



WuHan Healthgen Biotechnology Corp.

Certificate of Analysis

Product Name	Human Serum Albumin Recombinant (OsrHSA)		
Lot No.	C201504003	Analysis Date	05/11/2015
Packing Specification	20%, 50ml/bottle	Date of Certification	05/20/2015
Manufacture Date	04/28/2015	Expiration Date	04/27/2017
Manufacturer	WuHan Healthgen Biotechnology Corp. P. R. China		

Test Item	Specification	Result
Appearance	Slightly viscous, clear yellow to brown solution, should not appear turbid	Slightly viscous, clear light brown solution, no turbid
Identification- western blotting	Positive	Positive
Visual foreign matters	Conforms to standard	Conforms
Particulate matter	No more than 6000 per container for 10 μ m particles and greater.	90
	No more than 600 per container for 25 μ m particles and greater.	5
Osmotic pressure molar concentration	210~400 mOsmol/kg	291 mOsmol/kg
Filling volume	Not less than labeled volume	Meets requirement
pH	6.4~7.4	7.0
Absorbance	≤ 0.15	0.03
Protein Content	95.0%~110.0% of labeled content	102.1%
Purity (SDS-PAGE)	$\geq 96.0\%$	99.0%
Host cell DNA	≤ 0.5 ng/g protein	None detected



WuHan Healthgen Biotechnology Corp.

Certificate of Analysis

Product Name	Human Serum Albumin Recombinant (OsrHSA)
Lot No.	C201504001

Test Item	Specification	Result
Sodium	≤ 160 mmol/L	146 mmol/L
Host cell protein	≤ 5 $\mu\text{g/g}$ protein	3.3 $\mu\text{g/g}$
Polymer	$\leq 1.0\%$	None detected
Octanoate	0.140~0.180 mmol/g protein	0.152 mmol/g
Aluminum	≤ 200 $\mu\text{g/L}$	43 $\mu\text{g/L}$
Ammonium sulfate	≤ 0.5 g/L	0.08 g/L
Sterility	Sterile	Conforms
Pyrogens	Pyrogens free	Conforms
Abnormal toxicity test	Conforms to standard	Conforms
Conclusion	Complied with specifications	

	Checked by	Approved by
Signature		
Date	05/20/2015	05/20/2015