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High performance liquid chromatographic method for determination of clarithromycin in lyophilized form

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Clarithromycin (3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*S*,12*R*,13*S*,14*S*)-6-{[(2*S*,3*R*,4*S*,6*R*) -4-(dimethylamino)-3-hydroxy-6-methyloxan-2-yl]oxy} -14-ethyl-12,13-dihydroxy-4-{[(2*R*,4*S*,5*S*,6*S*)-5-hydroxy -4-methoxy-4,6-dimethyloxan-2-yl]oxy}-7 -methoxy-3,5,7,9,11,13-hexamethyl -1-oxacyclotetradecane-2,10-dione). Clarithromycin is a macrolide antibiotic used to treat pharyngitis, tonsillitis, acute maxillary sinusitis, acute bacterial exacerbation of chronic bronchitis, pneumonia (especially atypical pneumonias associated with Chlamydophila pneumoniae), skin and skin structure infections.[1]

Clarithromycin prevents bacteria from growing by interfering with their protein synthesis. It binds to the subunit 50S of the bacterial ribosome and thus inhibits the translation of peptides. Clarithromycin has similar antimicrobial spectrum as erythromycin, but is more effective against certain Gram-negative bacteria, particularly Legionella pneumophila.[2] For this reason the quality control and routine analysis is very important analytical task for the research study and pharmaceutical industry. In this context, we developed a new, rapid, accurate, precision and validated HPLC method for the analysis of azitromisin in pharmaceutical sample.

A new HPLC method was developed for the quantitative analysis of Clarithromycin in intravascular samples. Chromatographic separation was performed on the reverse phase column Kromasil C18 15x4 6 mm 5µ by using a mobile phase system consisting of acetonitrile and 0.476 % KH2PO4 solution (pH 4.4). Gradient elution was used with the flow rate of 1.3 mL/min . The recorded chromatograms were performed at the UV detection at 205 nm. Calibration graph of the related drug in the concentration range of 120 and 1200µg/mL was obtained by using the relationship between concentration and chromatographic area. The validity of the developed HPLC method was carried out by analyzing independent artificial samples of clarithromycin and by using related ICH regulation. The proposed HPLC approach was successfully applied to the quality control and quantitative estimation of Clarithromycin in the developed intravascular formulation. A good agreement for the determination of the related drug was reported.

Biography

Sanaz Ataei has completed her license at the age of 24 years from Tabriz University Chemistry department and completed master studies at the age of 29 from Ankara University, Institute of Biotechnology, Pharmaceutical Chemistry and currently continues her PhD at Ankara University, Institute of Biotechnology, Pharmaceutical Chemistry on molecular modeling and drug discovery.

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