

Test Data From Certificate of Analysis Manufacturer

Report No. 20170406

Product Name	Hepato-ST	#MO	/	Product SKU	HCD_FD-004-010
Product Spec.	120 (94g)	Quantity	1816	Lot No.	A170224A
Mfg. Date	2017/02/24	Expired Date	24 months	Report Date	2017/04/21

No.	Testing Item	Mode: Internal- External	According	Standard	Results	PASS/FAIL
1	Total Aerobic Microbial Count	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	≤ 1000 cfu/g	<10cfu/g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
2	Total combined molds and yeasts count	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	≤ 100 cfu/g	<10cfu/g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
3	Bile-tolerant gram-negative bacteria	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	≤ 100 cfu/g	<10cfu/g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
4	Staphylococcus aureus	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	Not detected	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
5	Salmonella Species	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	Not detected	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
6	Escherichia coli	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	Not detected	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
7	Clostridium species	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	Not detected	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
8	Loss on drying	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 10%	0.93%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
9	Residue on ignition	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 10%	5.36%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
10	Methanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 3000 ppm	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
11	Ethanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 5000 ppm	44pm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
12	Nitrite	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 10 ppm	0.37ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
13	Lead	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 2.0 ppm	0.03ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
14	Arsenic	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 1.0 ppm	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
15	Mecury	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 0.3 ppm	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
16		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 20 ppb	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
17		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 5 ppb	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
18	Net Weight	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	84.6 - 103.4g	96.2	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
19	Disintegration	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	37 ± 2°, 30 min All of the capsules disintegrated within 30 min	8 - 10 min	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
20	Packaging labels	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	Comply with design	Complies	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
Conclusion		<input checked="" type="checkbox"/> This batch of products comply with USP standard and contract requirements, test results is PASS. <input type="checkbox"/> This batch of products does not comply with USP standard and contract requirements, test results is FAILED.				