

CERTIFICATE OF ANALYSIS

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Product Name: Recombinant Human IL-15 Final Vial Product (Research Grade)*	Project Number: 0063	Part Number: 50388
NSC Number: 745101	Production Date: 10/25/2011	Lot Number: L1010008R/D
Container Size/Fill Volume: 3 mL vial / 0.3 mL fill	Storage Temperature: ≤-70°C	
Description: rhIL-15 is an immunomodulating cytokine. Colorless liquid in a solution of 25 mM Na ₂ HPO ₄ , 500 mM NaCl, pH 7.4.		

Test Description	Assay Specification	Test SOP # or Study #	QC Test Request Number	Result
Appearance Color, Appearance and Clarity	Clear, colorless liquid with no evidence of foreign matter or particulates	BQC 22925	<u>QC-049356</u>	Clear, colorless liquid with no evidence of foreign matter or particulates
Identity N-terminal sequence ¹	Report Results, Conforms to predicted IL-15 sequence: MNWVNVISDL	BQC 22127	<u>QC-049367</u>	Conforms to predicted IL-15 sequence: MNWVNVISDL
HPLC-IEX ¹	Chromatographic profile conforms to Reference Standard ¹	BQC 22178	<u>QC-049366</u>	Chromatographic profile conforms to Reference Standard
SDS-PAGE, Non-reduced, Silver Stain ¹	Two major bands between 5 kDa and 10 kDa; Conforms to Standard ¹	BQC 22176, 22177, 22161, 22906	<u>QC-049365</u>	8.11 and 5.57 kDa bands; conforms to standard
SDS-PAGE, Reduced, Silver Stain ¹	Two major bands between 5 kDa and 10 kDa; Conforms to Standard ¹	BQC 22176, 22177, 22161, 22906	<u>QC-049365</u>	8.71 and 6.61 kDa bands; conforms to standard
Content Protein Concentration by Pierce Coomassie Plus	0.50 ± 0.10 mg/mL	BQC 22164	<u>QC-049371</u>	0.49 mg/mL
Potency CTLL-2 Cell Proliferation Assay ¹	50% to 200% of reference standard ¹ ; report ED ₅₀ value	BQC 16133	<u>QC-049364</u>	93% of reference standard; 0.126 ng/mL ED ₅₀
Purity ExHPLC-RP ¹	≥ 70% Native rhIL-15; ≤ 15% Deamidated rhIL-15	BQC 22178	<u>QC-049363</u>	84.6% native rhIL-15; 12.4% deamidated rhIL-15
SDS-PAGE, Non-reduced, Coomassie Stain with Densitometry ¹	Report molecular weight and percentages of two major bands between 4.5 kDa and 9 kDa; The sum of the percentages of the two major bands must be ≥ 95% of total protein; Conforms to Standard ¹	BQC 22176, 22175, 22161, 22906	<u>QC-049362</u>	8.49 kDa (0.4%) and 5.68 kDa (99.6%) bands; sum = 100% of total protein; conforms to standard
SDS-PAGE, Reduced, Coomassie Stain with Densitometry ¹	Report molecular weight and percentages of two major bands between 4.5 kDa and 9 kDa; The sum of the percentages of the two major bands must be ≥ 95% of total protein; Conforms to Standard ¹	BQC 22176, 22175, 22161, 22906	<u>QC-049362</u>	8.14 kDa (94.0%) and 6.87 kDa (6.0%) bands; sum = 100% of total protein; conforms to standard
HPLC-SEC ¹	≤ 5% High Molecular Weight species (larger than rhIL-15)	BQC 22935	<u>QC-049361</u>	99.9% purity (main peak and leading shoulder); 0.1% Aggregates

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Container Size/Fill Volume: 3 mL vial / 0.3 mL fill	Storage Temperature: ≤-70°C	
Description: rhIL-15 is an immunomodulating cytokine. Colorless liquid in a solution of 25 mM Na ₂ HPO ₄ , 500 mM NaCl, pH 7.4.		

Test Description	Assay Specification	Test SOP # or Study #	QC Test Request Number	Result
Free Thiol	≤ 1.25 µg/mL	Charles River Malvern #CTM-2295	<u>QC-049343</u>	< 0.25 µg/mL
Safety				
Endotoxin (LAL)	≤ 5 EU/mg	BQC 22135	<u>QC-049357</u>	< 0.1 EU/mg
pH	7.4 ± 0.4	BQC 22124	<u>QC-049358</u>	7.4
Sterility	No growth	Celsis Laboratory, 21 CFR 610.12	<u>QC-049342</u>	No growth
Bacteriostasis and Fungistasis ²	Non-bacteriostatic/ Non-fungistatic	Celsis Laboratory, USP 31 <71>, 21 CFR 610.12	<u>QC-039658</u>	Non-bacteriostatic/ Non-fungistatic
For Information Only				
Rapid ExHPLC-RP ¹	Report Results (% Deamidated)	BQC 22178	<u>QC-049359</u>	7.1% Deamidated IL-15 (87.8% native IL-15)
HPLC-SEC Light Scattering ¹	Report Results	BQC 16134	<u>QC-049360</u>	Trace aggregate peaks; profile comparable to reference standard

*Testing performed on clinical rhIL-15 Lot L1010008.
¹ Tested in conjunction with Reference Standard Lot L0806002.
² Performed on rhIL-15 Reference Standard, Lot L0806002 (QC-039658).

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