

# CERTIFICATE OF ANALYSIS

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<b>Product Name:</b> Recombinant Human IL-7 Final Vial Product	<b>Project Number:</b> 0064	<b>Part Number:</b> 50373
<b>NSC Number:</b> 644800	<b>Production Date:</b> 10/13/2011	<b>Lot Number:</b> L1101006
<b>Container Size/Fill Volume:</b> 3 mL vial / 0.3 mL fill	<b>Storage Temperature:</b> ≤-70°C	
<b>Description:</b> rhIL-7 is a recombinant cytokine and T cell growth factor. Colorless liquid in a solution of 25 mM Na <sub>2</sub> HPO <sub>4</sub> , 250 mM NaCl, pH 6.8.		

Test Description	Assay Specification	Test SOP # or Study #	QC Test Request Number	Result
<b>Appearance</b>				
Color, Appearance and Clarity	Clear, colorless liquid with no evidence of foreign matter or particulates	BQC 22925	<u>QC-048914</u>	Clear, colorless liquid with no evidence of foreign matter or particulates
<b>Identity</b>				
N-terminal sequence <sup>1</sup>	Report Results, Conforms to predicted IL-7 sequence: MD(C)DIEGK*	BQC 22127	<u>QC-048917</u>	Conforms to predicted IL-7 sequence: MD(C)DIEGK*
SDS-PAGE, Non-reduced, Silver Stain <sup>1</sup>	Single major band with an apparent MW of ~14.5 ± 5 kDa; Conforms to Standard <sup>1</sup>	BQC 22176, 22177, 22161, 22906	<u>QC-048918</u>	Major band at 14.4 kDa; conforms to standard
SDS-PAGE, Reduced, Silver Stain <sup>1</sup>	Single major band with an apparent MW of ~14.5 ± 5 kDa; Conforms to Standard <sup>1</sup>	BQC 22176, 22177, 22161, 22906	<u>QC-048918</u>	Major band at 16.4 kDa; conforms to standard
<b>Identity / Purity</b>				
HPLC-IEX <sup>1</sup>	Chromatographic profile conforms to Reference Standard <sup>1</sup>	BQC 22178	<u>QC-048919</u>	Single peak (100%); Chromatographic profile conforms to Reference Standard
<b>Content</b>				
Protein Concentration by Pierce Coomassie Plus	0.50 ± 0.10 mg/mL	BQC 22164	<u>QC-048940</u>	0.59 mg/mL
<b>Potency</b>				
2E8 Cell Proliferation Assay <sup>1</sup>	50% to 200% of reference standard <sup>1</sup> ; report ED <sub>50</sub> value	BQC 16140	<u>QC-048920</u>	63% to 78% of reference lots; Average 1.68 ng/mL ED <sub>50</sub>
<b>Purity</b>				
HPLC-RP <sup>1</sup>	≥ 90% Native rhIL-7	BQC 22178	<u>QC-048922</u>	98.6% Native rhIL-7
SDS-PAGE, Non-reduced, Coomassie Stain with Densitometry <sup>1</sup>	Report molecular weight and percentage of major band with an apparent MW of ~14.5 ± 5 kDa; The major band must be ≥ 95% of total protein; Conforms to Standard <sup>1</sup>	BQC 22176, 22175, 22161, 22906	<u>QC-048921</u>	Major band at 15.1 kDa (100%); conforms to standard
SDS-PAGE, Reduced, Coomassie Stain with Densitometry <sup>1</sup>	Report molecular weight and percentage of major band with an apparent MW of ~14.5 ± 5 kDa; The major band must be ≥ 95% of total protein; Conforms to Standard <sup>1</sup>	BQC 22176, 22175, 22161, 22906	<u>QC-048921</u>	Major band at 16.7 kDa (100%); conforms to standard
HPLC-SEC <sup>1</sup>	≤ 10% High Molecular Weight species (larger than rhIL-7)	BQC 22935	<u>QC-048923</u>	No High Molecular Weight species detected
Free Thiol	≤ 1.25 µg/mL	Charles River Malvern #CTM-2295	<u>QC-048939</u>	< 0.25 µg/mL

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Test Description	Assay Specification	Test SOP # or Study #	QC Test Request Number	Result
<b>Safety</b>				
Endotoxin (LAL)	≤ 5 EU/mg	BQC 22135	<u>QC-048915</u>	< 0.10 EU/mg
pH	6.8 ± 0.4	BQC 22124	<u>QC-048916</u>	6.8
Sterility	No growth	Celsis Laboratory, 21 CFR 610.12	<u>QC-048938</u>	No growth
Bacteriostasis and Fungistasis <sup>2</sup>	Non-bacteriostatic/ Non-fungistatic	Celsis Laboratory, USP 24 <71>, 21 CFR 610.12	<u>QC-006759</u>	Non-bacteriostatic/ Non-fungistatic
<b>For Information Only</b>				
HPLC-SEC Light Scattering <sup>1</sup>	Report Results	BQC 16134	<u>QC-048924</u>	Trace product aggregate peak; profile comparable to reference standard

<sup>1</sup> Tested in conjunction with Reference Material Lot #L0302004 and Reference Standard Lot #101018.

<sup>2</sup> B&F test performed on IL-7 buffer formulation.

\* The Cysteine (C) residue is not recovered following Edman Degradation and is shown for completeness only.

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