A COLLECTION OF DATA ON SEVERAL DRUG FORMULATIONS ASSAY TYPES AND SUBTYPES

By

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Declaration

It is hereby declared that

1. The thesis submitted is my/our own original work while completing degree at Brac University.
2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.
3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.
4. I/We have acknowledged all main sources of help.

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Approval

The thesis titled “A collection of data on several formulations assay types and subtypes” submitted by Senjuti Sarma (18346066), of Summer, 2023 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Bachelor of Pharmacy.

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Ethics Statement

No human or animals of any kind were involved as sample for this study.

Abstract

This paper reviews a number of the British Pharmacopeia-approved drug analysis methods. A list was created by compiling the several assay types and subtypes that were performed for each formulation. Bar and pie charts were made to quickly understand the most common assay. Chromatography was discovered to be the most common test type. This project might serve as a teaching tool. This database can be used by those who develop analytical procedures because it is beneficial to them.

Keywords: Chromatography, Spectroscopy, Titration.

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UV	Ultra Violet
HPLC	High Performance Liquid Chromatography
BP	British Pharmacopeia

Chapter 1

Introduction

Pharmacopeia

A thorough collection of quality requirements for drugs and pharmaceuticals used in the UK is known as the British Pharmacopoeia (BP). The British Pharmacopoeia Commission, a section of the Medicines and Healthcare products Regulatory Agency (MHRA), is responsible for publishing it. The BP's main goals are to advance public health and guarantee the reliability and safety of UK pharmaceuticals. It establishes requirements for the identification, purity, potency, and quality assurance of materials used in the production of pharmaceuticals. The BP is revised frequently to reflect changes in medical procedures and breakthroughs in science.

A variety of consumers can access it because it is also available electronically. The BP is essential in assuring the efficacy and safety of medications in the UK by offering standards and guidelines that safeguard public health and encourage their proper use.(Ho, 1961)

Assay

A lab test or analysis known as an assay is used to determine the presence or concentration of a certain medicine or component in a sample. It is used to ensure that the manufactured product complies with all legal and regulatory requirements, that the appropriate amount of the active ingredient is present in the product, and that the medicine formulation is consistent and of high quality. Assays are crucial for the production and quality control of pharmaceuticals because they provide measurable information on the drug's active ingredient and help to spot contaminants that could affect the formulation's safety and quality. To ensure adherence to

quality standards and laws, regulatory bodies frequently want assay data as part of the drug approval process. (Riley et al., 2014)

The Techniques performed in assay identification

Chromatography

The term "chromatography," which comes from the Greek terms "chroma" and "graphein," describes a method that is frequently utilized in many scientific domains for isolating and evaluating mixture components. In the process of chromatography, a mixture is split into two phases: a stationary phase and a mobile phase. The mobile phase is a liquid or gas that carries the sample through the stationary phase. The stationary phase is a solid or liquid that is immobilized on a solid support. Each component separation happens as it moves through the system as a result of the various manners that components interact with the stationary and mobile phases.

There are numerous chromatographic methods, including liquid chromatography (LC), which uses a liquid-only system for the mobile phase and a solid substrate that has been coated with liquid as the stationary phase. Other LC versions exist, such as high-performance liquid chromatography (HPLC), which uses high-pressure pumps to move the mobile phase through the apparatus. Additionally, thin-Layer Chromatography (TLC) uses a thin layer of solid material as the stationary phase on a flat substrate, such as a glass plate, and a liquid that is pushed up the plate by capillary action as the mobile phase. Ion-Exchange Chromatography is a technique that separates matter based on the ionic characteristics of the mobile phase's oppositely charged ions by interacting with charged groups in the stationary phase. In Size-Exclusion Chromatography (SEC), the stationary phase is made up of porous particles that segregate constituents according to their size or molecular weight. Gas chromatography (GC)

uses a gas as the mobile phase and a solid or liquid as the stationary phase that is immobilized on a solid support. Volatile ingredient analysis frequently involves the use of GC. Moreover, atomic chromatography is a specialized method for element separation and quantitative analysis that blends chromatography principles with atomic spectroscopy. Elements separate as a result of differential interactions between stationary and mobile phases.(Coskun, 2016)

Titration

Titration method in drug testing involves reacting drug material with standardized reagent to determine potency, with the objective of reaching a stoichiometric equivalency point. (FERNANDEZ-MAESTRE, 2020)

Titrimetric techniques for drug assays include acid-base titration, oxidation-reduction (redox) titration, and complexometric titration. The option is determined by the characteristics of the medication and the target analyte. Acid-base titration involves reacting the medicinal material with a titrant of known concentration to measure the concentration of acid or base in the sample. Utilizing a pH indicator or meter, the endpoint is commonly found. Redox titration involves the exchange of electrons between a drug ingredient and a titrant, such as iodine in the case of the measurement of vitamin C. When detecting metal ions or chelating agents, complexometric titration generally results in the formation of a stable complex between the drug component and titrant. In pharmaceutical analysis, ethylenediaminetetraacetic acid (EDTA) is a frequent complexing agent. For accurate findings, titrimetric assays need to choose their titrants, markers, and experimental setups carefully. Since the reaction's stoichiometry is known, the concentration of the drug component can be determined using calibration curves or standard solutions.(Caffrey & Borrelli, 2020)

