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A REVIEW ON ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF ANTICANCER DRUG BY HPLC METHOD

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ABSTRACT

Anticancer drugs are medicines, which is used in the treatment of various type of cancer. The drugs are classified according to their origin or mechanism of action. The analysis of drugs was done by various HPLC methods. This review describes published HPLC method for the development and validation of various anticancer drugs. The collective data related to analytical method development and validation such as pH, column, mobile phase and detector are reported. This review is helpful for further study for various researchers.

KEYWORDS: Anticancer drug, HPLC.

1. INTRODUCTION

Anticancer drug, are also known as antineoplastic drug. This drug is effective in the treatment of malignant and cancerous disease. In the cancer, the uncontrolled growth of cells interferes in the growth of normal cells. The cancer is cure through surgery, chemotherapy, radiation, or combination of this method. Anti-cancer drugs are targeted to control cancerous cell. The major anticancer drugs include alkylating agents, antimetabolites, natural products, and hormones.[1]

2. Classification of anticancer drugs

A. Alkylating agent – mechlorethamine HCl, Ifosfamide, Chlorambucil, Carmustine, Thiotepa, Dacarbazine, Cyclophosphamide, Melphalan, Busulfan, Lomustine, Procarbazine HCL.

B. Antimetabolites – Mercaptopurine, Thioguanine, Fluororacil, Cytarabine, Methotrexate, cladribine, Fludarabine phosphate, Foxuridine, Capecitabine, Pntostatin, Azathioprine.

C. **Antibiotics –** Dactinomycin, Doxorubicin HCl, Valrubicin, Mitomycin, streptozocin, Daunorubicin HCL, Idarubicin HCL, and Bleomycin sulfate, Plicamycin.

D. **Plant products –** Etoposide, Vinblastine sulfate, vinorelbine tartrate, Docetaxel, Teniposide, and Vincristine sulfate, Paclitaxel.

E. **Miscellaneous compound –** Cisplatin, Hydroxyurea, Pegaspargase, Mitoxantrone HCL, Arsenic trioxide, Sargramostim, porfimer sodium, carboplatin, Asparaginase, Altretamine, Gallium Nitrate, Bexarotene, Fligrastim.

F. **Hormones –** Mitotane, Testolactone, Tamoxifen citrate, Flutamide, Bicalutamide, Leuprolide acetate, Goserelin acetate, Letrozole, Dromostanolone propionate, Magestrol acetate, Toremifene citrate, Nilutamide, Estramustine phosphate, Triptoralen pamoate, Anastrozole, Exemestane.

G. **Signal transduction inhibitors –** Imatinib

H. **Immunotherapy –** Interferon Alfa -2a, Interferon Alfa- 2b, Interferon Alfa-n3, Aldesleukin, Denileukin Diftitox, Bacillus calmette-Guerin (BCG).

I. **Monoclonal antibodies –** Rituximab, Gemtuzumab ozogamicin.

J. **Radiotherapeutic agent** – Chromic phosphate P32, Sodium iodide I 131, Samarium SM 153 lexidronam, Sodium phosphate P32, Strontium 89 chloride.

K. **Cytoprotective agent –** Mensa, Dexrazoxane, Amifostine.[2]

3. High performance liquid chromatography:- High performance liquid chromatography (HPLC), is referred to as high-pressure liquid chromatography is an analytical chemistry technique. The HPLC is used to separate, identify, and quantify components from mixture. In the HPLC pressurized liquid solvent containing sample pumps through column filled with adsorbent material. HPLC are used to qualitative and quantitative analysis of unknown compound for the determining what is there, and how much. The separation is depending on physical interaction with a stationary and mobile phase. In the HPLC the standard particle size for column chromatography is 60 microns. The parts of HPLC are pump, an injector, the column, and detector or recorder. These parts are connected in series.[3,4]

