

CERTIFICATE OF ANALYSIS

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Product Name: Recombinant Human IL-15 Final Vial Product (Clinical Grade)	Project Number: 535	Part Number: 50341
NSC Number: 745101	Production Date: 4/14/2009	Lot Number: L0902006
Container Size/Fill Volume: 3 mL vial / 1 mL fill	Lot Size: 2313 vials	
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.		
Storage Temperature: ≤-70°C		

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	QC-040579	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	QC-040583	Conforms to predicted IL-15 sequence: MNWVNVISDL
HPLC-IEX ¹	Chromatographic profile conforms to Reference Standard ¹	BQC 22178	QC-040584	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	QC-040585	8.50 and 6.15 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	QC-040585	Major bands at 8.69 kDa ⁴ ; conforms to standard
Content				
Protein Concentration by Pierce Coomassie Plus	0.50 ± 0.10 mg/mL	BQC 22164	QC-040593	0.51 mg/mL
Potency				
CTLL-2 Cell Proliferation Assay ¹	50% to 200% of reference standard ¹ ; report ED ₅₀ value	BQC 16133	QC-040586	93% of reference standard; 0.089 ng/mL ED ₅₀
Purity				
ExHPLC-RP ^{1,2}	≥ 70% Native rhIL-15; ≤ 15% Deamidated rhIL-15	BQC 22178	QC-040590	84.9% native rhIL-15; 9.0% 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	QC-040587	7.68 kDa (1.8%) and 5.62 kDa (98.0%) bands; sum = 99.8% 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	QC-040587	7.71 kDa (88.2%) and 6.52 kDa (11.8%) bands; sum = 100% of total protein; conforms to standard
HPLC-SEC ¹	≤ 5% High Molecular Weight species (larger than rhIL-15)	BQC 22935	QC-040588	No High Molecular Weight species detected

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Test Description	Assay Specification	Test SOP # or Study #	QC Test Request Number	Result
Free Thiol	≤ 1.25 µg/mL	Charles River Malvern #CTM-2295	QC-040591	< 0.25 µg/mL
Safety				
Endotoxin (LAL)	≤ 5 EU/mg	BQC 22135	QC-040580	0.10 EU/mg
pH	7.4 ± 0.4	BQC 22124	QC-040581	7.4
Sterility	No growth	Celsis Laboratory, 21 CFR 610.12	QC-040592	No growth
Bacteriostasis and Fungistasis ³	Non-bacteriostatic/ Non-fungistatic	Celsis Laboratory, USP 31 <71>, 21 CFR 610.12	QC-039658	Non-bacteriostatic/ Non-fungistatic
For Information Only				
Rapid ExHPLC-RP ^{1,2}	Report Results (% Deamidated)	BQC 22178	QC-040589	7.3% Deamidated IL-15 (91.0% native IL-15)
HPLC-SEC Light Scattering ¹	Report Results	Bioanalytical Development	QC-040582	No detectable product aggregate peaks; profile comparable to reference standard

¹ Tested in conjunction with Reference Standard Lot L0806002.

² Tested in conjunction with prior rhIL-15 Reference Lot L07006002.

³ Performed on rhIL-15 Reference Standard, Lot L0806002 (QC-039658).

⁴ Two major bands are visually observed in the reduced rhIL-15 Sterile Filtered Bulk, Final Vial Product, and Reference Standard lots but SDS-PAGE densitometry software only calls a single band consisting of 88.8% of total protein with a weighted average molecular weight of 8.69 kDa.

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