ABSTRACT OF THE THESIS ENTITLED

COMPARISON AND IMPROVEMENT OF MICROBIOLOGICAL ASSAY TECHNIQUES USED IN THE QUALITY CONTROL OF ERYTHROMYCIN STEARATE

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At present State Pharmaceutical Manufacturing Corporation (SPMC) produces Erythromycin Stearate 250mg tablets. They claim the BP (British Pharmacopoeia) label for the product. Therefore they need to follow all the quality control procedures as per BP. But they failed to carry out the potency test for the BP product to get the required precision and accuracy.

They followed the USP (United State Pharmacopoeia) potency test for the erythromycin stearate 250mg tablets in the quality control procedures while all other criteria controlled by the BP procedures. Due to this a problem has been arisen by the National Drug Quality Control Authority laboratory (NDQAL) for the label claim BP. Because they are following the USP test for the potency assay for a BP product.

Then they need to improve the potency test, which is a microbiological assay technique to get the required precision as per BP.

Therefore this project aims to improve the techniques used in the microbiological assay of erythromycin stearate and the comparison of the two assay techniques as per BP and as per USP. In addition to that the assessment of the quality of the raw materials and assessment of the other materials other than the active ingredient (exipients) for the interference to the biological activity of the active ingredient.

The assay techniques are based on the agar diffusion technique for both pharmacopoeia called cylinder plate assay. The difference between the two assays are,

This thesis contains following studies.

1. Assay of large number of erythromycin stearate tablets and raw materials as per BP method.
2. Assay of large number of erythromycin stearate tablets and raw materials as per USP method
3. Study and improvement of assay parameters such as agar concentration, population density of inoculum, and improvement of assay techniques.
4. Preparation of standard curve using standard material and generate a direct graphical method for potency calculation
5. Introduction of pure culture technique and stock maintenance and purification and identification of the bacterial strains used in the assay techniques.
6. Comparison of results of the BP and USP assays.
7. Comparison of the potencies of the tablets at two processing stages (before coating & after coating)
8. Analysis & comparison of few market samples with SPMC product.

After starting this study 71% of the results of the assay complied BP (25 samples out of 35 samples were BP complied), where before the study it was only 32% successful (8 samples out of 27 samples were BP complied). Reproducibility of the results also achieved by repeated assays. By comparison BP and USP assays a positive correlation was gained. Market samples analyzed were of good quality as per BP criteria in most of the times. It was found no biological activity is reduced before coating and after coating of the erythromycin tablets