

スピロノラクトン錠の溶出試験に用いるポリソルベート80の品質に関する研究*2

川口 正美*1, #, 土井 崇広*1, 東 雄貴*1, 田中 未紗*1, 田上 貴臣*1

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Study on the Quality of Polysorbate 80 Used for Dissolution Test of Spironolactone Tablets *2

Masami KAWAGUCHI *1, #, Takahiro DOI *1, Yuki AZUMA *1, Misa TANAKA *1
and Takaomi TAGAMI *1

Summary

Dissolution tests of spironolactone tablets were conducted by UV-visible spectrophotometry using six different polysorbate 80 (PS80) reagents purchased, which were conformed to the specification of The Japanese Pharmacopoeia. Four of six PS80 were used in the dissolution media, spironolactone could not be measured due to interference by high absorbance around 230 nm, which is derived from the used PS80 reagents.

On the other hand, the HPLC method was able to measure spironolactone in the PS80 solution used for dissolution medium without any particular interference.

Analysis of these PS80 samples by LC-PDA and LC-QTOFMS revealed that there were differences in chromatographic patterns between products, which showed high absorbance around UV 230 nm or not.

In addition, ¹H-NMR measurements demonstrated some characteristic signals in the product with high absorbance around UV230 nm.

To use PS80 a test solution for dissolution test employing UV-visible spectrophotometry as the measurement method, it was necessary to confirm PS80 have no interference at the measurement wavelength. In case any interference are observed, it may be preferable to perform dissolution tests using HPLC as the detection method.

Key words

Polysorbate 80, Spironolactone tablet, Dissolution test, UV spectrum, LC-PDA, LC-QTOFMS, ¹H-NMR