Study of Efficiency Time of Recombinant DNA Insulin via Accelerated Life Testing and Interval Censoring

P. S. Ilambwetsi [1], G. D. R. Gouvêa [2], F. L. P. Oliveira [2], F. R. B. Cruz [3]

[1]*Departamento de Estatística, Universidade Federal de Viçosa*
36570.977 - Viçosa - MG, Brazil

[2]*Departamento de Estatística, Universidade Federal de Ouro Preto*
35400-000 - Ouro Preto - MG, Brazil

[3]*Departamento de Estatística, Universidade Federal de Minas Gerais*
31270-901 - Belo Horizonte - MG, Brazil

jpatysousa@yahoo.com.br, gragouvea@gmail.com
fernandoluiz@iceb.ufop.br, fcruz@est.ufmg.br

Abstract

This paper aims to study the efficiency of recombinant DNA insulin via models for accelerated life tests. The potency loss of these insulin products was evaluated periodically, subject to the conditions of temperature of 8 °C, 25 °C and 37 °C. Insulin samples with potency at less than 100% were considered unfit for consumption, which characterizes the event of interest. Samples suitable for consumption were considered to be censored. The response variable was observed periodically for 736 days. For data analysis, statistical models of stress-response regression were used. The deterministic part of these models is the Arrhenius model because the stress variable is the temperature, while the probabilistic part was comprised of the Exponential, Weibull, and Log-normal models. The techniques of accelerated life tests proved adequate to address the time of potency loss of the insulin for the various temperature levels. The times of occurrence of the events were treated in three different ways, which were compared in this study. First, interval censoring was considered, or only the upper and lower limits of the interval in which the failure occurred were known. Then, the midpoint of this interval was considered as a failure time. Finally, only the lower limit of the interval in which the failure occurred was considered. According to the results, it is concluded that the use of the interval lower limit is more appropriate for estimating the reliability curves, as the estimates are closer to those using interval censoring then using the midpoint of the interval. For the specific case of the recombinant DNA insulin data, it was observed that the Arrhenius-Weibull model and the Arrhenius-lognormal are suitable for adjusting the data. It follows also that the temperature affects the power of the insulin: The higher the temperature are, the lesser the efficiency.

Keywords: Accelerated life tests; stress variable; interval censoring; exact failure times.

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