

CERTIFICATE OF ANALYSIS

HUMAN URINE PROTEIN

Human Albumin

Code No.	P140-0
Grade	Ultra Pure
Lot No.	

RECEIVER INFORMATION

Expiry Date	
Manufacturing Date	
Storage Temperature	Store at 2-8°C.
Storage Notes	Do not freeze.
Shipping Notes	Cool pack.

PRODUCT INFORMATION

Source	Human urine from patients with chronic renal failure.
Nominal Purity	>99%.
Presentation	Single homogenous batch, lyophilised from 0.02M NH ₄ HCO ₃ . May contain traces of buffer salts.
Reconstitution Advice	Use of phosphate buffer, pH >7.0 containing 0.15M NaCl 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.
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Infectious Disease Tests

A sample has been tested for:	Result
HIV 1 & 2 antibodies	
Hepatitis B Surface Antigen	
Hepatitis C virus antibodies	

Precaution	No test can guarantee the absence of an infectious agent. Please handle as potentially hazardous.
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Material Safety	For further information and technical details, please download a Safety Data Sheet at www.bbisolutions.com or contact your BBI Account Manager.
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ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<u>Determination Method</u>		
Protein concentration by optical density at 280nm using $E_{0.1\%}^{1\text{cm}} = 0.58$	≥ 1 mg/ml	mg/ml
SDS-Polyacrylamide Gel Electrophoresis.	To show one band corresponding to Albumin molecular weight of 66kD.	Pass/Fail
Radial Immunodiffusion (RID) using BBI standard.	To give a positive reaction to confirm identity and verify dispensed quantity.	Pass/Fail
2-D Immunoelectrophoresis vs antiserum to whole normal human serum.	To show a single arc.	Pass/Fail
Bioburden.	<100 CFU/ml	Pass/Fail

Physical Appearance White, lyophilised solid.

Purity Defined as a major band on coomassie stained SDS-PAGE.

Name:		Position:	
Signed:		Date:	