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Review Article

Analytical Techniques for the Assay of Afatinib: A Review

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Abstract

Afatinib is an antineoplastic agent used for the treatment of lung cancer. In the present study the authors have summarised the analytical methods so far published for the estimation of Afatinib in the literature.

Keywords: Afatinib; Lung Cancer

Introduction

Afatinib (Figure 1) is a 4-anilinoquinazoline derivative acts by inhibiting the tyrosine kinase enzyme. Afatinib is an initial treatment for patients with metastatic lung cancer [1,2] with common epidermal growth factor receptor mutations as detected by an FDA-approved test [3]. Chemically, it is 2E)-N-{4-[(3-Chloro-4-fluoro phenyl) amino]-7-[(3S)-tetra hydro-3-furanyloxy]-6-quinazolinyl}-4-(dimethylamino)-2-butenamide. with molecular formula $C_{23}H_{27}FN_4O_2$ and molecular weight 485.937 grams/mole. Afatinib (CAS no. 850140-72-6) is a potent and selective, irreversible ErbB family blocker and covalently binds to and irreversibly blocks signalling from all homo and heterodimers formed by the ErbB family members EGFR (ErbB1), HER2 (ErbB2), ErbB3 and ErbB4.

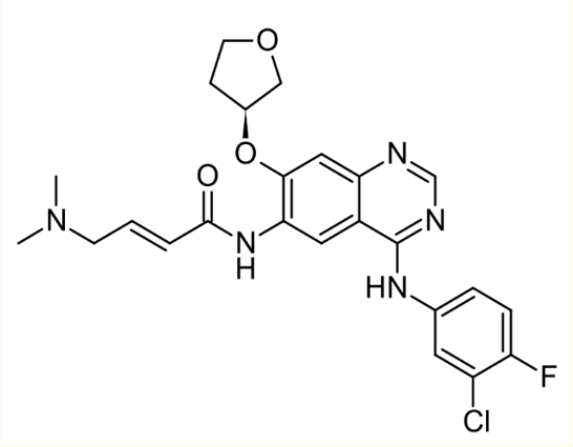

Figure 1: Structure of Afatinib ($C_{24}H_{25}ClFN_5O_3$).

Literature survey reveals that various analytical methods such as spectrophotometry [4], RP-HPLC [5-7] and LC-ESI-MS/MS [8,9] in human plasma were developed for the estimation of Afatinib and were summarized in Table 1.

Table 1: Review of analytical methods.

Reagent/Mobile phase (v/v)	Linearity (µg/ml)	Wavelength (nm)	Method	References
Aq. Sodium citrate	5-25	246	UV Spectroscopy	[4]
Methanol: 0.1% Triethylamine (pH 3.3) (65:35)	10-50	256	RP-HPLC	[5]
Methanol: Methyl tertiary butyl ether: Diethyl amine (80:20:0.1)	0.15-22.5	254	RP-HPLC (R-isomer)	[6]
Mobile phase A: Potassium dihydrogen ortho phosphate buffer adjusted pH at 3.0 with ortho phosphoric acid: Mobile phase B: Acetonitrile: Methanol (70: 30) (Gradient mode)	120-360	258	RP-HPLC	[7]
Acetonitrile: 10 mm Aq. Ammonium formate buffer (pH 4.5) adjusted with formic acid (40:60)	0.0005-5.0	-	LC-ESI-MS/MS (Human plasma)	[8]
Acetonitrile: 0.2% Aq. Ammonia (70:30) Cabozantinib (Internal standard)	0.002-1.0	-	LC-ESI-MS/MS (Human plasma)	[9]

Conclusion

This review article explains different analytical methods developed for the estimation of Afatinib in pharmaceutical dosage forms as well as biological fluids.

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