Certificate of Analysis Number: COA-####.##	Ab Biotechnology Limited

Product Name:	Affinity Purified Antibodies to ###
Product Application:	For R &D purposes only
Product Code:	####
Batch Number:	##-####-###
Specification:	IP-####.##
Manufacture Date:	DDMMMYYYY
Expiry Date:	DDMMMYYYY
Manufacturer:	Ab Biotechnology Limited (UK)
Storage:	Validated temperature monitored unit. Store at or below minus 70°C, protected from light.
Transportation Temperature:	Transportation temperature validated range between minus (60 – 90) °C

Parameter	Method	Acceptance Criteria	Result
Appearance	Visual Examination based on Ph. Eur. (Section 2.2.1 and 2.2.2) procedures **SOP-QCD-3020**	After thawing: clear, colourless liquid containing no visible particulates	#
pH	pH determination in accordance with Ph. Eur. (Section 2.2.3) procedure **SOP-QCD-3023**	pH 6.0 – 7.5	#
Protein Content	Total Protein determination in accordance with Ph. Eur. (Section 2.5.33) procedure using A_{280} determination **SOP-QCD-3061**	1.5 – 3.0 mg/mL	#

Ab Biotechnology Ltd, Pentlands Science Park, Bush Loan, Penicuik, Edinburgh, EH26 0PZ
Telephone Number; 0131 445 6077

Certificate of Analysis Number: COA-####.##	Ab Biotechnology Limited

Parameter	Method	Acceptance Criteria	Result
Identity	Reducing SDS-PAGE in accordance with Ph. Eur. (Section 2.2.31) procedure **SOP-QCD-3024**	Main bands of approximately 50 kDa and 25 kDa molecular weight are visible and comparable to current in-house reference standard A band of approximately 81 kDa corresponding to IgM µ heavy chain may be visible in either drug substance or current in-house reference standard and should not be taken into account when comparing band profiles	#
	Non-reducing SDS-PAGE in accordance with Ph. Eur. (Section 2.2.31) procedure **SOP-QCD-3024**	Main band of approximately 150 kDa molecular weight is visible and comparable to current in-house reference standard	#
Impurities	Determination of Rabbit Albumin Content by Reducing SDS-PAGE (Coomassie) in accordance with Ph. Eur. (Section 2.2.31) procedure **SOP-QCD-3058**	Less than or equal to 3 % Rabbit Albumin	#
Specific Activity / Identity	Competitive ELISA for detection of ## Antibodies **PSM-####-####**	O.D. decrease caused by competitive binding must be at least ##.# % compared to non-competitive binding	#

Certificate of Analysis Number: COA-####.##	Ab Biotechnology Limited

Parameter	Method	Acceptance Criteria	Result
Distribution of Molecular Size	SEC-HPLC in accordance with Ph. Eur. (Section 2.2.30) procedure **SOP-QCD-3063**	Greater than or Equal to 95 % Total Monomers/Dimers/ Pentamers Less than or Equal to 5 % Total Degradants and Aggregates	#
Purity	Non-reducing SDS-PAGE in accordance with Ph. Eur. (Section 2.2.31) procedure **SOP-QCD-3024**	No additional bands, comparable to current in-house reference standard; with the exception of known Rabbit Albumin impurity band which may resolve at approximately 55 kDa in either drug substance or current in-house reference standard and should not be taken into account when comparing band profiles	#
	SEC-HPLC in accordance with Ph. Eur. (Section 2.2.30) procedure **SOP-QCD-3063**	Greater than or Equal to 95 % Purity	#
Bioburden	TAMC and TYMC in accordance with Ph. Eur. (Section 2.6.12) procedure	TAMC <10 cfu/mL TYMC <10 cfu/mL	#
	Specified organism testing in accordance with Ph. Eur. (Section 2.6.13) procedure	Absence of *Staphylococcus aureus* and absence of *Pseudomonas aeruginosa*	#

Certificate of Analysis Number: COA-####.##	

REVISION HISTORY

Version No	Reason for Change
00	New Document

I confirm that the above product has been examined against the relevant release specification and meets all the required criteria.

Quality Control			
Signature		**Date**	
Print Name			
Position (Originator)			
Quality Control Approval			
Signature		**Date**	
Print Name			
Position (Approver)			
Quality Assurance Approval			
Signature		**Date**	
Print Name			
Position (Approver)			