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SPECIFICATION SHEET

L-Leucine

Item Code: 321

Updated: September 2012

Country of Origin: China

TEST ITEMS	SPECIFICATIONS	TEST METHODS
Description	White or almost white crystalline powder	Visual
Identification	As per USP33	USP33<197K>
Specific Rotation	+ 14.9° to + 16.8°	USP33<781S>
pH	5.5 – 7.0	USP33<791>
Loss on Drying	≤ 0.2%	USP33<731>
Residue on Ignition	≤ 0.1%	USP33<281>
Chloride	≤ 0.05%	USP33<221>
Sulfate	≤ 0.03%	USP33<221>
Iron	≤ 30ppm	USP33<241>
Heavy Metals	≤ 15ppm	USP33<231>
Lead (Pb)	≤ 5 ppm	/
Chromatographic Purity:		
Total Impurities	≤2.0%	USP33
Individual Impurities	≤0.5%	USP33
Organic Volatile Impurities	As per USP33	USP33<467>
Residual solvents	As per USP323	USP33
Assay	98.5% - 101.5%	USP33
Microbiology:		
Total aerobic plate count	≤1,000 cfu/g	CP
Yeast & Mold	≤100 cfu/g	CP
Coliforms	≤10 cfu/g	CP
E. coli	Negative	CP
Salmonella	Negative	CP
Staphylococcus aureus	Negative	CP
Conclusion:	Conforms to USP33 standards	
Shelf Life:	2 years	
Storage:	Preserve in well-closed containers, protected from light	
Packing:	In drums of 25 kgs	

- Kosher certified
- Halal certified

Gayathri Vasudevan

Manager, Quality Assurance & Regulatory