

## QUALITY CONTROL TEST CERTIFICATE FENBENDAZOLE EU/U.S. Ph.

09.07.2020

| Lot No.   |  | F19/1-05   |                                  |
|---|--|--|----------------------------------|
| Storage Condition   |  | Store in closed container protected from light.  |                                  |
| Customer Name   |  | COMMON   |                                  |
| S.No.   | Test parameter   | Specification  | Result                           |
| 1   | Description  | A white or almost white powder.  | Almost white powder.             |
| 2   | Solubility   | Almost insoluble in water, fairly soluble in Dimethyl formamide and modestly soluble in methanol.  | Complies                         |
| 3   | Identification   | Investigated by infrared absorption spectrophotometry comparing with the spectrum of Fenbendazole standard. Investigated the substances prepared as discs. | Complies                         |
| 4   | Related Substances by HPLC<br>Fenbendazole impurity A<br>Fenbendazole impurity B<br>Other impurity<br>Total impurity | Not more than 0.50%<br>Not more than 0.50%<br>Not more than 0.20%<br>Not more than 1.00%   | 0.02%<br>0.04%<br>0.05%<br>0.10% |
| 5   | Heavy Metals   | Not more than 10 ppm   | Complies                         |
| 6   | Loss on drying   | Not more than 1.0% w/w   | 0.10% w/w                        |
| 7   | Sulphated Ash  | Not more than 0.3% w/w   | 0.07% w/w                        |
| 8   | Assay  | 98.0 to 101.0% w/w (Titration)   | 100.2% w/w                       |
| Remarks: The above batch complies to European Pharmacopoeia/ U.S. Pharmacopeia Specifications |  |  |                                  |