

Test Data From Certificate of Analysis Manufacturer

Report No. 20170601

Product Name	Hepato-CL Capsule	#MO	/	Product SKU	HCD_FD-04-001
Product Spec.	90 (79g)	Quantity	2205	Lot No.	A170516A
Mfg. Date	2017/05/16	Expired Date	2019/05/15	Report Date	2017/06/29

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	59cfu/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%	2.2%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
9	Residue on ignition	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 10%	9.01%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
10	Hexachlorocyclohexane	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 0.3 ppm	<0.002ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
11	DDT	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 1.0 ppm	<0.009ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
12	Parathion	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 0.5 ppm	<0.01ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
13	Methanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 3000 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
14	Ethanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 5000 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
15	Nitrite	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 10 ppm	0.33ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
16	Lead	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 2.0 ppm	0.12ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
17	Arsenic	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 1.0 ppm	0.12ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
18	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
19		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 20 ppb	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
20		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 5 ppb	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
21	Net Weight	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	71.1 - 86.9g	78.16g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
22	Disintegration	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	37 ± 2°, 30 min All of the capsules disintegrated within 30 min	9 - 11min	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
23	Packaging labels	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	Comply with design	Complied	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
Conclusion		<input checked="" type="checkbox"/> This batch of products comply with USP standard and contract requirments, test results is PASS. <input type="checkbox"/> This batch of products does not comply with USP standard and contract requirments, test results is FAILED.				