

Test Data From Certificate of Analysis Manufacturer

Report No. 20161118

Product Name	Effecsulin Capsule	#MO	/	Product SKU	HCD_FD-04-004
Product Spec.	90 Capsules per bottle (63g)	Quantity	3783	Lot No.	A161029A
Mfg. Date	2016/10/29	Expired Date	24 months	Report Date	2016/11/21

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	<10 cfu/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	<10 cfu/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	<10 cfu/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	USP39	≤ 10%	4.69%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
9	Residue on ignition	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP39	≤ 10%	2.23%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
10	Hexachlorocyclohexane	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 0.3 ppm	<0.002 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
11	DDT	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 1.0 ppm	<0.009 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
12	Parathion	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 0.5 ppm	<0.01 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
13	Methanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 3000 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
14	Ethanol	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 5000 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
15	Nitrite	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP39	≤ 2 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
16	Heavy metal	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	Contract	≤ 20 ppm	<20 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
17	Lead	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 2.0 ppm	<0.05 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
18	Arsenic	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 1.0 ppm	<0.05 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
19	Mecury	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 0.3 ppm	<0.01 ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
20	Aflatoxin B1, B2, G1, G2	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 20 ppb	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
21	Aflatoxin B1	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP39	≤ 5 ppb	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
22	Net Weight	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP39	56.7 ~ 69.3g	62.57g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
23	Disintegration	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP39	37 ± 2°, 30 min All of the capsules disintegrated within 30 min	5 ~ 7 min	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
24	Packaging and label	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP39	Comply with design	Not Detected	<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 requirements, test results is FAILED.				