Abstract

Levothyroxine sodium tablets dissolution test

Levothyroxine sodium is the sodium salt of the levo-isomer of thyroxine (T4), an active physiological compound used in the thyroid gland. It has a narrow therapeutic index such that doses which are merely 20–25% outside of the therapeutic window can place patients at the risk of severe adverse effects. Regarding its chemical stability, levothyroxine sodium is sensitive to light, temperature, moisture, pH and oxidation. A proper analytical method is vey important to assess the safety and effectiveness of levothyroxine sodium commercial tablets. The compendial dissolution tests were ran with and without the protection from light for the marketed 0.1 mg levothyroxine sodium tablets. A simple, sensitive UPLC method was developed and validated to analyze the dissolution samples. The validation characteristics of the UPLC method included accuracy, precision, linearity, stability and filter binding. The standard curve was found to have a linear relationship ($r^2 > 0.99$) over the analytical range of 0.05–0.25 μg/mL. Data from dissolution studies with and without light exposure were compared to investigate possible occurrence of photodegradation during the 45 min dissolution run and the potential influence of degradation on the *in vitro* drug release performance. With the protection from light, the untreated dissolution profile was demonstrating the release mechanisms and kinetics of levothyroxine sodium tablets under compendial conditions. A potential degradation curve was deconvoluted from the dissolution profile ran without protection from light, the mechanism and kinetics of degradation during the compendial dissolution studies were elucidated. Approximately average 15% difference in percentage release was founded from 6 lots data (2 runs/lot) because of the degradation of standard during the preparation. Stirring 2 hours at 150 rpm after the Q time, almost 20% degradation was founded. Further studies are needed to test the more details regarding all the factors of degradation.

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