

## Chapter V

### CONCLUSIONS

The results of this study can be concluded as follows:

1. To develop the qualitative model for optimal solid ratio between Eudragit<sup>®</sup> E PO and AZD, mixing time and to develop quantitative model on homogeneity state by chemometric.

Principal component analysis (PCA) is a reduction method for variation in spectral detection, which shows the fundamental for multivariate analysis. The loadings identified the key-wavelengths, the score plot confirmed statistical differences between the solid ratio of Eudragit<sup>®</sup> E PO and AZD, and blending time in taste masking process. The optimal solid Eudragit<sup>®</sup> E PO to azithromycin and blending time by using Erweka<sup>®</sup> AR400 Universal Lab mixer were 0.4:1 and 20-30 minutes respectively.

PLS model exhibits a good predictive correlation between calibration and validation data set from taste masking process by PMS<sup>®</sup> MG15T high speed mixer in total number of 20 cycles. The a taste-masked AZD blending process monitoring was successfully applied by PLS model. This quantitative model was described by RMSEC, RMSEP and r values.

2. To apply Process Analytical Technology (PAT) using NIR spectroscopy for process monitoring of masking azithromycin powder unpleasant taste, in order to evaluate the homogeneity end-point of the final product.

The homogeneity end-point of taste masking process determination shows



the results of PCA and PLS models for supporting this application. NIR spectroscopy is a non-destructive tool. The at-line mode of monitoring the homogeneity of mixture in taste masking process was proved by using NIR spectroscopy. The quality of taste masking process was improved and verified by multivariate analysis that have increase the reliability, the critical sampling methods, and suitable process software. PAT using NIR spectroscopy provides a way to quantify the variation of process analysis in at-line mode from secondary method by statistical values of linear regression related to the primary method in off-line mode by %RSD of drug amount in final mixture. In addition to the distance values from discriminant analysis were confirmed to apply with sampling evaluation in Erweka<sup>®</sup> AR400 Universal Lab mixer and PMS<sup>®</sup> MG15T high speed mixer.

