

Approved Deviation of D Value and that of Population by ISO is Scientifically Correct?

Hideharu Shintani*

Faculty of Science and Engineering, Chuo University, Tokyo, Japan

Decimal reduction value (D value) is approved in ISO (International Organization for Standardization) standards of 11138-1 (Sterilization of health care products-Biological indicators, Part 1: General requirement), 11138-2 (Part 2: Biological indicators for ethylene oxide sterilization processes) and 11138-3 (Part 3: Biological indicators for moist heat sterilization processes) are 2.5-3.5 min for ethylene oxide sterilization and 1.5-2.5 min for moist heat sterilization. In addition, recovered population should be -50 to +300% of the labeled value (ISO 11138-1,2,3).

Now as I reported [1-5] if you handled healthy microorganisms, a significant deviation of population will not occur. However, D value and population are addressed for sterilized, injured and survived microorganisms, so they are significantly differ from healthy microorganisms [2,3]. For example, as pointed out in citation 5, Ca deleted from the culture medium, injured microorganisms cannot grow and when added Ca to the culture medium injured microorganisms can grow again. In citations 2 and 3, we add several components to grow the sterilized and injured microorganisms and found out some components are effective to grow [2,3]. The sterilization procedures utilized were γ -ray, β -ray, ethylene oxide gas, dry heat, moist heat exposures. From these, we confirmed not define D value and population deviation, but amount of essential components to recover injured and damaged microorganisms in the culture medium. I stress the importance to settle the concentration of culture medium constituents. The above described essential components are glucose, amino acids mixtures, alanine, Ca, Mg and so on [2,3,5,6]. In addition, it is important to decrease deviation of population. In healthy microorganisms, population deviation was not significant, but when handling injured and damaged microorganisms by sterilization, deviation of essential components was significantly

differ [2,3,5,6] and by adding amino acids mixtures, alanine, Ca, Mg and so on to the culture medium [2,3,5,6], deviation of population number can become constant with relatively higher population. From the culture medium Ca removed by EDTA, healthy microorganisms can survival without Ca, but injured and damaged microorganisms cannot grow [5], so constituents of culture medium components has an essential key role, therefore ISO documents define not only D value and population deviation, but also the constituent of culture medium for damaged and injured microorganisms. The importance of defining constituents of culture medium components has never discussed so far, which is scientifically faults. In that sense, I am now submitting How to recover of damaged microorganisms by supplying several sorts of nutrients to OMICS J on this matter [6].

References

1. Shintani H, Akers JE (2000) On the cause of performance variation of biological indicator used for sterility assurance, *PDA J Pharm Sci Technol* 54: 332-342.
2. Shintani H (2014) Important points to attain reproducible sterility assurance, *Biochem Physiol* 3: 135.
3. Shintani H (2013) Importance considering increased recovery of injured microorganisms to attain reproducible sterilization validation, *Pharmaceut Anal Acta* 4: 210.
4. Shintani H, Akers JE (1999) On the cause of performance variation of culture medium. *PDA J Pharm Sci Technol* 54: 6-12.
5. Sasaki K, Shintani H, Itoh J, Kamogawa T, Kajihara Y (2000) Effect of calcium in assay medium on D value of *Bacillus stearothermophilus* ATCC 7953 spores. *Appl Environ Microbiol* 66: 5509-5513.
6. Shintani H (in submission, 2014) How to recover of damaged microorganisms by supplying several sorts of nutrients, OMICS J.

*Corresponding author: Hideharu Shintani, Faculty of Science and Engineering, Chuo University, 1-13-27, Kasuga, Bunkyo, 112-8551, Tokyo, Japan, Tel: +81425922336, Fax: +81425922336; E-mail: shintani@mail.hinocatu.ne.jp

Received August 14, 2014; Accepted August 15, 2014; Published August 28, 2014

Citation: Shintani H (2014) Approved Deviation of D Value and that of Population by ISO is Scientifically Correct? *Pharmaceut Reg Affairs* 3: e137. doi:[10.4172/2167-7689.1000e137](https://doi.org/10.4172/2167-7689.1000e137)

Copyright: © 2014 Shintani H. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.