Spectroscopy

The study of the interaction between matter and electromagnetic radiation is known as spectroscopy. UV-Vis, infrared, nuclear magnetic resonance, atomic absorption, flame emission, mass spectrometry, fluorescence, and electron microscopy are just a few of the techniques it employs. In this study the findings show two crucial methods like UV and atomic absorption spectroscopy. For the identification of drugs used in assays, atomic and UV spectroscopy are crucial analytical techniques because they reveal important details about the material being tested, including its composition and quantity. For both qualitative and quantitative investigation, UV spectroscopy involves the absorption of ultraviolet or visible light by molecules in a sample. It functions by calculating the sample's absorption at various wavelengths of light, spotting electronic transitions, and capturing the absorption spectrum. The spectrum may have distinctive peaks that correspond to functional groups or chromophores in the drug molecule. UV absorption can be used to identify a drug or determine its purity by comparing it to reference spectra of well-known pharmaceuticals or drug standards. Furthermore, by employing calibration curves made from standard solutions, UV spectroscopy can be utilized for quantitative analysis to establish the amount of a drug present in a sample.(M et al., 2021). Atomic spectroscopy is a method used to examine the elemental makeup of a sample, including pharmacological compounds. It consists of Atomic Absorption Spectroscopy (AAS), Atomic Emission Spectroscopy (AES), Atomic Fluorescence Spectroscopy (AFS), Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES), and Inductively Coupled Plasma-Mass Spectrometry (ICP-MS). AES monitors the emission of light from excited atoms, while AAS measures the absorption of light by ground-state atoms. For the analysis of trace elements, AFS is a more sensitive method. Both methods can be utilized for multi-element analysis and are quite sensitive. Atomic spectroscopy is frequently used in drug assay identification to measure the concentration of trace elements, notably heavy metals,

which can be dangerous if present in pharmaceutical products above allowable levels.(Izrio Filho et al., 2012; Lewen, 2011)

Aim & objectives:

The creation of a database that will make it straightforward for researchers and students to find out the assay-type of drug compounds is the aim of this project. The assay type table is containing information about each type of assay, including its name and subtype. They can learn the assay type for each formulation.

Chapter 2

Methodology

This study has been done by following this method.

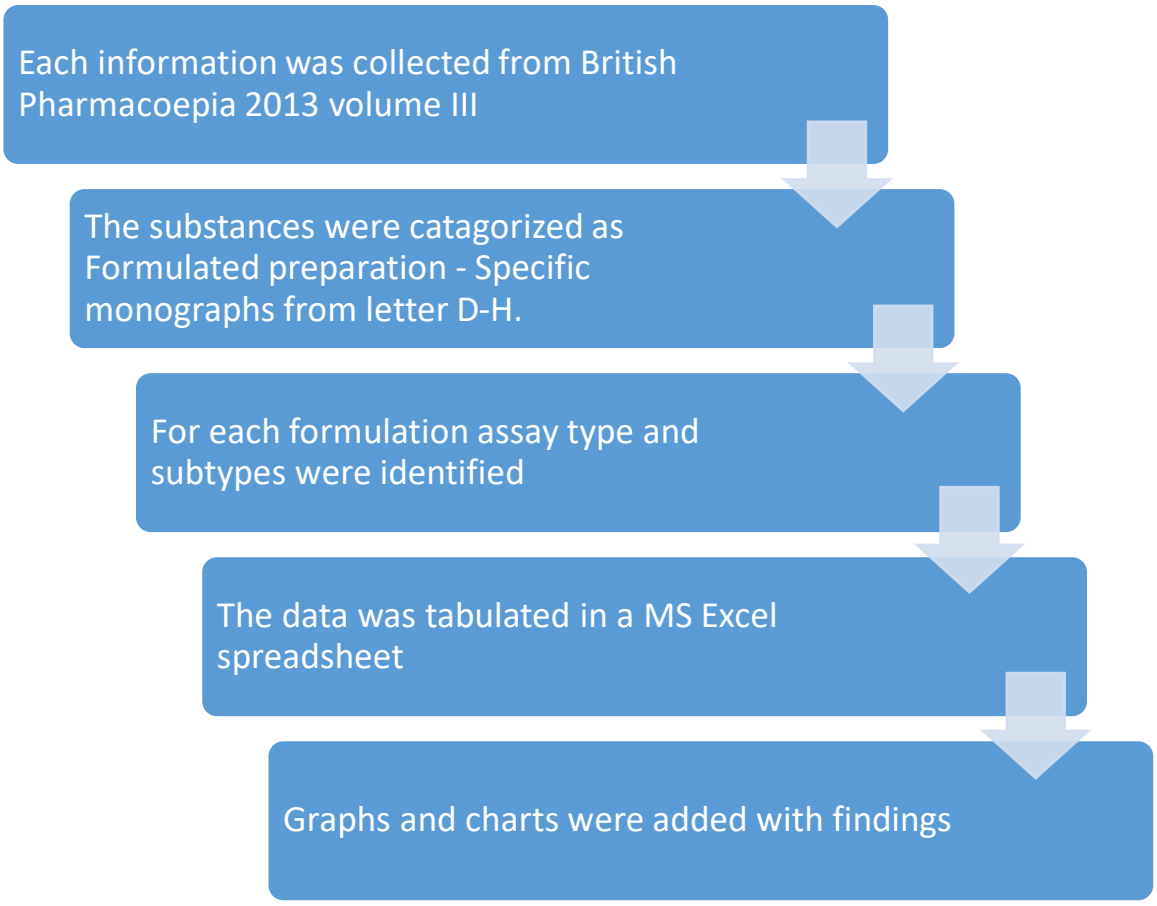

Figure 1: Methodology

Chapter 3

Result & Discussion

Here is the data collection of the formulations. This table contains the information of the assay types and Subtypes.

Formulation	**Dosage form**	**Assay type**	**Subtype**
Disulfiram Tablets	tablet	spectroscopic	UV
Dithranol Cream	cream	chromatographic	normal phase HPLC
Dithranol Ointment	ointment	chromatographic	normal phase HPLC
Dithranol Paste (dithranol)	paste	chromatographic	normal phase HPLC
Dithranol Paste (salicylic acid)	paste	spectroscopic	UV
Dithranol Paste (zinc oxide)	paste	titrimetric	complexometric titration
Dobutamine Infusion	injection/infusion	chromatographic	reverse phase HPLC
Docusate Capsules	capsule	chromatographic	reverse phase HPLC
Compound Docusate Enema	enema	chromatographic	ion exchange

