

**PRODUCT SPECIFICATIONS SHEET**  
**WORLD/GMP GRADE**  
**PROPYLENE GLYCOL**

Meets USP/EP/JP/FCC Grade Monographs  
 Kosher

With USP<232>, EMA and ICH Q3D Test Results

Catalog Number: 369WORLD-Size Code\*

\*Individual package sizes have unique size codes

**Manufactured in compliance with cGMP**

| TEST   | MONO-GRAPH             | SPECIFICATION   | TYPICAL RESULT               |
|--|------------------------|---|------------------------------|
| Assay (on anhydrous basis)<br>Assay, wt%   | USP<br>FCC             | NLT 99.5%   | 99.93%                       |
| Identification A – Infrared Absorption   | USP/FCC                | Conforms to Reference Spectrum  | Conforms                     |
| Identification A – Relative Density<br>Specific Gravity                                  | EP<br>USP/FCC<br>JP    | 1.035 - 1.040 @ 20°C<br>1.035 – 1.037 @ 25°C<br>1.035 – 1.040 @ 20°C                          | 1.038<br>1.035<br>1.038      |
| Identification B – Limit of Diethylene Glycol and Ethylene Glycol                        | USP                    | Ethylene Glycol, NMT 0.1%<br>Diethylene Glycol, NMT 0.1%                                      | <0.1%<br><0.1%               |
| Identification B – Refractive Index  | EP                     | 1.431 – 1.433 @ 20°C  | 1.432                        |
| Identification C – GC  | USP                    | Conforms to Reference Chromatogram  | Pass                         |
| Identification C – Boiling Point<br>Distilling Range<br>Distilling Range                 | EP<br>JP<br>FCC        | 184°C – 189°C<br>No less than 95% volume<br>Between 185°C – 189°C                             | Pass<br>Pass<br>Pass         |
| Identification D   | EP                     | Meets Requirements of Test  | Pass                         |
| Identification (1)   | JP                     | The crystals melt between 174C – 178C   | Pass                         |
| Identification (2)   | JP                     | Characteristic odor is evolved  | Pass                         |
| Acidity<br>Purity 1 - Acidity  | USP<br>EP<br>FCC<br>JP | NMT 0.20 mL 0.10N NaOH<br>NMT 0.05 mL 0.1M NaOH<br>To Pass Test<br>The solution has red color | Pass                         |
| Inorganic Impurities - Residue on Ignition<br>Residue on Ignition<br>Residue on Ignition | USP<br>JP<br>FCC       | NMT 3.5mg<br>NMT 0.005%<br>NMT 0.007%   | <3.5mg<br><0.005%<br><0.005% |
| Inorganic Impurities – Chloride and Sulfate<br>Purity 2 - Chloride                       | USP<br>JP              | NMT 70ppm as Chloride<br>NMT 0.007%   | <10ppm<br><0.001%            |
| Inorganic Impurities – Chloride and Sulfate<br>Purity 3 - Sulfate                        | USP<br>JP              | NMT 60ppm as Sulfate<br>NMT 0.002%  | <10ppm<br><0.001%            |
| Inorganic Impurities - Heavy Metals<br>Purity 4 – Heavy Metals<br>Heavy Metals           | USP<br>JP<br>EP        | NMT 5 ppm   | Pass                         |
| Elemental Impurities   | USP <232><br>& <233>   | Complies with requirements  | Complies*                    |
| Lead   | FCC                    | NMT 1 mg/kg   | <1 mg/kg                     |
| Purity 5 – Arsenic   | JP                     | NMT 2ppm  | Pass                         |

| TEST                 | MONO-GRAPH       | SPECIFICATION                      | TYPICAL RESULT |
|----------------------|------------------|------------------------------------|----------------|
| Purity 6 – Glycerin  | JP               | No odor of acrolein is perceptible | Pass           |
| Oxidizing Substances | EP               | Meets Requirements of Test         | Pass           |
| Reducing Substances  | EP               | Meets Requirements of Test         | Pass           |
| Sulfated Ash         | EP               | 0.01% max                          | <0.01%         |
| Water                | USP/EP/FCC<br>JP | 0.20% Max.<br>0.5% Max.            | 0.03%          |

\*For specific results on individual metals, please inquire.

### Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients<sup>1</sup>

Reported in µg/g (ppm)

| Element        | Class | Oral Concentration µg/g | Parenteral Concentration µg/g | Inhalation Concentration µg/g | TYPICAL RESULT (in µg/g) (ppm) |
|----------------|-------|-------------------------|-------------------------------|-------------------------------|--------------------------------|
| Cd (Cadmium)   | 1     | 0.5                     | 0.2                           | 0.2                           | 0.00                           |
| Pb (Lead)      | 1     | 0.5                     | 0.5                           | 0.5                           | 0.00                           |
| As (Arsenic)   | 1     | 1.5                     | 1.5                           | 0.2                           | 0.00                           |
| Hg (Mercury)   | 1     | 3                       | 0.3                           | 0.1                           | 0.00                           |
| Co (Cobalt)    | 2A    | 5                       | 0.5                           | 0.3                           | 0.00                           |
| V (Vanadium)   | 2A    | 10                      | 1                             | 0.1                           | 0.00                           |
| Ni (Nickel)    | 2A    | 20                      | 2                             | 0.5                           | 0.00                           |
| Tl (Thallium)  | 2B    | 0.8                     | 0.8                           | 0.8                           | 0.00                           |
| Au (Gold)      | 2B    | 10                      | 10                            | 0.1                           | 0.00                           |
| Pd (Palladium) | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Ir (Iridium)   | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Os (Osmium)    | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Rh (Rhodium)   | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Ru (Ruthenium) | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Se (Selenium)  | 2B    | 15                      | 8                             | 13                            | 0.00                           |
| Ag (Silver)    | 2B    | 15                      | 1                             | 0.7                           | 0.00                           |
| Pt (Platinum)  | 2B    | 10                      | 1                             | 0.1                           | 0.00                           |
| Li (Lithium)   | 3     | 55                      | 25                            | 2.5                           | 0.00                           |
| Sb (Antimony)  | 3     | 120                     | 9                             | 2                             | 0.00                           |
| Ba (Barium)    | 3     | 140                     | 70                            | 30                            | 0.00                           |

|                 |   |      |     |     |      |
|-----------------|---|------|-----|-----|------|
| Mo (Molybdenum) | 3 | 300  | 150 | 1   | 0.00 |
| Cu (Copper)     | 3 | 300  | 30  | 3   | 0.00 |
| Sn (Tin)        | 3 | 600  | 60  | 6   | 0.00 |
| Cr (Chromium)   | 3 | 1100 | 110 | 0.3 | 0.00 |

<sup>1</sup>Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.  
Form: Propylene Glycol, USP/EP/JP/FCC, Rev. 2.0, 08/16, AM

This product is for further commercial manufacturing, laboratory or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.