CHAPTER V

CONCLUSIONS

1. The cold kit for preparation of Technetium Tc99m Succimer Injection can be formulated successfully. The kits meet the USP standard requirement in both chemical and biological aspects. The techniques used in the formulation procedures are not complicate. However, some critical steps that can be affected by leakage of air into the formulation such as lyophilization depends on the capability of the instrument. Selection of proper instrument leads to the production of good quality products. From the 3 month stability study there is a tendency that protection of the leakage of the air into the formulation can prolong the stability of the formulation.

2. From the study the formulation suitable for use as a cold kit for preparation of Technetium Tc99m Succimer Injection is formulation 3. This formulation has satisfactory stability during 3 month storage and can yield the good labeled product. From the in vivo studies the characteristics of organ distributions in rats obtained from the study of decomposed succimer cold kits (the three months old formulation 1 without stabilizer) are the higher radioactivity distributions mainly in urinary bladders and the remaining carcasses.. These effects are possibly occurred in patients resulting in obtaining the high-background images.

No significant change was observed in liver and spleen. Forthermore, it can be notified that the formulations that can yield equivalent radiochemical purity (by means of labeled to free ^{99m}Tc as in USP method) do not always give bioequivalent results in in vitro studies. The biodistribution test is very important to assure the quality and specificity of the formulations especially for the commercial production. Every production batch must be certified with the satisfactory biodistribution data.

3. The ^{99m}Tc Succimer Injection is stable during 3 hours after labeling but there is some change occurred during 3 to 24 hour's period. Thus, this formulation can be used as multidose formulation within 3 hours after labeling. This duration is long enough for one day use because the gamma scintigraphy must be operated at 1 to 3 hours after injection and the operation time required is not less than 30 minutes. The in house quality control must be preliminary tested by using the proper paper chromatography, such as the method purposed by Zimmer and Pavel (1977), to ensure the proper labeling. However, it is not nescessary to be repeated every time before the next use.