natural***
Schercemol™ OLO ester	Oleyl Oleate	2.55%	1-10%	Medium emollient Natural***
Schercemol™ 1688 ester	Cetearyl Ethylhexanoate	3%	1-10%	Medium emollient Derived-natural***
Glucam™ P-20 distearate emollient	PPG-20 Methyl Glucose Ether Distearate	4.75%	1-10%	Light emollient Barrier for water loss, moisturization
Solulan™ 75 (Solulan™ L-575) lanolin derivative	PEG-75 Lanolin	1.5%	1-10%	Emollient Non-ionic O/W emulsifier (HLB 15) Water, alcohol soluble (miscible)
Vilvanolin™ L-101 lanolin derivative	Mineral Oil (and) Lanolin Alcohol	11%	0.5-5%	Emollient Non-ionic W/O emulsifier (HLB 8)
<b>Emulsifiers</b>				
Glucate™ SS emulsifier	Methyl Glucose Sesquistearate	3.5%	0.5-3%	Non-ionic W/O emulsifier (HLB 6.4), co-emulsifier Structurant Derived-natural***
Glucamate™ SSE-20 emulsifier	PEG-20 Methyl Glucose Sesquistearate	3.5%	0.5-3%	Non-ionic O/W emulsifier (HLB 15.4), co-emulsifier
Promulgen™ D nonionic emulsifier	Cetearyl Alcohol (and) Cetareth 20	8%	1-5%	Non-ionic O/W emulsifier (HLB 12) Structurant Derived-natural***
Promulgen™ G nonionic emulsifier	Stearyl Alcohol (and) Cetareth 20	4%	1-5%	Non-ionic O/W emulsifier (HLB 12.5) Structurant Derived-natural***
<b>Humectants</b>				
Glucam™ E-10 humectant	Methyl Gluceth-10	5%	1-5%	Humectant, tackiness reduction
Glucam™ E-20 humectant	Methyl Gluceth-20	5%	1-5%	Humectant, tackiness reduction

\*US Food and Drug Administration’s Inactive Ingredient Database.

\*\*The IID is updated quarterly. For the most current information, please refer to the FDA Inactive Ingredient Database.

\*\*\*Renewable Carbon Index (RCI) is calculated under ISO 16128. RCI = 1.00 meets the definition of natural under the ISO standard. RCI > 0.50 meets the definition of derived-natural.



## Formulating with confidence:

### Our Excipients:

- Are manufactured under GMPs in ISO:9001 certified facilities (applies to Carbopol® polymers, Pemulen™ polymers, and Noveon® polycarbophil)
- Have established DMFs (applies to Carbopol® polymers, Pemulen™ polymers, and Noveon® polycarbophil)
- Have been extensively tested for safety



### Partnering for all Development Phases:

- Worldwide technical and application support services
- Dedicated global regulatory staff and quality assurance
- Sustainable supplier owned by Berkshire Hathaway
- Decades of manufacturing and polymer expertise

### Driven by Consumers:

- Improving patient lives by providing a full excipient portfolio for nearly all dosage forms
- Advancing medical innovation by progressing partner products quickly to market
- Proactively responding to ever-changing regulatory and market needs