1. Introduction

Quality can be defined as the character, which defines the grade of excellence. Quality is important in every aspect of life and when it comes to life it is crucial. The quality drug is something, which will meet the established product specifications, can be safely bought and confidently used for the purpose for which it is intended. There is no fear of adulteration or unpredictable side effects with such a quality drug. Development of analytical methods for bulk drug and their formulations is an important aspect in the drug product development as it helps to maintain the quality and efficacy of the drug product right from the product development process till its ultimate therapeutic use.

Therefore quality issues such as the studies of impurity, stability, degradation and analysis of drug product would be the research work to stress upon. These demands analytical development and standardization of sensitive and specific instrumental methods for testing of simultaneous, product study and analysis of drug product

Antineoplastics or Anticancer drugs are the drugs that prevent or inhibit the maturation and proliferation of neoplasms. Antineoplastic agents travel the body and destroy cancer cells. Many of the side effects associated with antineoplastic agents occur because treatment destroys the body's normal cells in addition to cancerous cells. Anticancer or Antineoplastic drugs are used to treat malignancies, cancerous growths. Anticancer drugs are used to control the growth of cancerous cells. Cancer is commonly defined as the uncontrolled growth of cells, with loss of differentiation with metastasis, spread of the cancer to other tissues and organs. Cancers are malignant growths. In contrast, benign growths remain encapsulated and grow within a well-defined area. Although benign tumors may be fatal if untreated, due to pressure on essential organs, as in the case of a benign brain tumor, surgery or radiation are the preferred methods of treating growths which have a well defined location. Drug therapy is used when the tumor has spread or may spread to all areas of the body. Drug therapy may be used alone or in combination with other treatments such as surgery or radiation therapy. [1]

The concept of Analytical Chemistry it’s in the precise and accurate measurements. The determination requires highly sophisticated instruments and methods like HPLC, GC, Spectrophotometry etc. HPLC method is sensitive, accurate, reuse and desirable for regular determination of drugs in bulk and formulation thereby is advantageous than volumetric methods. In the view of the need in the industry for routine analysis anticancer drugs attempts are being made to develop simple and accurate instrumental methods for quantitative estimation of their determination in formulation. Thus there is a need for the development of newer, simple, sensitive, accurate and economic analytical methods for effective estimation of Anticancer Drugs. [38]
Introduction to High-Performance Liquid Chromatography (HPLC)

High performance liquid chromatography is the fastest growing analytical technique for the analysis of drugs. Its simplicity, high specificity and wide range of sensitivity make it ideal for the analysis of many drugs in both dosage forms and biological fluids. The rapid growth of HPLC has been facilitated by the development of reliable, moderately priced instruments and efficient columns. [2], [10].

**Normal phase chromatography:** Retention by interaction of the stationary phase’s polar hydrocarbon chain with non-polar parts of the sample molecules.

**Reverse-phase chromatography:** Retention by interaction of the stationary phase’s non-polar hydrocarbon chain with polar parts of the sample molecules.

**Temozolomide:**

(4-methyl-5-oxo- 2, 3, 4, 6, 8-pentazabicyclo [4.3.0] nona-2, 7, 9-triene- 9-carboxamide)

![Temozolomide molecule](image)

**Molecular Formula:** C_{6}H_{6}N_{6}O_{2}

**Molecular Weight:** 194.15

**Solubility in water:** Slightly soluble

**Density:** 1.97 g/cm³ (20°C)

**PKa/pKb:** 15.29 (pKa)

**Partition Coefficient:** -1.15

Temozolomide is a chemotherapy drug that works by slowing cancer cell growth. Temozolomide is an imidazotetrazine derivate and an antineoplastic agent. It is a prodrug that has little to no pharmacological activity until it is hydrolyzed in vivo to 5-(3-methyltriazen-1-yl)imidazole-4-carboxamide (MTIC). After administration, temozolomide undergoes rapid, nonenzymatic hydrolysis at physiological pH to MTIC, which is the active form of the drug. MTIC is generated through the effect of water at the highly electropositive C4 position of temozolomide, causing the ring of temozolomide to open, release carbon dioxide, and generate MTIC. Temozolomide is administered orally and penetrates well into the central nervous system. Temozolomide (sometimes referred to as TMZ) medication is used to treat certain types of brain cancer. It is a chemotherapy drug that works by slowing cancer cell growth. In some patients, Temozolomide decreases the size of brain tumors. [3], [33]
Anastrozole:
1,3-Benzenediacetonitrile, alpha, alpha, alpha', alpha'-tetramethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-2-[3-(2-
Cyanopropan-2-yl)-5-(1,2,4-triazol-1-ylmethyl)phenyl]-2-methylpropanenitrile

Molecular Formula: C_{17}H_{19}N_{5}
Molecular Weight: 293.3663

**Solubility in water:** Insoluble
**Density:** 1.08 g/cm³
**PKa/pKb:** 11.38 (pKb)
**Partition Coefficient:** 0.969

Anastrozole (an-ASS-troh-zole) is a medicine, used extensively in the treatment of breast cancer. Anastrozole is a potent and selective non-steroidal aromatase inhibitor indicated for the treatment of advanced breast cancer in post-menopausal women with disease progression following tamoxifen therapy. Many breast cancers have estrogen receptors and growth of these tumors can be stimulated by estrogens. In post-menopausal women, the principal source of circulating estrogen (primarily estradiol) is conversion of adrenally-generated androstenedione to estrone by aromatase in peripheral tissues, such as adipose tissue, with further conversion of estrone to estradiol. Many breast cancers also contain aromatase; the importance of tumor-generated estrogens is uncertain. Treatment of breast cancer has included efforts to decrease estrogen levels by ovariectomy premenopausally and by use of anti-estrogens and progestational agents both pre- and post-menopausally, and these interventions lead to decreased tumor mass or delayed progression of tumor growth in some women. Anastrozole is a potent and selective non-steroidal aromatase inhibitor. It significantly lowers serum estradiol concentrations and has no detectable effect on formation of adrenal corticosteroids or aldosterone.

Anastrozole (INN) marketed under the trade name (Arimidex) by AstraZeneca, is a drug used to treat breast cancer after surgery and for metastases in both pre and post-menopausal women. Some breast cancer cells require estrogen to grow, and eliminating estrogen suppresses their growth. [4]