



CERTIFICATE OF ANALYSIS

Product: Unfilled HPMC GAR enteric capsules  
Size: #0  
Color: Natural  
Batch no.: GAR021031203  
Manufacturing date: Mar.2021  
Test date: Mar.29<sup>th</sup>,2021  
Expiration date: Five years

<i>ITEM</i>	<i>SPECIFICATION</i>	<i>RESULTS</i>	<i>METHOD</i>
Loss on drying	≤9.0%	7.2%	USP<731>
Weight –average (20 capsules)	96 ± 6mg	98mg	USP<2091>
Hypromellose ID method B and C	Positive	Pass	USP 35
Intact in gastric fluid for 120 minutes	>99.99%	100%	USP <701>
Disintegration in intestine fluid	90 – 95% dissolve < 60 min	15min	USP <701>
Residual on ignition	< 5%	0.9%	USP<281>
Heavy metals total	< 10 PPM	Conform	USP<231>
Mercury (Hg)	< 0.1 PPM	<0.1 PPM	AAS
Lead (Pb)	< 1 PPM	<1 PPM	USP<251>
Cadmium (Cd)	< 1 PPM	<1 PPM	AAS
Arsenic (As)	< 1 PPM	<1 PPM	USP<211>
Microbiological quality			
Total plate counts	< 1000 CFU/g	< 10 CFU/g	USP<61>
Yeast and molds	< 100 CFU/g	< 10 CFU/g	USP<61>
E. Coli	Negative	Negative	USP<62>
Salmonella	Negative	Negative	USP<62>
Staphylococcus aureus	Negative	Negative	USP<62>
Defects			
Critical	< 0.01%	< 0.01%	calculate
Major	< 0.05%	< 0.05%	calculate
Minor	< 0.1%	< 0.1%	calculate
Length			
Cap	11.0 ± 0.3 mm	Conform	caliper
Body	18.6 ± 0.3 mm	Conform	caliper
Closed	21.2 ± 0.3 mm	Conform	caliper

QA: Hongmei Zhang

Signature: Hongmei Zhang

Date: 2021/04/03