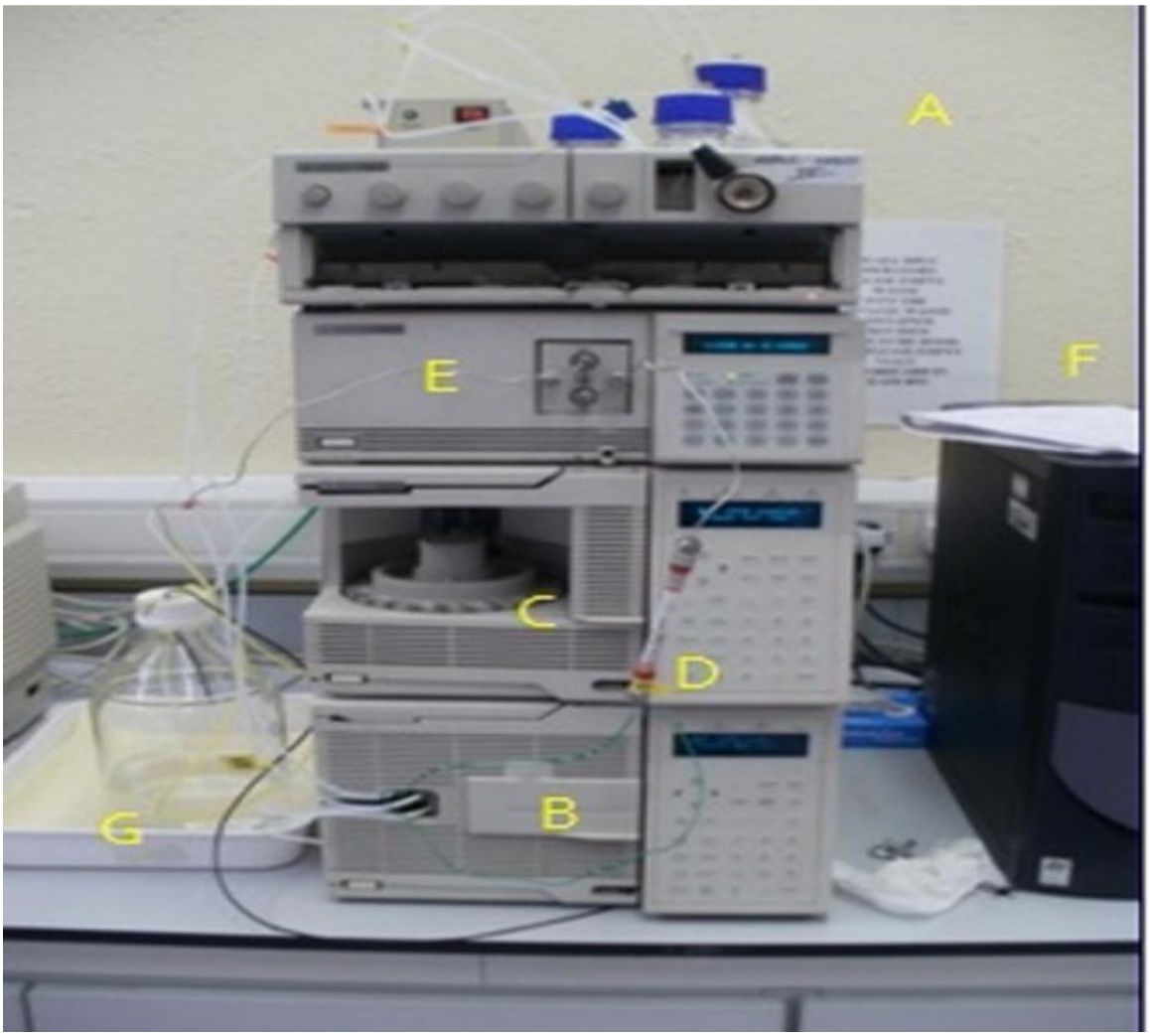

Fig. 1: Photograph of High performance liquid chromatography.

Method development and validation able (fig. 2).

Drug	Method	Chromatographic condition	Result	Ref no.
Daunorubicin	RP-HPLC	Column – kromasil C18 Mobile phase – methano:acetonitrile (75:25) Flow rate – 1.0 mL/min Detector – UV Wavelength – 254 nm	RT – 4.59min Linearity range – 5-10 µg/mL RSD – 0.48% Accuracy – 98.04-100.67% LOD & LOQ – 0.13 & 1.00µg/mL Robustness – less than 2%	[5]
Capecitabine	RP-HPLC	Column – Hypersil BDS C8 Mobile phase – Buffer : ACN (80:40) Flow rate – 1.2 ml/min RT – 15 min	Calibration range (µg/ml) – 40-60 Tailing factor – 1.8 LOD – 0.088(µg/ml) LOQ – 0.26(µg/ml)	[6]

5-Fluorouracil	RP-HPLC	Column – Lichrosphere C8 Mobile phase – methanol : water (50:50) Flow rate – 1ml/min Detector – UV Wavelength – 254nm	Linear range – 0.1-20µg/mL R^2- 0.997 Recoveries – 99.06-101.25% LOD & LOQ – 0.05 & 0.15µg/ml	[7]
Clofarabine	RP-HPLC	Column – Luna C18 Mobile phase – water : methanol (60:40) Flow rate – 1.0ml/min Detector – UV Wavelength – 266nm	LOD & LOQ – 0.01(µg/ml & 0.05(µg/ml Accuracy – 99.58-100.95% Repeatability – 1.27	[8]
Hydroxycamptothecin	RP-HPLC	Column – ZORBAX Sb-C18 Mobile phase – 0.1% triethylamine phosphoric acid buffer : acetonitrile Detector – fluorescence Wavelength – excitation (382nm) & emission (528)	Linearity range – 2-100ng/ml Correlation coefficient – 0.9999 Recovery – between 86.5&105.2%	[9]
Lapatinib	RP-HPLC	Column – kromasil C18 Mobile phase – methanol : KH_2PO_4: THF (60:35:5) Wavelength – 253nm Detector – UV Flow rate – 1ml/min	R^2-0.9532 Recovery – 99.66% Precision – 0.064 & 0.509 LOD – 10ng/ml LOQ – 35ng/ml	[10]
Afatinib Dimaleate	RP-HPLC	Column – X-Terra RP-8 Mobile phase – water : ACN (70:30) Flow rate – 1.0mL/min Run time – 20min Wavelength – 258nm	Rt – 10.558min Linearity range – 0.12-0.36mg/mL Correlation coefficient – 0.998 RSD – 0.03 % error in bulk sample – 0.15%	[11]

CONCLUSION

The present review contains maximum information related to analytical method development and validation of anticancer drugs by HPLC method. The HPLC method is most commonly used method into the routine analysis. The present review is advantageous to researchers in this area engaged in analysis of anticancer drugs.

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