Docusate Oral Solution	solution	chromatographic	ion exchange
Pediatric Docusate Oral Solution	solution	chromatographic	ion exchange
Domperidone Tablets	tablet	chromatographic	reverse phase HPLC
Dopamine Intravenous Infusion	injection/infusion	chromatographic	TLC
Dorzolamide Eye Drops	eye drops	chromatographic	reverse phase HPLC
Dorzolamide and Timolol Eye drops (dorzolamide)	eye drops	chromatographic	reverse phase HPLC
Dorzolamide and Timolol Eye drops (timolol)	eye drops	chromatographic	reverse phase HPLC
Dosulepin Capsules	capsule	titrimetric	non-aqueous titration
Dosulepin Oral Solution	solution	chromatographic	reverse phase HPLC
Dosulepin Tablets	tablet	chromatographic	reverse phase HPLC
Doxapram Injection	injection/infusion	spectroscopic	UV
Doxepin Capsules	capsule	chromatographic	reverse phase HPLC

Doxorubicin Injection	injection/infusion	chromatographic	reverse phase HPLC
Doxycycline Capsules	capsule	chromatographic	reverse phase HPLC
Dispersible Doxycycline Tablets	tablet	chromatographic	reverse phase HPLC
Droperidol Injection	injection/infusion	chromatographic	reverse phase HPLC
Droperidol Tablets	tablet	chromatographic	reverse phase HPLC
Dydrogesterone Tablets	tablet	spectroscopic	UV
Econazole Cream	cream	chromatographic	reverse phase HPLC
Econazole Pessaries	pessary	titrimetric	non-aqueous titration
Edrophonium Injection	injection/infusion	spectroscopic	UV
Emulsifying Ointment	ointment	Not mentioned	
Emulsifying Wax	miscellaneous	Not mentioned	
Enalapril Tablets	tablet	chromatographic	reverse phase HPLC
Enoxaparin Sodium Injection	injection/infusion	biological	ELISA

Ephedrine Elixir	spirit/elixir/linctus	chromatographic	reverse phase HPLC
Ephedrine Injection	injection/infusion	chromatographic	reverse phase HPLC
Ephedrine Nasal drops	Nasal Drop	chromatographic	reverse phase HPLC
Ephedrine Hydrochloride Tablets	tablet	chromatographic	reverse phase HPLC
Epirubicin Injection	injection/infusion	chromatographic	reverse phase HPLC
Ergocalciferol Injection	injection/infusion	spectroscopic	UV
Ergocalciferol Tablets	tablet	spectroscopic	UV
Ergometrine Injection	injection/infusion	spectroscopic	UV
Ergometrine and Oxytocin Injection (ergometrine)	injection/infusion	chromatographic	reverse phase HPLC
Ergometrine and Oxytocin Injection (ovytocin)	injection/infusion	chromatographic	reverse phase HPLC
Ergometrine Tablets	tablet	spectroscopic	UV

Ergotamine Sublingual Tablets	tablet	chromatographic	reverse phase HPLC
Gastro-resistant Erythromycin Capsule	capsule	biological	
Gastro-resistant Erythromycin Tablets	tablet	chromatographic	reverse phase HPLC
Erythromycin Estolate Capsule	capsule	biological	
Erythromycin Ethyl Succinate Oral Suspention	suspension	biological	
Erythromycin Ethyl Succinate Oral Tablets	tablet	biological	
Erythromycin Lactobionate Infusion	injection/infusion	chromatographic	reverse phase HPLC
Erythomycin Stearate Tablets	tablet	biological	
Erythomycin and zinc Acetate Lotion (erythromycin)	lotion	chromatographic	reverse phase HPLC

Erythomycin and zinc Acetate Lotion (zinc acetate)	lotion	titrimetric	complexometric titration
Erythopoietin Injection	injection/infusion	biological	
Estradiol Injection	injection/infusion	chromatographic	normal phase HPLC
Estradiol Transdermal Patches	implant/patch	chromatographic	reverse phase HPLC
Estradiol and Norethisterone Tablets (estradiol)	tablet	chromatographic	reverse phase HPLC
Estradiol and Norethisterone Tablets (norethisterone)	tablet	chromatographic	reverse phase HPLC
Estradiol and Norethisterone Acetate Tablets (estradiol)	tablet	chromatographic	reverse phase HPLC
Estradiol and Norethisterone Acetate Tablets (norethisterone)	tablet	chromatographic	reverse phase HPLC

Estramustine Phosphate Capsules	capsule	spectroscopic	UV
Estriol Cream	cream	chromatographic	reverse phase HPLC
Estriopipate Tablets	tablet	chromatographic	reverse phase HPLC
Ethambutol Tablets	tablet	titrimetric	non-aqueous titration
Ethanolamine Oleate Injection (ethanolamine)	injection/infusion	titrimetric	aqueous acid base titration
Ethanolamine Oleate Injection (oleic acid)	injection/infusion	titrimetric	aqueous acid base titration
Ethinylestradiol Tablets	tablet	chromatographic	reverse phase HPLC
Ethosuximide Capsules	capsule	titrimetric	non-aqueous titration
Ethosuximide Oral Solution	solution	chromatographic	gas chromatography
Etidronate Tablets	tablet	chromatographic	ion exchange
Etodolac Capsules	capsule	chromatographic	reverse phase HPLC
Etodolac Tablets	tablet	chromatographic	reverse phase HPLC

Etoposide Capsules	capsule	chromatographic	reverse phase HPLC
Etopside Intravenous Infusion	injection/infusion	chromatographic	reverse phase HPLC
Famotidine Tablets	tablet	chromatographic	reverse phase HPLC
Felbinac Cutaneous Foam	foam	chromatographic	reverse phase HPLC
Felbinac Gel	gel	chromatographic	reverse phase HPLC
Prolonged-Release Felodipine Tablets	tablet	chromatographic	reverse phase HPLC
Fenbufen Capsules	capsule	chromatographic	reverse phase HPLC
Fenbufen Tablets	tablet	chromatographic	reverse phase HPLC
Fenoprofen Tablets	tablet	spectroscopic	UV
Fenoterol Pressurised Inhalation	spray	chromatographic	reverse phase HPLC
Fentanyl Injection	injection/infusion	chromatographic	reverse phase HPLC
Ferrous Fumarate Capsules	capsule	titrimetric	redox titration

