

济南亚西亚药业有限公司
JINAN ASIA PHARMACEUTICAL CO., LTD.
 XINSHI TOWN,JIYANG COUNTY, JINAN CITY, CHINA

CERTIFICATE OF ANALYSIS

Product Name	Betaine Hydrochloride
Lot Number	170151211
Batch Quantity	900Kgs
MFG.Date	Dec.11, 2015
EXP.Date	Dec.10, 2017
Product Code	BH170
CAS	590-46-5
Country of Origin	China
Standard	USP
ID	BH20151211V3

Items of Analysis	Specifications	Results	Test Method
Identification A&B	Positive Reaction	Conforms	USP<197k>/USP<191>
Appearance	White granular crystals	Conforms	Q/JYXY 0003Y-2013
Assay(calculated on the anhydrous basis)	99.0%-100.5%	99.1%	USP
pH(1 in 4)	0.8-1.2	1.1	USP<791>
Water	NMT0.5%	0.21%	USP<921>
Residue on ignition	NMT0.1%	0.06%	USP<281>
Heavy metals	NMT10ppm	<10ppm	GB-T 5009.74-2003
Arsenic	NMT 2ppm	<2ppm	GB-T 5009.76-2003
Cadmium	NMT 0.3ppm	<0.3ppm	GB/T 5009.15-2003
Chromium	NMT 2ppm	<2ppm	GB/T 5009.123-2003
Lead	NMT 0.3ppm	<0.3ppm	GB-T 5009.75-2003
Mercury	NMT 0.2ppm	<0.2ppm	GB/T 5009.17-2003
Microbial			
Total Plate Count	≤1000CFU/g	<1000CFU/g	GB 4789.2-2010
Yeast and mold	≤100CFU/g	<100CFU/g	GB 4789.15-2010
E.Coli	Negative	Negative	GB 4789.38-2012
Salmonella	Negative	Negative	GB 4789.4-2010
Staphylococcus Aureus	Negative	Negative	GB 4789.10-2010
Particle size			
Through 20 Mesh	100%	100%	GBT 21524-2008

Meets the current USP prior to conditioning.

Storage: Preserve in well-closed containers with double inner lining

Packing: 25KG paperboard barrel with double inner lining

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Approved by: *Fengming Chu*

Checked by: *Qinghan Wu*

Tested by: *Sun Chunmin*