CERTIFICATE OF ANALYSIS

Customer Name: Next PharmaPack LLC

Lot Nr: 3663711

Residual Solvent Statement

In accordance with ICH Q3C residual solvent guideline, Class 3 solvents may be used according to good manufacturing practices such that their cumulative value does not exceed 5000ppm or 0.5%, under option 1 as defined in ICH Q3C, USP<467>, and EP General Text 5.4.

Physical Characteristics

Defect levels are in conformance with the Coni-Snap® Sigma Series specification for Visual attributes, as defined in the table below.

Defect Group	Class I	Class II	Class III
	Visual	Visual	Visual
Sigma Level	5.4	5.1	4.3
PPM	<50	<150	<2500

Appearance - Clean empty capsules, meeting the specified requirements of color and size.
Odor - Free of disagreeable odor.
The reported disintegration time is subjective, and is provided to indicate Pass/Fail status for 10 minutes.
Empty hard gelatin capsules are conform with the Japanese Pharmacopoeia monograph for capsules.

TSE/BSE Regulations

For the production of this product, no components are used which have been derived from TSE/BSE-relevant animal species. Consequently, we herewith confirm that this empty capsule product is not subject to any TSE/BSE regulations.

Manufacturing Processes:

No Addition of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment