

# Test Data From Certificate of Analysis Manufacturer

Report No. 20170403

|               |                    |              |            |             |               |
|---------------|--------------------|--------------|------------|-------------|---------------|
| Product Name  | Effecsulin Capsule | #MO          | /          | Product SKU | HDC_FD-04-004 |
| Product Spec. | 90 Capsules (63g)  | Quantity     | 2794       | Lot No.     | A170313A      |
| Mfg. Date     | 2017/03/13         | Expired Date | 2019/03/12 | Report Date | 2017/04/21    |

| No.        | Testing Item                          | Mode:<br>Internal-<br>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%  | 3.66%        | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 9          | Residue on ignition                   | <input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext  | USP       | ≤ 10%  | 3.78%        | <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   | 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   | <20ppm       | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 17         | Lead                                  | <input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext  | Contract  | ≤ 2.0 ppm  | 0.31ppm      | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 18         | Arsenic                               | <input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext  | Contract  | ≤ 1.0 ppm  | 0.65ppm      | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 19         | 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 |
| 20         |                                       | <input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext  | USP       | ≤ 20 ppb   | Not Detected | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 21         |                                       | <input type="checkbox"/> Int. <input checked="" type="checkbox"/> Ext  | USP       | ≤ 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  | USP       | 56.7 ~ 69.3g   | 64.5g        | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 23         | Disintegration                        | <input checked="" type="checkbox"/> Int. <input type="checkbox"/> Ext  | USP       | 37 ± 2°, 30 min<br>All of the capsules disintegrated within 30 min | 8-9 min      | <input checked="" type="checkbox"/> PASS; <input type="checkbox"/> FAIL |
| 24         | 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.<br><input type="checkbox"/> This batch of products does not comply with USP standard and contract requirements, test results is FAILED. |           |  |              |   |