Ferrous Fumarate Oral Suspension	suspension	titrimetric	redox titration
Ferrous Fumarate Tablets	tablet	titrimetric	redox titration
Ferrous Fumarate and Folic Acid Tablets (ferrous fumerate)	tablet	titrimetric	redox titration
Ferrous Fumarate and Folic Acid Tablets (folic acid)	tablet	chromatographic	reverse phase HPLC
Ferrous Gluconate Tablets	tablet	titrimetric	redox titration
Paediatric Ferrous Sulfate Oral Solution	solution	titrimetric	redox titration
Ferrous Sulfate Tablets	tablet	titrimetric	redox titration
Prolonged-Release Ferrous SulfateTablets	tablet	titrimetric	redox titration
Fexofenadine Tablets	tablet	chromatographic	reverse phase HPLC
Finasteride Tablets	tablet	chromatographic	reverse phase HPLC

Flavoxate Tablets	tablet	spectroscopic	UV
Flecainide Injection	injection/infusion	spectroscopic	UV
Flecainide Tablets	tablet	spectroscopic	UV
Flucloxacillin Capsules	capsule	chromatographic	reverse phase HPLC
Flucloxacillin Injection	injection/infusion	chromatographic	reverse phase HPLC
Flucloxacillin Oral Solution	solution	chromatographic	reverse phase HPLC
Flucloxacillin Oral Suspention	suspension	chromatographic	reverse phase HPLC
Flucytosine Tablets	tablet	spectroscopic	UV
Fludrocortisone Tablets	tablet	chromatographic	reverse phase HPLC
Fluocinolone Cream	cream	chromatographic	reverse phase HPLC
Fluocinolone Ointment	ointment	chromatographic	reverse phase HPLC
Fluocinonide Cream	cream	chromatographic	reverse phase HPLC
Fluocinonide Ointment	ointment	chromatographic	reverse phase HPLC
Fluocortolone Cream	cream	chromatographic	reverse phase HPLC

Fluorescein Eye Drops	eye drops	chromatographic	reverse phase HPLC
Fluorescein Injection	injection/infusion	chromatographic	reverse phase HPLC
Flurometholone Eye Drops	eye drops	chromatographic	reverse phase HPLC
Flurouracil Cream	cream	spectroscopic	UV
Flurouracil Injection	injection/infusion	spectroscopic	UV
Fluxetine Capsules	capsule	chromatographic	reverse phase HPLC
Fluxetine Oral Solution	solution	chromatographic	reverse phase HPLC
Flupentixol Injection	injection/infusion	chromatographic	reverse phase HPLC
Fluphenazine Decanoate Injection	injection/infusion	titrimetric	non-aqueous titration
Fluphenazine Tablets	tablet	spectroscopic	UV
Flurazepam Capsules	capsule	spectroscopic	UV
Flurbiprofen Eye Drops	eye drops	chromatographic	reverse phase HPLC
Flurbiprofen Suppositories	suppository	chromatographic	reverse phase HPLC

Flurbiprofen Tablets	tablet	chromatographic	reverse phase HPLC
Fluticasone Cream	cream	chromatographic	reverse phase HPLC
Fluticasone Nasal drops	miscellaneous	chromatographic	reverse phase HPLC
Fluticasone Nasal spray	spray	chromatographic	reverse phase HPLC
Fluticasone Ointment	ointment	chromatographic	reverse phase HPLC
Fluticasone Powder for Inhalation	powder	chromatographic	reverse phase HPLC
Fluticasone Pressurised Inhalation	Inhalation	chromatographic	reverse phase HPLC
Fluvoxamine Tablets	tablet	chromatographic	reverse phase HPLC
Folic Acid Injection	injection/infusion	chromatographic	reverse phase HPLC
Folic Acid Tablet	tablet	chromatographic	reverse phase HPLC
Foscarnet Intravenous Infusion	injection/infusion	chromatographic	reverse phase HPLC
Fosfestrol Injection	injection/infusion	spectroscopic	UV
Fosfestrol Tablets	tablet	spectroscopic	UV

Fructose intravenous Infusion	injection/infusion	polarimetry	optical rotation
Furosemide Injection	injection/infusion	spectroscopic	UV
Furosemide Tablets	tablet	spectroscopic	UV
Fusidic Acid Cream	cream	chromatographic	reverse phase HPLC
Fusidic Acid Eye Drops	eye drops	chromatographic	reverse phase HPLC
Fusidic Acid Oral Suspension	suspension	chromatographic	reverse phase HPLC
Gemfibrozil Capsules	capsule	chromatographic	reverse phase HPLC
Gemfibrozil Tablets	tablet	chromatographic	reverse phase HPLC
Gentamicin Cream	cream	biological	
Gentamicin Ear Drops	ear drops	biological	
Gentamicin Eye Drops	eye drops	biological	
Gentamicin Injection	injection/infusion	biological	
Gentamicin Ointment	ointment	biological	

Gentamicin and Hydrocortisone Acetate Ear Drops (Gentamicin)	ear drops	biological	
Gentamicin and Hydrocortisone Acetate Ear Drops (Hydrocortisone Acetate)	ear drops	chromatographic	reverse phase HPLC
Glibenclamide Tablets	tablet	chromatographic	reverse phase HPLC
Gliclazide Tablets	tablet	chromatographic	reverse phase HPLC
Glipizde Tablets	tablet	spectroscopic	UV
Gliquidone Tablets	tablet	spectroscopic	UV
Glucose Intravenous Infusion	injection/infusion	polarimetry	optical rotation
Glucose Irrigation Solution	solution	polarimetry	optical rotation
Compound Glucose,Sodium Chloride And Sodium Citrate Oral Solution (Glucose)	solution	polarimetry	optical rotation

Compound Glucose,Sodium Chloride And Sodium Citrate Oral Solution (NaCl)	solution	titrimetric	Precipitation
Compound Glucose,Sodium Chloride And Sodium Citrate Oral Solution	solution	titrimetric	non-aqueous titration
Glutaraldehyde Solution	solution	titrimetric	aqueous acid base titration
Glycerol Eye Drops	eye drops	titrimetric	aqueous acid base titration
Glycerol Suppositories	suppository	titrimetric	aqueous acid base titration
Glyceryl Trinitrate Sublingul Spray	spray	chromatographic	reverse phase HPLC
Glycerol Trinitrate Tablets	tablet	chromatographic	reverse phase HPLC
Glycerol Trinitrate Transdermal Patches	implant/patch	chromatographic	reverse phase HPLC
Glycine Irrigation Solution	solution	titrimetric	aqueous acid base titration

