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Mini Review

Analytical Techniques for the Assay of Clofarabine: A Review

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Abstract

Clofarabine is an antineoplastic drug which acts by inhibiting the DNA synthesis and ribonucleotide reductase. In the present study the authors have summarised the analytical methods so far published for the estimation of Clofarabine in the literature.

Keywords: Clofarabine; Food and Drug Administration (FDA)

Introduction

Clofarabine is an anti-cancer drug [1,2]. In 2004, the Food and Drug Administration (FDA) has approved. Chemically it is 5-(6-amino-2-chloro-purin-9-yl) -4-fluoro-2- (hydroxymethyl) oxolan-3-ol with molecular formula $C_{10}H_{11}ClFN_5O_3$ and molecular weight 303.68 grams/mole. Clofarabine (CAS no. 123318-82-1) converts in to its active triphosphate form and thereby competes with adenine triphosphate for use by DNA polymerase and finally leads to DNA damage that can trigger apoptotic pathways. Clofarabine (Figure 1) is used to treat leukemia in patients 1 to 21 years old.

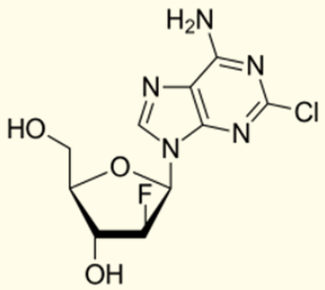

Figure 1: Structure of Clofarabine ($C_{10}H_{11}ClFN_5O_3$).

Literature survey reveals that Clofarabine was studied by different analytical methods such as LC-MS/MS [3-5] HPTLC [6], HPLC [7-11] and UPLC [12] were developed for the estimation of Clofarabine and its impurities in pharmaceutical formulations and biological fluids. The earlier reported methods were summarized in Table 1.

Method	Mobile phase (v/v)	Column	Flow rate (ml/min)	Detection wavelength (nm)	Linearity (µg/ml)	Comment	Reference
LC-MS/MS (Rabbit plasma)	Acetonitrile: Water: Formic acid (75:25:0.1)	Sunfire C18	1.0	-	0.000092-0.016937	Internal standard	[3]
LC-APCI-MS	0.1% Formic acid: Acetonitrile (Gradient mode)	Simpack C18		250	5.0-150	Rt 11.817 min	[4]
LC-MS/MS (Urine & Plasma)	Methanol: 1 mM Ammonium acetate (Gradient mode)	Aglient TC-C18	1.0	-	0.002-1.0	-	[5]
HPTLC	Toluene: Methanol (8:2)				50-1000 ng/spot	Rf = 0.34 ± 0.05	[6]
HPLC	Buffer: Acetonitrile (90:10)	Inertial C_{18}	1.0	263	5-25	Rt 3.07 min	[7]
HPLC	Phosphate buffer (pH4.0): Methanol (40:60)	Inertsil ODS3V	1.0	270	10-30	-	[8]

HPLC	Tri fluoro acetic acid buffer (pH 3.6): Methanol: Acetonitrile (70:15:15)	Develosil C18 MG-5	1.0	263	10-30	Rt 5.578 min	[9]
RP-HPLC (Process related impurities)	Phosphate buffer (pH 3.0): Acetonitrile (Gradient mode)	Inertsil ODS 3V	1.0	250	0.05-20	-	[10]
HPLC (Impurity)	Buffer: Acetonitrile (90:10)	Inertial C_{18}	1.0	263	5-25	Rt 2.07 min	[11]
UPLC (Related substances)	0.01M Ammonium formate buffer (pH 3.0): Acetonitrile (Gradient mode)	ACQUITY UPLC® CSH C18	0.28	264	0.2-1.5	-	[12]

Table 1: Review of Clofarabine.

Conclusion

This review article explains different analytical methods as well as techniques developed for the estimation of Clofarabine in pharmaceutical formulations as well as body fluids.

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