COPPERHEAD CHEMICAL COMPANY

Copperhead Chemical Company Inc.

120 River Road Tamaqua, PA 18252 USA Tel: (570) 386-6123 Fax: (570) 386-6158

DECLARATION OF GOOD MANUFACTURING PRACTICE

Copperhead Chemical Company Inc. hereby certifies that it manufactures nitroglycerin (glyceryl trinitrate) and the resultant diluted nitroglycerin mixture SDM[®]27, 10% Nitroglycerin in Propylene Glycol, USP in accordance with ICH Q7, Good Manufacturing Practice Guidelines for Active Pharmaceutical Ingredients and 21 CFR, Parts 210 and 211 as may be applicable.

Manufacturing is performed at Copperhead's Tamaqua plant located at 120 River Road, Tamaqua, PA, 18252 USA.

Copperhead is an FDA registered and inspected drug establishment and was last inspected by the FDA for GMP compliance on July 19 to 22 and August 4 and 11, 2016.

Copperhead's FDA Drug Establishment Registration Number is 2517101.

Sincerely,

Kim dun Shimerforcas

Kim Ann Shimukonas Quality Assurance Manager

Email: <u>kshimukonas@copperheadchemical.com</u> Tel: (570) 386-6103

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