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Mini Review

Analytical Methods for the Assay of Tucatinib – A Review

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Abstract

Tucatinib is anti-cancer agent. Tucatinib acts by binding to the human epidermal growth factor receptor 2 (HER2) protein and thereby preventing it from sending the signals that promote the cell growth. It is a tyrosine kinase inhibitor. In the present study the authors have reviewed and summarised the analytical methods so far developed for the estimation of Tucatinib in pharmaceutical formulations as well as biological fluids.

Keywords: Tucatinib; RP-HPLC

Introduction

Tucatinib (CAS: 937263-43-9) (Mol wt: 480.5g/mol) is a tyrosine kinase inhibitor showing anti-tumour activity. It is soluble in organic solvents such as DMSO and dimethyl formamide and sparingly soluble in aqueous buffers. Tucatinib is used in combination [1-3] to treat breast cancer, unresectable breast cancer, wild type Ras metastatic colorectal cancer, unresectable Ras wild type colorectal cancer.

Tucatinib is available as tablets with brand names Tucaxen 150 (Everest) Tukysa (Seetle Genetics), TukadxTM (Bigbear Pharmaceutical Laos) etc and label claim 150 mg. The analytical methods such as LC-MS/MS [4], UPLC-MS/MS [5], RP-HPLC [6,7] methods so far developed for the estimation of Tucatinib were given in Table 1.

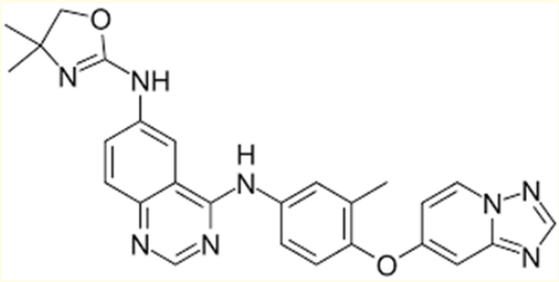

Figure 1: Chemical structure of Tucatinib (($C_{26}H_{24}N_8O_2$).

Table 1: Review of Analytical methods.

Method	Mobile Phase (v/v0	Linearity (µg/ml)	Column	Rt (min)	Reference
LC-MS/MS	Acetonitrile: 0.1% Formic acid (70:30)	5-100	Inertsil ODS C_{18}	3.734	[4]
UPLC-MS/MS (Internal standard: Talazoparib)	Acetonitrile: 0.1% Formic acid (Gradient mode)(Rat plasma)	0.5-400 x 10^{-3}	Acquity UPLC BEH C_{18}	0.74	[5]
RP-HPLC(Internal standard: Cisplatin)	Acetonitrile: 0.1% Formic acid (40:60)	50 x 10^{-3}	Symmetry C_{18}	4.204	[6]
RP-HPLC(Internal standard: Cisplatin)	0.1% Formic acid: Acetonitrile (40:60)	50 x 10^{-3}	Symmetry C_{18}	4.204	[7]

Conclusion

The authors have reviewed the analytical methods for the estimation of Tucatinib in pharmaceutical dosage forms as well as biological fluids.

Bibliography

1. Kulukian A., *et al*. "Preclinical Activity of HER2-selective tyrosine kinase inhibitor Tucatinib as a single agent or in combination with Trastuzumab or Docetaxel in solid tumor models". *Molecular Cancer Therapy* 19.4 (2020): 976-987.

2. Borges VF*., et al.* "Tucatinib combined with ado-Trastuzumab emtansine in advanced erbb2/her2-positive metastatic breast cancer: A phase 1b clinical trial". *JAMA Oncology* 4.9 (2018): 1214-1220.

3. Murthy R*., et al.* "Tucatinib with Capecitabine and Trastuzumab in advanced HER2-positive metastatic breast cancer with and without brain metastases: A non-randomised, open-label, phase 1b study". *Lancet Oncology* 19.7 (2018): 880-888.

4. Reehana SK and Sujana K. "LC-MS/MS characterization of forced degradation products of tucatinib, a novel tyrosine kinase inhibitor: Development and validation of RP-HPLC method". *International Journal Applied Pharmaceutics* 14.1 (2022): 58-66.

5. Zhang Y*., et al.* "Evaluation of the inhibitory effect of quercetin on the pharmacokinetics of tucatinib in rats by a novel UPLC-MS/MS assay". *Pharmaceutical Biology* 60.1 (2022): 621-626.

6. Usharani M., *et al*. "Bio analytic and analytic method quantitative to Tucatinib estimation in pure and pharmaceutical dosage form". *YMER* 21.8 (2022): 782-792.

7. Neeharika Tirumalasetty and Ramachandran Dittakavi. "Bio analytic and analytic method quantitative to tucatinib estimation in pure and pharmaceutical dosage form". *YMER*2 21.11 (2022): 1957-1967.