Glycopyrronium Bromide Oral Solution	solution	chromatographic	reverse phase HPLC
Goserelin Implants	implant/patch	chromatographic	size exclusion
Griseofulvin Tablets	tablet	spectroscopic	UV
Guanethidine Tablets	tablet	spectroscopic	UV
Haemodialysis Solutions (Na)	solution	spectroscopic	atomic
Haemodialysis Solutions (K)	solution	spectroscopic	atomic
Haemodialysis Solutions (Ca)	solution	spectroscopic	atomic
Haemodialysis Solutions (Mg)	solution	spectroscopic	atomic
Haemodialysis Solutions (chloride)	solution	titrimetric	Precipitation
Haemodialysis Solutions (acetate)	solution	titrimetric	aqueous acid base titration
Haemodialysis Solutions (lactate)	solution	titrimetric	aqueous acid base titration
Haemodialysis Solutions (NaHCO3)	solution	titrimetric	aqueous acid base titration

Haemodialysis Solutions (reducing sugars)	solution	titrimetric	redox titration
Water for Diluting Concentrated Haemodialysis Solutions (not mentioned)	solution	spectroscopic	atomic
Haemofiltration And Heamodiafiltration Solutions (Na)	solution	spectroscopic	atomic
Haemofiltration And Heamodiafiltration Solutions (K)	solution	spectroscopic	atomic
Haemofiltration And Heamodiafiltration Solutions (Ca)	solution	spectroscopic	atomic
Haemofiltration And Heamodiafiltration Solutions (Mg)	solution	spectroscopic	atomic
Haemofiltration And Heamodiafiltration Solutions (chloride)	solution	titrimetric	Precipitation

Haemofiltration And Heamodiafiltration Solutions (acetate)	solution	titrimetric	aqueous acid base titration
Haemofiltration And Heamodiafiltration Solutions (lactate)	solution	titrimetric	aqueous acid base titration
Haemofiltration And Heamodiafiltration Solutions (NaHCO3)	solution	titrimetric	aqueous acid base titration
Haemofiltration And Heamodiafiltration Solutions (reducing sugars)	solution	titrimetric	redox titration
Halibut-liver Oil Capsules	capsule	titrimetric	reverse phase HPLC
Haloperidol Capsules	capsule	chromatographic	reverse phase HPLC
Haloperidol Injection	injection/infusion	spectroscopic	UV
Haloperidol Oral Solution	solution	spectroscopic	UV
Strong Haloperidol Oral Solution	solution	spectroscopic	UV

Haloperidol Tablets	tablet	chromatographic	reverse phase HPLC
Heparin Injection	injection/infusion	biological	
Hexachlorophene Dusting Powder (hexachlorophene)	powder	spectroscopic	UV
Hexachlorophene Dusting Powder (zinc oxide)	powder	titrimetric	complexometric titration
Homatropine Eye Drops	eye drops	chromatographic	gas chromatography
Hyaluronidase Injections	injection/infusion	titrimetric	aqueous acid base titration
Hydralazine Injection	injection/infusion	titrimetric	redox titration
Hydralazine Tablets	tablet	titrimetric	redox titration
Hydrochlorothiazide Tablets	tablet	spectroscopic	UV
Hydrocortisone Cream	cream	chromatographic	reverse phase HPLC
Hydrocortisone Ointment	ointment	chromatographic	reverse phase HPLC
Hydrocortisone Oromucosal Tablets	tablet	spectroscopic	UV

Hydrocortisone Acetate Cream	cream	chromatographic	reverse phase HPLC
Hydrocortisone Acetate Injection	injection/infusion	chromatographic	reverse phase HPLC
Hydrocortisone Acetate Ointment	ointment	chromatographic	reverse phase HPLC
Hydrocortisone Acetate Oral Suspension	suspension	chromatographic	reverse phase HPLC
Hydrocortisone and Clioquinol Cream (hydrocortisone)	cream	chromatographic	reverse phase HPLC
Hydrocortisone and Clioquinol Cream (clioquinol)	cream	spectroscopic	UV
Hydrocortisone and Clioquinol Ointment (hydrocortisone)	ointment	chromatographic	reverse phase HPLC
Hydrocortisone and Clioquinol Ointment (clioquinol)	ointment	chromatographic	UV
Hydrocortisone and neomycin Cream (hydrocortisone)	cream	chromatographic	normal phase HPLC

Hydrocortisone and neomycin Cream (neomycin)	cream	biological	
Hydrocortisone Acetate and Neomycin Ear Drops (hydrocortisone)	ear drops	chromatographic	normal phase HPLC
Hydrocortisone Acetate and Neomycin Ear Drops (neomycin)	ear drops	biological	
Hydrocortisone Acetate and Neomycin Eye Drops (hydrocortisone)	eye drops	chromatographic	normal phase HPLC
Hydrocortisone Acetate and Neomycin Eye Drops (neomycin)	eye drops	biological	
Hydrocortisone Acetate and Neomycin Eye	ointment	chromatographic	

Ointment (hydrocortisone)			
Hydrocortisone Acetate and Neomycin Eye Ointment (neomycin)	ointment	biological	
Hydrocortisone Sodium Phosphate Injection	injection/infusion	spectroscopic	UV
Hydrocortisone Sodium Phosphate Oral Solution	solution	spectroscopic	UV
Hydrocortisone Sodium Succinate Injection	injection/infusion	spectroscopic	UV
Hydroflumethiazide Tablets	tablet	spectroscopic	UV
Hydrogen Peroxide Mouthwash	miscellaneous	titrimetric	redox titration
Hydrotalcite Tablets	tablet	titrimetric	complexometric titration
Hydrous ointment	ointment	Not Mentioned	
Hydroxocobalamin Injection	injection/infusion	spectroscopic	UV

