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Simultaneous Determination Of Amlodipine Besylate And Valsartan In Tablets By HPLC

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Amlodipine (as besylate salt) is a long-acting calcium channel blocker used as an anti-hypertensive and in the treatment of angina [1,2]. Valsartan, an angiotensin II receptor antagonist, works by blocking angiotensin hormone thereby relaxing blood vessels, causing them to widen which lowers blood pressure and improves blood flow [2,3]. It was noted that the combination of an angiotensin receptor blocker and a calcium channel blocker provides an effective option for patients with hypertension [4]. In the literature, there is not any method reported for the simultaneous HPLC determination of amlodipine besylate and valsartan in tablets. Thus, the aim of this study was to develop an HPLC method for simultaneous determination of these compounds. A C_{18} column (Waters Spherisorp ODS 2, 10 µm, 200 x 4.6 mm) was used for the separation and quantification. The mobile phase consisted of phosphate buffer (pH 3.6 , 0.01 M) : acetonitrile : methanol (46:44:10 v/v/v). The injection volume was 20 µL and the ultraviolet detector was set at 240 nm. Under these conditions, valsartan and amlodipine besylate were eluted at 3.4 min and 7.1 min, respectively. Run time was thus kept shorter than 9 min. The optimized HPLC method was validated according to the ICH definition [5] and found that the limits of detection (LOD) were 0.05 µg mL^{-1} and 0.2 µg mL^{-1} and the limits of quantitation (LOQ) were 0.20 µg mL^{-1} and 0.30 µg mL^{-1} for valsartan and amlodipine besylate respectively. Our findings indicate that, the developed HPLC method was precise, accurate, specific and sensitive for the simultaneous determination of these compounds. The uniformity of dosage units was investigated according to USP 29 Pharmacopoeia [6] and it was concluded that this method could be used for the quality control tests of valsartan and amlodipine besylate containing tablets.

References

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