METHOD DEVELOPMENT AND VALIDATION FOR DRUG ANALYSIS BY HPLC AND GC –MS

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ABSTRACT

Enalapril and its metabolite Enalaprilat were determined by gas chromatography – mass spectrometry (GC – MS) and high – performance liquid chromatography (HPLC). For HPLC, the detection limit of enalapril and enalaprilat was 10ng/ml in methanol, whereas for the GC – MS, the detection limit was 6.25ng/ml in plasma. These methods were compared and GC – MS was selected for routine analysis.

Enalapril and Enalaprilat in plasma were extracted and cleaned up by using Sep – Pak C18. Enalapril and Enalaprilat were detected after reaction with diazomethane and were identified by gas chromatography – mass spectrometry as methyl ester. Detection by selected ion monitoring (SIM) was selected to m/z 220 (enalaprilat) and m/z 234 (enalapril). Diazepam was used as an internal standard. This method is applied to the pharmacokinetic analysis of enalapril and enalaprilat in body fluids.

Content

List of Abbreviation

Abbreviation	Name
ACE	Angiotensin – converting enzyme
CI	chemical ionization
DB-1	Methylsilicone phase column
DB-5	5% phenyl, methylpolysiloxane phase column
DIAC	Enalaprilat
DKP	Diketopiperazine
e.g.	Example
EI	electron impact
EN	Enalapril
ENM	Enalapril Maleate
Fig.	Figure
FID	flame ionization detector
GC	gas chromatography
GC-MS	gas chromatography-Mass spectrometry
HPLC	high performance liquid chromatography
I.D.	internal diameter
LC	liquid chromatography
MA	Maleic acid
min.	Minute
MS	mass spectrometry
p.	page
PDA	photodiode array detector
ppb	part per billion
ppm	part per million
SIM	selected ion monitoring
SPE	solid phase extraction
TLC	thin layer chromatography
tr	retention time
UV	ultra violet

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