

**PT. KAPSULINDO NUSANTARA****MANUFACTURER OF HARD GELATIN CAPSULES**

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**ANALYSIS REPORT ON PHARMACEUTICAL CAPSULE**

Colour : GRN - WHT (5630-9090)  
Batch No. : 1060824IE  
Size : 3N  
Manufacturing Date : 08-2024  
Expiry Date : 08-2029

| TEST                                                 | UNIT        | RESULT OF ANALYSIS           | SPECIFICATION                 |
|------------------------------------------------------|-------------|------------------------------|-------------------------------|
| Weight<br>(3 Sigma Gross Weight<br>for 100 capsules) | ( mg )      | Pass                         | 46.00 - 54.00                 |
| Length - Cap                                         | ( mm )      | Pass                         | 7.60 - 8.50                   |
| Body                                                 | ( mm )      | Pass                         | 13.25 - 14.05                 |
| Moisture Content                                     | ( % )       | Pass                         | 13.00 - 16.00                 |
| Disintegration Time                                  | ( minutes ) | Pass                         | Less than 15                  |
| Ash Content                                          | ( % )       | 2.82                         | Less than 5 (USP)             |
| Arsenic                                              | ( ppm )     | Pass                         | Less than 1 (USP)             |
| Heavy Metals                                         | ( ppm )     | Pass                         | Less than 2 (USP)             |
| SO <sub>2</sub>                                      | ( ppm )     | 17.28                        | Less than 50 (USP)            |
| TiO <sub>2</sub> Identification                      |             | Positive                     | Positive                      |
| Colour Identification                                |             | FD&C Yellow 5<br>FD&C Blue 1 | Allowed as<br>a food additive |
| Total Aerobic Microbial Count                        | (cfu/g)     | < 10                         | Less than 1000 (USP)          |
| Total Yeasts/Molds                                   | (cfu/g)     | < 10                         | Less than 100 (USP)           |
| Staphylococcus aureus                                |             | Absent                       | Absence in 1 gram (USP)       |
| Eschericia Coli                                      |             | Absent                       | Absence in 1 gram (USP)       |
| Psedomonas Aeruginosa                                |             | Absent                       | Absence in 1 gram (USP)       |
| Salmonnella                                          |             | Absent                       | Absence in 10 gram (USP)      |

  
Certified By : Ari Setiadji S.Si., Apt  
Responsible Pharmacist