

CERTIFICATE OF ANALYSIS

| | | | |
|-------------------------|------------|-------------------|--------------|
| PRODUCT: | CHOLESTOL | GRADE: | NPN 80039395 |
| CODE: | 102347 | MANUFACTURE DATE: | 2019-11 |
| MANUFACTURED UNDER LOT: | SN19107202 | EXPIRATION DATE: | 2022-10 |
| PACKED UNDER LOT : | 20081 | | |

VERSION: 05

Issued Date: 2019-05-27


Approved by:



| TEST | LIMITS | METHOD | RESULTS |
|---|---|-----------------|----------------|
| IDENTITY | | | |
| Appearance: | Oval, plain on both sides, coated biconvex tablet | Visual | Complies |
| Color: | White | Visual | Complies |
| Odor: | Characteristic | Organoleptic | Complies |
| Average weight: | 1 080 - 1 320 mg/tab | USP <2091> | 1194 mg/tab |
| Weight variation: | USP limits | USP <2091> | Complies |
| Disintegration : | ≤ 60 minutes | USP <2040> | 2 minutes |
| ACTIVITY | | | |
| Free Plant Sterols (<i>Glycine max</i>) seed | 380 - 420 mg/tab (Target: 400 mg /tab) | Input | Complies |
| Providing: 80% Phytosterols | ≥ 320 mg/tab | GC | 334 mg/tab |
| L-Methionine | 38 - 42 mg/tab (Target: 40 mg /tab) | Input | Complies |
| Policosanol (<i>Saccharum officinarum</i>) wax | 4.75 - 5.25 mg/tab (Target: 5 mg /tab) | Input | Complies |
| PURITY | | | |
| Total aerobic microbial count | < 3 000 cfu/g | USP <2021> | 600 cfu/g |
| Yeasts / Moulds | < 300 cfu/g | USP <2021> | 20 cfu/g |
| <i>Escherichia coli</i> | Absence | USP <2022> | Absence |
| <i>Salmonella spp.</i> | Absence | USP <2022> | Absence |
| <i>Staphylococcus aureus</i> | Absence | USP <2022> | Absence |
| Arsenic | < 3.26 µg /tab | USP <232>/<233> | < 3.26 µg /tab |
| Cadmium | < 2.1 µg /tab | USP <232>/<233> | < 2.1 µg /tab |
| Lead | < 3.26 µg /tab | USP <232>/<233> | < 3.26 µg /tab |
| Mercury | < 0.66 µg /tab | USP <232>/<233> | < 0.66 µg /tab |
| Residual solvents ⁽¹⁾ | Complies | USP <467> | Complies |
| Pesticides ⁽¹⁾ | Complies | USP <561> | Complies |

⁽¹⁾Tested according to SOP CQ026

VERIFIED & APPROVED BY:


Quality Control and Assurance
2019-12-03

DATE