CHAPTER VI

CONCLUSION

The purpose of the present study was to determine a proper environment to yield a good PN quality and compared PN preparation cost form 2 different environments, a traditional separated room and a cleanroom. Settling plate method was used to validate the preparation area. The results revealed the significant differences in most position in LAFH. The most organisms found in the separated room were *Micrococcus spp*, a skin contaminant. When the sterility test was performed, there was 0.94% found bacterial contamination. Types of microorganism found were similar to those found in the environment in that period, while no microorganism was found in PN prepared from the cleanroom. The results showed a direct relationship between air cleanliness and microbiological quality of finished product. According to cost analysis, total direct cost was taken into accounted. The total cost of PN prepared of 3 PN formulas prepared in the cleanroom was 5.88-22.50% higher than ones from the separated room, principally from area construction cost.

In conclusion, the study indicated that the cleanroom could provide a cleaner environment, supporting a good quality of PN preparation. Although the PN preparation cost was higher, the patient safety must be firstly considered. Therefore, it will be fruitful if cleanroom can expand to support other sterile pharmaceutical products.

Recommendation for further studies

1. More than 1 nutrient media should be support the microorganism growth for wider range of microorganism which could occurred in the validation of sterile area and sterility test.
2. Settling plate method can be used for in process validation by placing in LAFH from the beginning to the end of preparation process.
3. Media fill simulation method could be replaced sterility test in order to validate the aseptic process.
4. Cost analysis should be thoroughly calculated by total direct cost and indirect cost.
5. Cost effectiveness should be studied.