

CERTIFICATE OF ANALYSIS		
Product Name :	Trastuzumab Biosimilar - Research Grade	
Product No .:	ICH4013	
Clone No .:	N/A	
Lot Number :	241014	
Storage :	2-8 °C Short-term or ≤ -70 °C Long-term	
Formulation :	0.01M Phosphate Buffered Saline, pH 7.4 (1X PBS) No carrier protein, potassium, or preservatives added	
Country of Origin :	United Kingdom	
Test	Specification	Result
Appearance	Clear and Colorless	Conforms
pH Determination	5.4~6.6	6.2
Endotoxin	1 EU/mg	Conforms
Concentration : Spectrophotometry $A_{280nm} E^{0.1\%} 1.4$	21.2±5.0 mg/Vial	25.1 mg/Vial
Purity Determination by SDS-PAGE Reduced:	Two main intense bands representing Ig Heavy and Light chain. Pattern compares in size and intensity to retain samples on the same gel if available.	Conforms
Purity Determination by SDS-PAGE Non-Reduced:	Pattern compares in size and intensity to retain samples on the same gel if available.	Conforms
Purity by Analytical SEC (%monomer)	Single peak representing ≥ 95% Monomer	> 98% Monomer

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