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Glass particles contamination in single dose ampoules: Patient safety concern

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Background: Glass particle fragmentation and ampoule contamination upon opening have been previously reported for more than 5 decades.

Aim: This study aimed to determine whether there were still glass particles contaminated in single dose glass ampoules.

Methods: Eight hundred (800) 10 ml sterile water for injection ampoules were inspected for glass particle contamination upon opening. Ampoules were opened by 400 nursing personnel of 3 tertiary care hospitals using their normal practices (2 ampoules per 1 nurse). Glass particle contamination was inspected by stereomicroscope and size and number of particles was inspected by Scanning Electron Microscope (SEM). Data were analyzed using descriptive statistics.

Results: 798 ampoules were inspected. Glass particles were detected in 65% of ampoules (95% CI: 61.6-68.3). Size of particles, detected from 20 positive samples from stereomicroscope inspection, ranged from 8-172 micron. The mean numbers of glass particles detected were: 47.8 ± 20.4 for particle size <50 micron, 3.7 ± 3.2 for size 51-100 micron and 0.6 ± 1.07 for size 101-200 micron. Among 20 negative samples from stereomicroscope inspection (no glass particle detected), SEM could detect glass particles with sizes ranged from 8 to 54 microns. The mean numbers of glass particles detected were: 27.8 ± 21.8 for particle size <50 micron, 0.75 ± 1.2 for size 51-100 micron and 0.5 ± 0.2 for size 101-200 micron.

Conclusion: Glass particle contamination occurs on opening single dose glass ampoules. Hospital personnel should be aware and carefully draw the content in the ampoule.

Biography

Akeau Unahalekhaka is a Professor at Faculty of Nursing, Chiang Mai University, Thailand. She has graduated with Bachelor of Science in Nursing, Master of Science and PhD in Epidemiology. She has also received certificate in Surveillance and Applied Epidemiology for HIV and AIDS from CDC, USA and certificate in Statistical, Epidemiological and Operational Methods Applied in Medicine and Public Health from University of Brussels, Belgium. She is the President of Nursing Association for Prevention and Control of Infections (NAPCI) Thailand, Consultant of Central Sterilization Service Association of Thailand and many hospitals in Infection Prevention and Control (IPC). She is currently an Editorial Council Member of *The International Journal of Infection Control* (IJIC) of the International Federation of Infection Control (IFIC). She has written many books on IPC and disinfection and sterilization. Her research interest includes infection, prevention and control; disinfection and sterilization and epidemiology.

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