

VI. SUMMARY

In preparations of two level lyophilized bovine control sera, 8.5% saccharose was chosen to use as protein and lipoprotein stabilizer. Saccharose prevented protein and lipoprotein from denaturation during lyophilization process and clarified the reconstituted quality control bovine serum matrix. In addition, this disaccharide played a role in maintaining the storage shelf life of the control serum products kept in the dried solid form. Two level lyophilized bovine control sera adding 8.5% saccharose as stabilizer were evaluated for use as a control material in monitoring precision of protein and lipid components analyzed in clinical chemistry laboratories. The assignment values (acceptable ranges of analyses) for each constituent on different levels were established. Shelf life of the control products containing 8.5% saccharose determined by accelerated temperature test were 1.5 years. The average cost of preparations in a vial was 71 baht, for both levels. The lyophilized bovine matrix control products were evaluated by three different external clinical chemistry laboratories using the methods based on manual, Autoanalyzer using reagent and dry chemistry which favorably used in clinical chemistry laboratories.