



SN - Cp142/21/210319

**CENTRE FOR PLANT MEDICINE RESEARCH**  
**PHARMACOLOGY & TOXICOLOGY DEPARTMENT**

| Product Code | Product Form | Date Received                | Date Analysed               | Test Conducted      |
|--------------|--------------|------------------------------|-----------------------------|---------------------|
| Cp/021/21    | Capsules     | 16 <sup>th</sup> April, 2021 | 2 <sup>nd</sup> March, 2023 | Acute Toxicity Test |

**RESULTS:**

Table Showing Results of Acute Toxicity Test on Capsules (Cp/021/21) in test.

|  |      |
|--|------|
| Animal Model                                     | test |
| No. of Animals                                   | test |
| Sex  | test |
| No. of Groups                                    | test |
| Route of Administration                          | test |
| Formulation                                      | test |
| Preparation                                      | wrw  |
| Dose Administered                                | Text |
| Period of Observation                            | test |
| No. of Deaths Recorded                           | test |
| Estimated Median Lethal Dose (LD <sub>50</sub> ) | test |
| Physical Signs of Toxicity                       | wer  |

**REMARKS:**

The LD<sub>50</sub> is estimated to be greater than 5000 mg/kg which is greater or equal to level 5 on the Hodge and Sterner Scale<sup>1</sup> and also 93 times more than the recommended dose (take 2 to 4 capsules twice day with meal. equivalent to 5.0 mg/kg ), as indicated by the manufacturer. Thus, the product, Cp/021/21, may not be toxic and is within the accepted margin of safety (Hodge and Sterner Scale) at the recommended dose.

|                |            |
|----------------|------------|
| Animal Model   | Wistar Rat |
| No. of Animals | 12         |
| Sex            | Male       |
| No. of Groups  | 2(n=6)     |

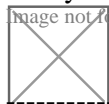
|  |                                      |
|--|--------------------------------------|
| Route of Administration                          | Oral                                 |
| Formulation                                      | Decoction                            |
| Preparation                                      | Freeze - dried sample of De/006/21 ) |
| Dose Administered                                | 5000 mg/kg                           |
| Period of Observation                            | 14 Days                              |
| No. of Deaths Recorded                           | Nil                                  |
| Estimated Median Lethal Dose (LD <sub>50</sub> ) | Greater than 5000 mg/kg              |
| Physical Signs of Toxicity                       | Nil                                  |

#### REMARKS:

The LD<sub>50</sub> is estimated to be greater than 5000 mg/kg which is greater or equal to level 5 on the Hodge and Sterner Scale<sup>1</sup> and also 139 times more than the recommended dose (three tablespoonsful three times daily, equivalent to 36.04 mg/kg ), as indicated by the manufacturer. Thus, De/006/21 may not be toxic and is within the accepted margin of safety (Hodge and Sterner Scale) at the recommended dose.

Analysed by

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Mr. Pharm System  
Admin  
Research Officer

Approved by



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Admin  
Research Officer

**Reference:** 1- Canadian Centre for Occupation Health and Safety (2019)