Material No.: 4874-26
:
Revision No.: 0

Product Specification

Meets E.P. Chemical Specifications, Meets N.F. Requirements, GMP Manufactured Product

Test	Specification
NF - Assay	≥ 99.0 %
NF - Methanol	≤ 600 ppm
NF - Water	≤ 0.02 %
EP - Water (KF)	≤ 0.02 %
EP - Ethanol, v/v	≤ 2.0 %
EP - 2-methylbut-2-ene, v/v	≤ 300 ppm
EP - Carbon tetrachloride, v/v	≤ 10 ppm
EP - Chloroform, v/v	≤ 50 %
EP - Total other impurities v/v	≤ 0.1 %

GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
Residual Solvents - The Class 1 solvent 1,1-dichloroethene is likely to be present. The concentration of 1,1-dichloroethene is quantified and reported for each batch. Methanol and amylene (2-methyl-butylene) are intentionally added as stabilizers. The concentration of methanol is reported in the batch results. The concentration of amylene is less than 40 ppm based on in-process controls. The Class 2 solvents cyclohexane (less than 20 ppm) and 1,2-dichloroethene (less than 50 ppm) may be present due to their presence in the process raw material. They are not selectively removed during processing.
Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Phillipsburg Mfg Ctr & DC