ABSTRACT

HPLC method for determination of lamotrigine and related substances in tablets

Rigorous thesis

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The method for determination of purity and stability of lamotrigine was optimized. Lamotrigine was exposed to such conditions to reach its degradation into degradation products which are also possible impurities of lamotrigine. Several chromatography columns were tested and the composition of mobile phase was optimized. Chromatography column Waters Spherisorb 5 µm Phenyl, 4,6 x 250mm was chosen and mobile phase containing acetonitril : phosphate buffer (1,4 g K_2HPO_4 /l) 35:65, final pH of the mobile phase was adjusted to 6.0 by orthophosphoric acid. Flow rate was 1 ml/min, injected volume 20 µl, column temperature 25ºC and UV detection at 309 nm. Linearity of this method was tested under these conditions. This method was worked up to enable its using in determination of content of lamotrigine and related substances in tablets containing lamotrigine. Validation parameters of this method were tested.