

# CareLifeTECH™

## CERTIFICATE OF ANALYSIS

<b>Product:</b>	<b>Tyloxapol, USP</b>
<b>Lot Number:</b>	<b>R0007054</b>
<b>Manufacturing Date:</b>	<b>9/2016</b>
<b>Re-evaluation Date:</b>	<b>3/2019</b>
<b>Release Date:</b>	<b>10/17/2016</b>
<b>Monograph Date:</b>	<b>9/8/2014</b>

Test	Specification	Results
<b>USP</b>		
Description	Viscous amber liquid, may exhibit slight turbidity	Viscous amber liquid
Solubility	Slowly but freely miscible with water. Soluble in glacial acetic acid, toluene and chloroform	Slowly but freely miscible with water. Soluble in glacial acetic acid, toluene and chloroform
Identification Infrared Absorption Spectrum	Exhibits maxima at the same wavelengths as that of a similarly prepared RS	Exhibits maxima at the same wavelengths as that of a similarly prepared RS
pH	4.0 - 7.0	5.2
Cloud Point	92 – 97 °C	95 degrees C
Residue on Ignition	NMT 1.0%	0.41%
Free Phenol	No cloudiness or precipitation immediately	No cloudiness or precipitation immediately
Limit of Anionic Detergents	NMT 0.075% as sodium lauryl sulfate	NMT 0.075% of anionic detergents (as sodium lauryl sulfate)
Absence of Cationic Detergents	No blue color in the organic solvent layer	No blue color in the organic solvent layer
Limit of Formaldehyde	NMT 0.0075%	LT 0.0075%
Ethylene Oxide	NMT 10 ppm	Not performed
<b>INTERNAL:</b>		
Identification UV Spectrum	Exhibits maximum and minimum at the same wavelengths as RS	Exhibits maximum and minimum at the same wavelengths as RS
Toluene	NMT 100 ppm (Action Limit) NMT 400 ppm (0.04%)	Trace, LT 30 ppm

Test	Specification	Results
Color Value	NMT 150 ppm	31
Water - Titrimetric	NMT 1.0%	0.09%
Refractive Index (25 °C)	1.495 - 1.501	1.498
Ethylene Oxide (Internal Method)	NMT 10 ppm	None detected, LT 0.5 ppm

This is to certify this Lot was manufactured, handled and stored in accordance with current Good Manufacturing Practices.