

# Test Data From Certificate of Analysis Manufacturer

Report No. 20170202

Product Name	Effecsulin Capsule	#MO	/	Product SKU	HDC_FD-04-004
Product Spec.	90 Capsules (63g)	Quantity	2958	Lot No.	A170107A
Mfg. Date	2017/01/07	Expired Date	24 months	Report Date	2017/02/17

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%	4.92%	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
9	Residue on ignition	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 10%	3.30%	<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	Nitrite	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 10 ppm	Not Detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
14	Heavy metal	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	≤ 20 ppm	<20ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
15	Lead	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	USP	≤ 2.0 ppm	0.93ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
16	Arsenic	<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 1.0 ppm	0.093ppm	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
17	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
18		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 20 ppb	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
19		<input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext	Contract	≤ 5 ppb	Not detected	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
20	Net Weight	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	56.7 ~ 69.3g	63.5g	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
21	Disintegration	<input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext	USP	37 ± 2°, 30 min All of the capsules disintegrated within 30 min	6~8 min	<input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL
22	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.				