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Lifetime Assessment for Test Strips of POCT Device through Accelerated Degradation Test

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Abstract : In general, single parameter, i.e. temperature, as an accelerating parameter is used to assess the accelerated stability of Point-of-Care Testing (POCT) diagnostic devices. However, humidity also plays an important role in deteriorating the strip performance since major components of test strips are proteins such as enzymes. 4 different Temp./Humi. Conditions were used to assess the lifetime of strips. Degradation of test strips were studied through the accelerated stability test and the lifetime was assessed using commercial POCT products. The life distribution of strips, which were obtained by monitoring the failure time of test strip under each stress condition, revealed that the weibull distribution was the most proper distribution describing the life distribution of strips used in the present study. Equal shape parameters were calculated to be 0.9395 and 0.9132 for low and high concentrations, respectively. The lifetime prediction was made by adopting Peck Eq. Model for Stress-Life relationship, and the B10 life was calculated to be 70.09 and 46.65 hrs for low and high concentrations, respectively.

Keywords : accelerated degradation, diagnostic device, lifetime assessment, POCT
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