Hydroxycarbamide Capsules	capsule	chromatographic	reverse phase HPLC
Hydroxychloroquine Tablets	tablet	chromatographic	reverse phase HPLC
Hydroxyzine Oral Solution	solution	chromatographic	reverse phase HPLC
Hydroxyzine Tablets	tablet	chromatographic	reverse phase HPLC
Hyoscine Eye Drops	eye drops	chromatographic	reverse phase HPLC
Hyoscine Injection	injection/infusion	chromatographic	reverse phase HPLC
Hyoscine Tablets	tablet	chromatographic	reverse phase HPLC
Hyoscine Butylbromide Injection	Injection/infusion	chromatographic	reverse phase HPLC
Hyoscine Butylbromide Tablets	tablet	chromatographic	reverse phase HPLC
Hypromellose Eye Drops	eye drops	Not mentioned	

Table 1: Data Table of Formulations

All the information was gathered from the British Pharmacopeia in this project. For the monographs studied chromatographic assays account for 54% of all assays, followed by spectroscopic (20%), titrimetric (16%), biological (8%), polarimetric (2%), and gravimetric (0%).

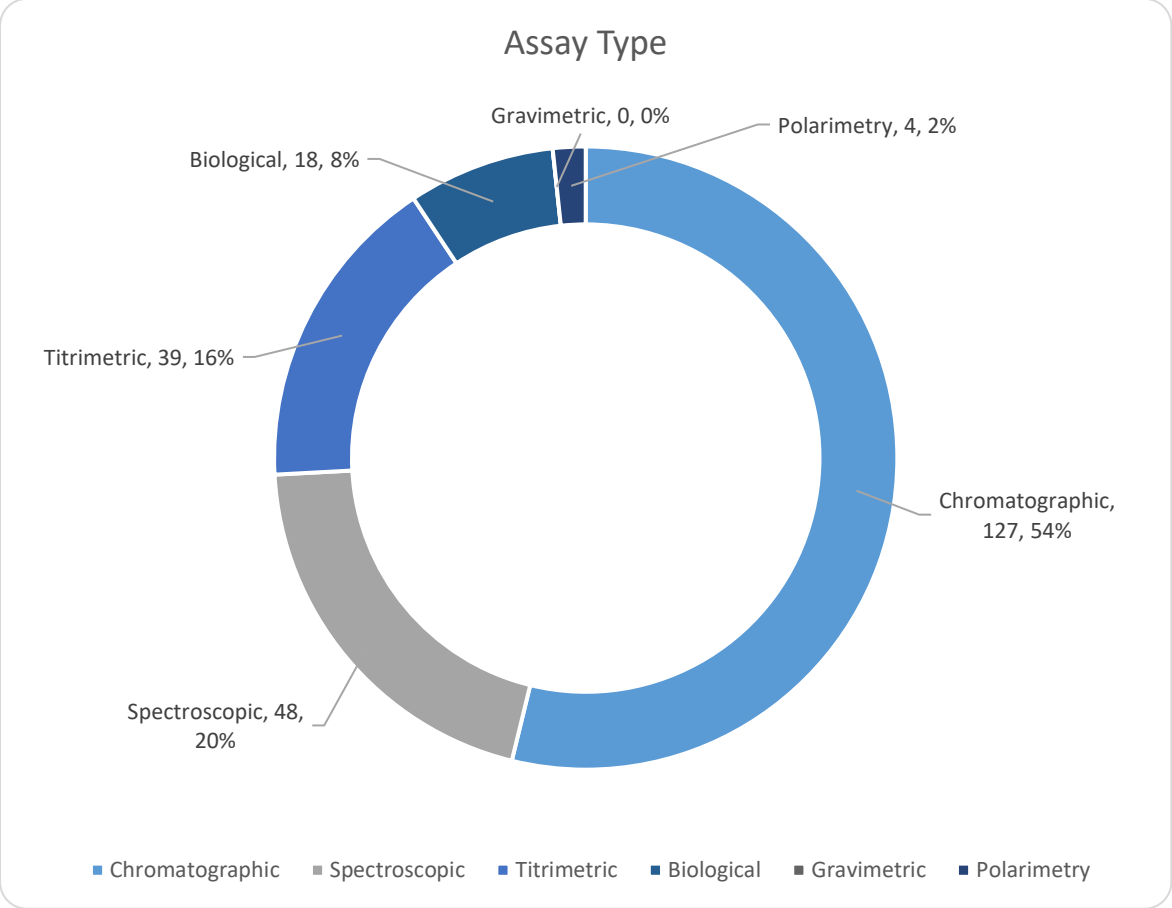

Figure 2 : The assay types

According to the findings, chromatography is being used the most because of its advantages

Chromatography has exceptional separation characteristics that make it possible to isolate and analyze complex mixtures. Formulation contain drugs, excipients. Then there was chromatographic techniques are extremely sensitive, making it possible to detect and quantify substances even at low concentrations. This is very important in the analysis of

pharmaceuticals since accurate measurements are necessary to assess the potency, purity, and safety of drugs. In order to discriminate and separate molecules based on their chemical characteristics, chromatography facilitates selectivity. Chromatography can successfully separate pharmaceuticals from influencing molecules by utilizing several stationary and mobile phases, enabling exact identification and quantification. After that chromatography includes a number of methods, including HPLC, GC, and TLC, which can be adjusted to diverse drug molecules and are useful for a variety of drug assays. As an environmentally friendly analytical method, chromatography leaves the material untainted after examination. This is especially helpful when there is a need for additional testing or assurance or when there are only a few samples available.

Gravimetric technique has no use here because of its limitations like,

It cannot be used to reliably measure medicines at low concentrations. Because the approach is less sensitive than other analytical techniques, it is difficult to identify and measure trace levels of drugs. Gravimetric techniques can also be tiring and demand intricate sample preparation procedures, which makes them less useful for regular analysis. The procedure is also prone to mistakes because of things like sample contaminants, partial precipitation, and moisture content. In summary, due to these shortcomings, analytical methods that are more accurate and effective are preferred over gravimetric approaches for drug analysis.

