



## Summary of Studies Supporting USDA Product Licensure

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| Establishment Name  | Elanco US Inc.   |
| USDA Vet Biologics Establishment Number                                   | 196  |
| Product Code  | 2703.19  |
| True Name   | Pasteurella Multocida Bacterin, Avian Isolates, Types 1 & 4 & 3 X 4  |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | AviPro 108 FC3 Platinum - Bio Pharma Trading Co. - Lohmann Animal Health International<br>AviPro 108 FC3 Platinum - Eli Lilly Philippines, Inc. - Lohmann Animal Health International<br>AviPro 108 FC3 Platinum - Lohmann Animal Health International<br>AviPro 108 FC3 Platinum - No distributor specified |
| Date of Compilation Summary   | March 27, 2020   |

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | <i>Pasteurella multocida</i>  |
| <b>Study Purpose</b>                     | To demonstrate efficacy against <i>Pasteurella multocida</i> , type 1 in chickens<br>To demonstrate efficacy against <i>Pasteurella multocida</i> , types 4 and 3x4 in turkeys  |
| <b>Product Administration</b>            | Intramuscular   |
| <b>Study Animals</b>                     | Chickens and turkeys  |
| <b>Challenge Description</b>             |   |
| <b>Interval observed after challenge</b> |   |
| <b>Results</b>                           | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>                | March 8, 2002   |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | <i>Pasteurella multocida</i>  |
| <b>Study Purpose</b>                     | To demonstrate efficacy against <i>Pasteurella multocida</i> , type 1 in chickens<br>To demonstrate efficacy against <i>Pasteurella multocida</i> , types 4 and 3x4 in turkeys  |
| <b>Product Administration</b>            | Subcutaneous  |
| <b>Study Animals</b>                     | Chickens and turkeys  |
| <b>Challenge Description</b>             |   |
| <b>Interval observed after challenge</b> |   |
| <b>Results</b>                           | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>                | September 20, 1996  |

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| <b>Study Type</b>                        | Safety  |
| <b>Pertaining to</b>                     | All fractions   |
| <b>Study Purpose</b>                     | To demonstrate safety under field conditions  |
| <b>Product Administration</b>            | Subcutaneous or intramuscular injection   |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             |   |
| <b>Interval observed after challenge</b> |   |
| <b>Results</b>                           | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>                | March 8, 2002   |

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| <b>Study Type</b>                        | Safety   |
| <b>Pertaining to</b>                     | All fractions  |
| <b>Study Purpose</b>                     | To demonstrate safety under field conditions   |
| <b>Product Administration</b>            | Subcutaneous or intramuscular injection  |
| <b>Study Animals</b>                     | Turkeys  |
| <b>Challenge Description</b>             |  |
| <b>Interval observed after challenge</b> |  |
| <b>Results</b>                           | Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. |