Effectivity Of Bioburden Sterilization Method On L-arginine Infusion

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Poster Preseter : The 2nd International Seminar on Chemistry 2011
Aula PSBJ Jatinangor Campus, Universitas Padjadjaran 24-25 November 2011

FAKULTAS FARMASI
UNIVERSITAS PADJADJARAN

ISC-2011 | International Year of CHEMISTRY 2011 | HKI Himpunan Kimia Indonesia

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The 2nd International Seminar on Chemistry 2011

"Chemistry for a better future"

held at

Aula Pusat Studi Bahasa Jepang, Jatinangor Campus, Universitas Padjadjaran

24-25 November 2011

as

Poster Presenter

organized by

Department of Chemistry, Faculty of Mathematics and Natural Sciences, Universitas Padjadjaran

in cooperation with

Indonesian Chemical Society

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ISC-2011
International Seminar on Chemistry

ABSTRACT

Infusion can be sterilized with various methods one of that is bioburden method. Bioburden method consider microbial burden on preparations before sterilization process, and can be carried out under temperature 121^{0}C. To ensure sterility and determine the effectiveness of bioburden on the sterilization method of preparation of intravenous amino acid L-Arginine, so this this study tested the effectiveness of bioburden methods on the infusion of the amino acid L-Arginine 0.4%. Stages of research involves determining the value of D at a temperature of 115^{0}C, the manufacture of amino acid infusion dosage of L-arginine 0.4%, contamination test preparation, sterilization bioburden preparations using the method, observations on the absorbance of L-Arginine infusion preparations amino acid L-arginine, as well as evaluation of dosage (organoleptis, pH, sterility test and pyrogen test by using the Spearman Karber method, the value of D obtained is 2.5 minutes and time with the method of bioburden on the sterilization temperature of 115^{0}C is 15 minutes. the results of the sterility test spreparations are sterilized with bioburden method 115^{0}C during 15 minutes has fulfilled the requirements of sterility, stable and free of pyrogens.

***Key word** : Bioburden, sterility test, Amino Acid L-Arginine 0,4% infusion*

INTRODUCTION

Infusion of amino acid ussually is sterilized by overkill sterilization method. There is an argument about infusion sterilization using Bioburden Method at year of 2007, it seem the sterility of product is under standard requirement (Sarnianto, 2007). Some researcher showed their verification that infusion which is sterilized by Bioburden Method is sterile compare to sterilization overkill (121^0 C, 15 minute) and gave recomendation, this method is suitable for sterilization of high heat sensitive drug. (Boom FA *et al*, 1991).

To avoid the degradation of amino acid, the sterilization proces can be done at 120^0 C (Lieberman, 1989). Rudi Mantik Farmakope Indonesian Advicer said, infusion can be sterilized with different kind of sterilization method but must be fulfilled of requirement of Sterility Assurance Level. (SAL) (Tempo Interaktif, 2007).

Sterilization Bioburden Method need tigh monitoring and controlling envourement for any microorganism at production area before sterilization process, and achieve sterility level requirement of SAL 10^{-6} (S. Lukas, 2006).). SAL is a number for determining of possibility any living mycroorganism in one unit after product has been sterilized (Halls, 1994). Study of D value must be done for determining of total and heat resistency microorganism in product. Base on it, the research of effectivity test of sterilization of Bioburden with L-Arginin infus as a amino acid model has been carried out

MATERIAL AND METHOD

MATERIAL

Alkohol 70% (Brataco®), water for injection pyrogen free (IPHA Pharma®), , fenol, L-Arginin (Sigma®), Natrii Metabisulfit (Merck®), NaCl (Merck®), indicator pH universal (Merck®), LAL reagent water (Cape code®), Pyrotell LAL Test (Single Test Vial) (Cape Code®), Pyrosol Reconstitution Buffer (Cape Code®), Spiritus (Brataco®), SGM *Spore Strip* and endotoksin controlle standard