Here reverse phase HPLC as we can see in the graph below it is the most used technique when it comes to assay sub type, over 111 formulations were found in 241 formulations that was recommended in this process according to my findings.

Reverse phase high performance liquid chromatography is very frequently used because of its various advantages, Reverse phase HPLC is the best method for testing hydrophobic pharmacological molecules because it effectively separates and retains these substances using a nonpolar stationary phase. Also, reverse phase HPLC is a good choice for investigating the formation of complex mixtures seen in pharmacological compounds because of its more successful separation performance and resolution. Then reverse phase for precise determination of drug content and undesirable substances quantities during pharmaceutical analysis, HPLC offers great sensitivity. This is a very versatile technique, this allow detection and proper identification of drug substances and increase analytical capability

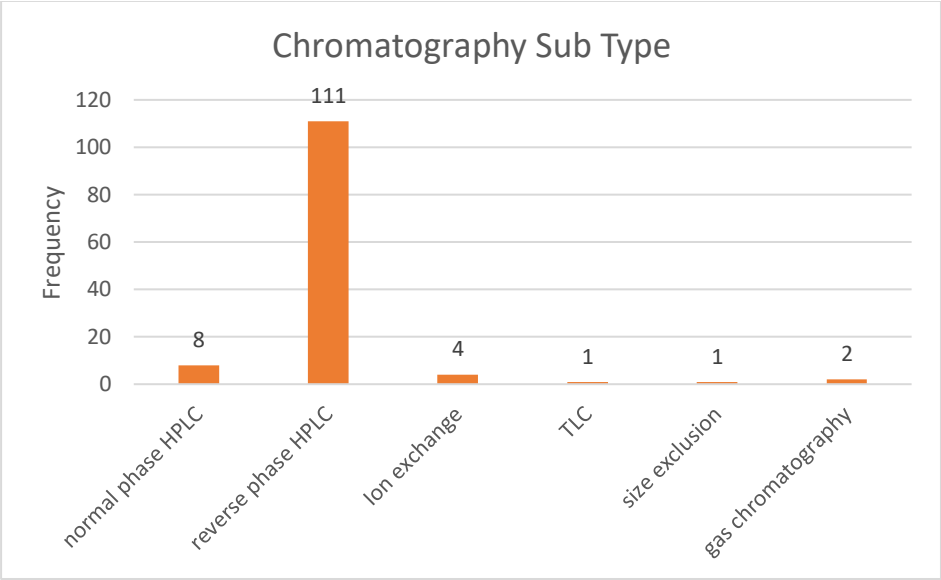

Figure 3: Chromatography Subtypes

On the other hand, normal phase HPLC, ion exchange, TLC, size exclusion and gas chromatography has very few uses. Due to its polarity, normal phase HPLC is useless for compounds that firmly adsorb onto the stationary phase and has a restricted application for hydrophobic molecules. Due to its separation and detection procedures, it is also less sensitive

than reverse phase HPLC. Ion exchange chromatography only separates and resolves distantly related molecules with poor efficiency for charged substances. TLC (Thin-Layer Chromatography) has poor quantification accuracy, sensitivity, and separation power, making it unsuitable for trace-level analysis and impurity identification at low concentrations. It is also subjective and less exact, making it unsuitable for trace-level examination or detecting contaminants at low concentrations. Low molecular weight chemicals, inadequate separation of closely eluting molecules, and poor retention of non-polar medicinal substances are all limitations of size exclusion chromatography. Lastly, gas chromatography (GC) has a restricted applicability for nonvolatile chemicals, as well as potential temperature instability and compatibility with polar stationary phases.

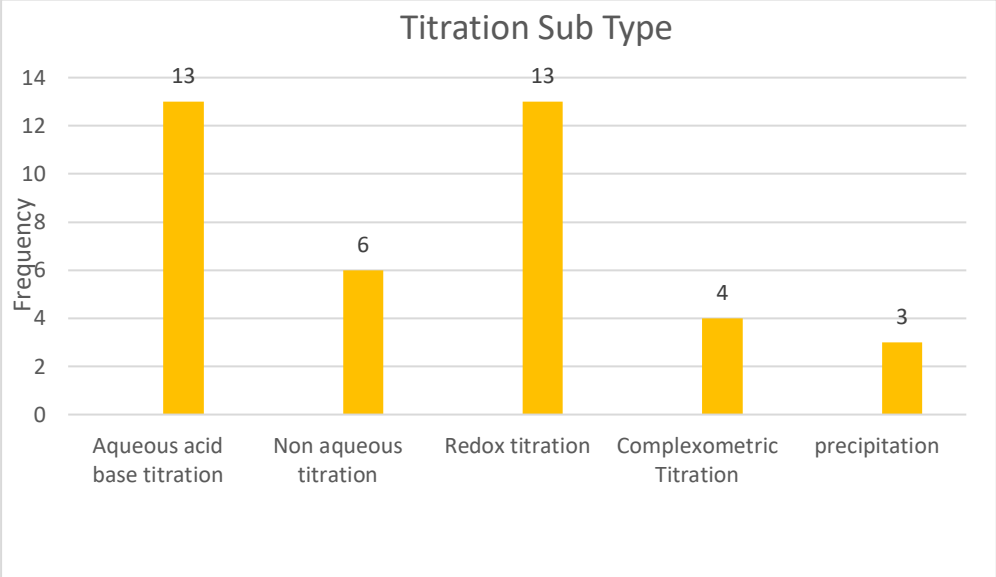

Figure 4: Titration subtypes

After that, in titration techniques have very less use compared to chromatographic techniques like, Due to their lack of specificity, aqueous acid-base titrations cannot be applied to medicines that are neither acidic nor basic. Also, redox titrations are used for materials that go through oxidation-reduction processes, however they are only applicable to materials with particular redox properties. The reliability of the findings may be hampered by potential impurity

interference. Non-aqueous titrations are not suitable for substances with limited solubility in non-aqueous solvents or medications that are insoluble in water. They require careful selection of titrants and solvents that are compatible with the drug ingredient and can create a clearly defined end point. Then complexometric titrations are limited to molecules that form stable complexes, and interference from other complexing agents or ligands can cause unreliable findings. Precipitation titrations have poorer sensitivity and precision, and are limited to compounds that create precipitates.

