



Proficiency Testing as a Tool to Assess the Performance of Visual TLC Quantitation Estimates

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Thin-layer chromatography (TLC) has been used as a separation tool for an array of analytical applications. For example, TLC visual detection test procedures to assess pharmaceutical product quality has been included in a convenient kit concept developed by the German Pharma Health Fund (GPHF) called the Minilab.[®] The Tanzania Food and Drugs Authority (TFDA) has established a drug product screening program using the Minilab[®] testing technology. All of the inspectors who participate in this testing program are pharmaceutical technicians or pharmacists who have had prior laboratory training in volumetric procedures. Prior to performing the screening procedures, the inspectors completed a one-week training program. After the training, each of the inspectors was sent with a Minilab[®] to perform the product screening tests at various locations in the country.

As a part of the TFDA Quality Assurance (QA) program, a proficiency test procedure was established to provide assurance that the Minilab[®] screening tests were being competently performed. The results of the first proficiency test indicated that although all of the inspectors could differentiate between zero content—which corresponds to no drug or the wrong drug present—and 100%—indicating the drug is present approximately in the right amount—they had difficulty discerning subpotent level. In only 4 of 28 instances did the inspectors correctly identify the subpotent samples; the incorrect assessments all indicated that the sample contained 100%. To reinforce the training on discerning these differences, a performance qualification test set was developed to improve their ability to discern the differences. Following the inspectors' successful performance of the qualification exercise, a second proficiency test was initiated and a marked improvement was achieved in that 8 of 32 subpotent samples were incorrectly identified. Eight incorrect assessments were made by two individuals who also had incorrectly identified all their subpotent samples. It is important to include proficiency testing in the Minilab[®] implementation plan to provide an added measure of confidence in these screening tests and to identify additional training needs or other interventions to assure quality performance. The performance qualification intervention along with the follow-up proficiency test results will be presented.