

COAP700-1v6/Template

CERTIFICATE OF ANALYSIS RECOMBINANT HUMAN PROTEIN

Recombinant Human Prolactin

Code No. Grade Lot No.	P700-1 Highly pure			
RECEIVER INFORMATION				
Expiry Date Manufacture Date Storage Temperature	Below -15°C.			
Shipping Notes	Cool pack.			
PRODUCT INFORMATION				
Source	Expressed in Pichia pastoris.			
Nominal Purity	>96%.			
Presentation	Single homogenous batch, supplied lyophilised from 50mM NH_4HCO_3 and 1mM EDTA. May contain traces of buffer salts.			
Reconstitution Advice	Use of a pH neutral buffer is recommended. To ensure full product recovery, it is advised that reconstitution is performed directly into supplied vial incorporating further washings with the reconstitution buffer.			
Recovery	In order to meet our customer needs, it should be noted that there is normally a dispensing overage allowance and the product recovery may, therefore, be greater than expected.			
HEALTH AND SAFETY				
Application	For Research and Manufacturing Only.			
Material Safety	For further information and technical details, please download a Safety Data Sheet at <u>www.bbisolutions.com</u> or contact your BBI Account Manager.			

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ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
Determination Method		
Protein concentration by Bradford of dispensing solution	≥1.5 mg/ml	mg/ml
SDS- Polyacrylamide Gel Electrophoresis	To show a major band corresponding to Prolactin molecular weight of 23kDa. Other forms may be present.	Pass/Fail
Activity as determined by Roche Modular E170	≥30 iu/mg	iu/mg
Western Blot	Positive reaction with specific polyclonal anti-Prolactin antibody.	Pass/Fail
Bioburden	<100 CFU/ml	Pass/Fail
Physical Appearance	White, lyophilised solid	
Purity	Defined by Coomassie stained SDS-PA	GE

Name:	Position:	
Signed:	Date:	

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