A 1New and Simple HPLC Method for Determination of Etamsylate in Human P2lasma and its Application to Pharmacokinetic Study in healthy adult male Volunteers

Sa lly A. Helmy1 and Heba M. El Bedaiwy2

1D epartment of Pharmaceutics, Faculty of Pharmacy, Damanhour University, Damanhour, 31527,
Eg ypt.
2D epartment of Industrial Pharmacy, Faculty of Pharmacy, Damanhour University, Damanhour,
31 527, Egypt.

Corresponding author: Sally Aly Helmy, Ph.D., CPHQ
e-mail: Sallyhelmy@yahoo.com

Abstract

A new and simple HPLC assay method was developed and validated for the determination of eta msylate in human plasma. After protein precipitation with 6% perchloric acid, satisfactory se paration was achieved on a HyPURITY C18 column (250 mm X 4.6 mm, 5µm) using a mobile phase co mprised 20 mM sodium dihydrogen phosphate-2 hydrate (pH was adjusted to 3.5 by phosphoric ac id) and acetonitrile at a ratio of 95:5 v/v. The elution was isocratic at ambient temperature with a flow rate of 0.75 ml/min. Allopurinol was used as internal standard. The calibration curve was linear over the range from 0.25 to 20 µg/ml (r 2= 0.999). The limit of quantification for etamsylate in plasma was 0. 25 µg/ml. The day-to-day coefficient of variance (%CV) ranged from 3.9% to 10.2 %, whereas

th e between-days %CV ranged from 3.1% to 8.7%. The assay method has been successfully used to estimate the pharmacokinetics of etamsylate after oral administration of a 500 mg tablet under fasting co nditions to 24 healthy Egyptian human male volunteers. Various pharmacokinetic parameters including AUC0–t, AUC0–∞, Cmax, Tmax, t1/2, MRT, Cl/F, and Vd/F were determined from plasma co ncentration-time profile of etamsylate.

K eywords:
Etamsylate; HPLC; validation; plasma; pharmacokinetics

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