Following there is spectroscopic sub types are UV, florescence and atomic spectroscopy

Here, UV has been recommended for 40 formulations,

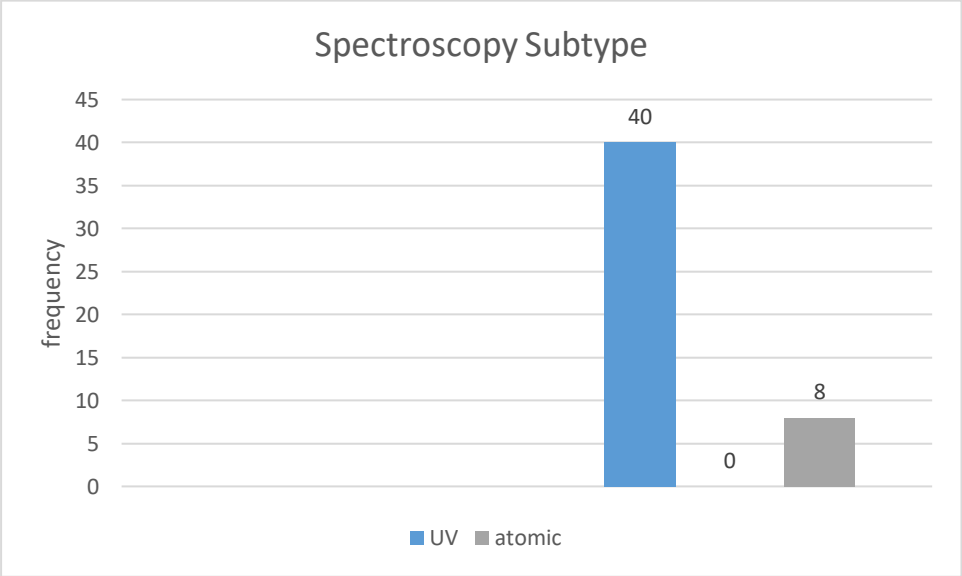

Figure 5: Spectroscopy Subtype

Then there are limitations of fluorescence and atomic spectroscopy-

Fluorescence-based assays are limited to fluorescent molecules emitting light, have a limited capacity. Atomic spectroscopy is constrained by sample preparation, a lack of molecular specificity, and reduced sensitivity in subtyping experiments. Sample preparation can take a long time and involve stages like digestion, extraction, or volatilization that could result in mistakes or sample losses. Atomic spectroscopy methods might not be able to detect low-

abundance subtypes with enough accuracy, and they might not be able to supply complicated biological targets with extensive subtype information.

Lastly, there were 18 formulations found for biological technique that uses sub types like ELISA & RIA. Although ELISA and RIA procedures are often sensitive, in some samples they may not be sensitive enough to identify low amounts of analytes. Issues with cross-reactivity might result in false positive or false negative results, and producing antibodies can be time-consuming and expensive. Inaccurate results might occur from sample matrix interference, which can affect the detection equipment or the antibody-antigen interaction. Accurately measuring analyte concentrations that are extremely low or extremely high can be challenging due to quantitative constraints. The usage of radioactive isotopes in radioactive waste (RIA) might raise safety issues and necessitate unique handling and disposal techniques to maintain radiation safety.

Chapter 4

Conclusion

To conclude, the goal of this project was to create a database that would aid researchers and students in identifying the assay types and subtypes for various formulations. Chromatography, titration, and spectroscopy were some of the techniques employed in the study. Chromatography was the technique most usually recommended due to its advantages in terms of solubility, stability, and selectivity. Generally speaking, the database created for this project provides relevant information on assay types for a number of medicinal compounds, supporting pharmaceutical research, development, and quality control. Through the use of various analytical techniques, it is possible to figure out the medications' purity, concentration, and stability easier. Even while the project is helpful for education, it has several drawbacks. Out of 1247 formulations, 233 monographs are included in this list. As a result, this database collection is incomplete. This database does not provide a complete picture.

References

Caffrey, A. R., & Borrelli, E. P. (2020). The art and science of drug titration. *Therapeutic Advances in Drug Safety*, *11*, 204209862095891. https://doi.org/10.1177/2042098620958910

Coskun, O. (2016). Separation Tecniques: CHROMATOGRAPHY. *Northern Clinics of Istanbul*. https://doi.org/10.14744/nci.2016.32757

FERNANDEZ-MAESTRE, R. (2020). THE IMPORTANCE OF TEACHING TITRATION CURVES IN ANALYTICAL CHEMISTRY. *Periódico Tchê Química*, *17*(34), 213–219. https://doi.org/10.52571/PTQ.v17.n34.2020.230_P34_pgs_213_219.pdf

Ho, N. (1961). British Pharmacopoeia. *American Journal of Health-System Pharmacy*, *18*(1), 88–88. https://doi.org/10.1093/ajhp/18.1.88

Izrio Filho, H. J., Santos Salazar, R. F. dos, Rosa Capri, M. da, Capri, ngelo, de Alcntara, M. A. K., & Castro Peixoto, A. L. de. (2012). State-of-the-Art and Trends in Atomic Absorption Spectrometry. In *Atomic Absorption Spectroscopy*. InTech. https://doi.org/10.5772/26076

Lewen, N. (2011). The use of atomic spectroscopy in the pharmaceutical industry for the determination of trace elements in pharmaceuticals. *Journal of Pharmaceutical and Biomedical Analysis*, *55*(4), 653–661. https://doi.org/10.1016/j.jpba.2010.11.030

M, S., S, M., & S, S. (2021). Highlights of Spectroscopic Analysis – A Review. *International Journal of Life Science and Pharma Research*. https://doi.org/10.22376/ijpbs/lpr.2021.11.2.P136-145

Riley, C. M., Riley, S. R. R., & Phelps, R. L. (2014). Assay and impurities. *Specification of Drug Substances and Products: Development and Validation of Analytical Methods*, 109–142. https://doi.org/10.1016/B978-0-08-098350-9.00006-0