

Residual Solvents

SDM[®]12, Diluted Nitroglycerin USP (1.95% Nitroglycerin on Lactose Monohydrate)

Manufacturing Facility:

Copperhead Chemical Company Inc.
120 River Road, Tamaqua, PA 18252

According to General Chapter <467> “Residual Solvents” of the current United States Pharmacopoeia (USP), all drug substances (APIs) and drug products are to be subject to relevant control of solvents likely to be present in the substance or product.

To assist our customers in determining the Residual Solvents content of their drug products, Copperhead Chemical includes a value for **Residual Solvents (Acetone)** as part of the Certificate of Analysis (CoA) that we provide with each shipment of SDM[®]12, Diluted Nitroglycerin USP (1.95% Nitroglycerin on Lactose Monohydrate).

Copperhead Chemical employs Acetone, NF as a processing aid in the blending of SDM[®]12 and routinely tests for this residual solvent against a specification of:

200 ppm (0.02%) maximum

This is the only organic solvent used in the manufacture of SDM[®]12 or its component ingredients, nitroglycerin and lactose monohydrate, i.e. only Class 3 solvents are present.

Please be advised that the USP default method for Class 3 solvents of Loss on Drying <731> is not suitable for use with SDM[®]12 due to the volatility of nitroglycerin. The test method employed by Copperhead Chemical Company is a validated in-house test method, TM-P131. A copy of the test method is available to customers upon request.

Sincerely,



Dawn Clarke
Regulatory Affairs Manager

Email: dclarke@copperheadchemical.com

Issued: January-21-2019