

A DATABASE BASED ON DIFFERENT ASSAY TECHNIQUES OF DRUG SUBSTANCES

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By

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the degree of Bachelor of Pharmacy (B. Pharm)

School of Pharmacy

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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

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Ethics Statement

No humans or animals of any kinds were involved as samples for this study.

Abstract

This paper reviews various analytical methods for drugs that are included in the British pharmacopeia. A list was created based on the different kinds of assay performed for each drug substance. This project can serve as an educational tool. This database is valuable to analytical method developers and they can utilize it. The most common assay may be quickly understood by looking at a bar and pie chart. Titration was found to be the most common assay type.

Keywords: Titration, Spectroscopy, Chromatography

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Table of Contents

Declaration.....	ii
Approval	iii
Ethics Statement.....	iv
Abstract.....	v
Acknowledgement	vi
Table of Contents	vii
List of Figures.....	viii
List of Acronyms	ix
Chapter 1 Introduction.....	1-4
Chapter 2 Method	5
Chapter 3 Result and discussion.....	6-9
Chapter 4 Conclusion	10
References.....	11
Appendix A.....	12-26

List of Figures

Figure 1: Flowchart of methodology	5
Figure 2: Different types of assay type used for analysis substance.....	6
Figure 3: Five different types of titration techniques.....	7
Figure 4: A bar chart of chromatography type.....	8
Figure 5: Ratio of UV spectroscopy and atomic absorption.....	9

List of Acronyms

UV - ultra violet

BP - British Pharmacopeia

HPLC - High Performance Liquid chromatography

GC - Gas Chromatography

Chapter 1

Introduction

Pharmacopeia

The national pharmacopeia of the United Kingdom is known as the British Pharmacopoeia (BP). Individuals and organizations engaged in pharmaceutical research, development, manufacture, and testing refer to it as a collection of quality standards for medicinal substances in the UK that is released annually. By establishing quality standards for UK pharmaceutical ingredients and medicinal goods, the BP significantly contributes to the work of the Medicines and Healthcare products Regulatory Agency (MHRA) in preserving public health. (Kumar et al., 2022)

Active Pharmaceutical Ingredients and Excipients

The chemical-based substances known as active pharmaceutical ingredients (APIs) are mostly produced in the United States, Europe, China, and India. APIs are mostly used in combination with other components to diagnose, treat, and cure disease. They contain pharmacological activity. However, in recent years, a lot of pharmaceutical companies have begun bringing these drugs back to their home nations from the nations that produce the active chemicals. People have employed contemporary medications to treat, diagnose, and cure illnesses. Every single medication is made up of two main parts: the active pharmaceutical ingredient (API), which is the main ingredient and is chemically and biologically active and must perform the action in your body, and the excipients, which are chemically inactive and provide things like volume, a sweet flavor, or color. These excipients aid in the transport of APIs throughout the body. An API is created through a multi-step reaction involving numerous chemical components and raw ingredients. All API, excipient, and reagent kinds as well as the various types of tests that are conducted on them are discussed in bp. The most valuable component of a pharmacological product is the API, which frequently has a higher negative impact on the environment than the excipients. The APIs in the unused medications can be recovered by recycling and later modified into new pharmacological formulations. (Pratama et al., 2020)

Titration

Titration is a method of chemical quantitative analysis used to determine the concentration of a certain analyte in a mixture. Titration is a crucial analytical chemistry technique that is also

frequently referred to as volumetric analysis. Acid-base titration is used in the pharmaceutical industry for a variety of purposes, including analysis, quality control, product development, content analysis by redox titration, and purity analysis of the active ingredients. For example, acetylsalicylic acid in aspirin or vitamin C in multivitamin tablets are examples of active components that can be identified using purity analysis. It is also used to check the purity of drug additives that are added during the manufacturing of pharmaceutical formulations. In order to treat bronchial asthma, cough syrups containing ephedrine hydrochloride must pass a purity test. Depending on the type of substance to be assessed or the sort of analysis to be performed, titration can be divided into a number of categories. Titration that takes place in an aqueous solution is known as "aqueous titration" (solution of water). When determining the concentration of a solute in a sample, aqueous titration uses water instead of a solvent to dissolve the sample. Water-less solvent is referred to as "non-aqueous titration." When using water is not an option, this titration is helpful for testing very weak acids and bases. An acid or base titrant is used to titrate the solute during this procedure. The Bronsted-Lowry theory, which governs acid-base titration, shares the same fundamental principles as non-aqueous titration. Redox titration is a technique used in laboratories to measure the concentration of an analyte by causing a redox reaction between the analyte and the titrant. A redox indicator or potentiometer is frequently required for the redox titration. The oxidation-reduction reaction that takes place between the analyte and the titrant is the basis for the Redox titration. It is also one of the techniques used most frequently to determine the concentration of unidentified analytes. It is crucial to identify the shape of the corresponding titration curve in order to evaluate the redox titrations. It is far more practical to measure the concentration of the reaction potential in redox titration as opposed to the reacting species. In a volumetric analysis called a complexometric titration, the creation of a colored complex serves as a marker for the analysis of titration's endpoint. It is most helpful for figuring out how many distinct metal ions are present in a solution. Complexometric titrations are those volumetric analyses or titrations where the endpoint is indicated by a colored complex. Chelatometric is another name for it. In this sort of titration, an indicator is utilized that can produce a visible color shift in titration that signals the titration's endpoint. The amount of metal ions present in the solution is measured using complexometric titrations. It is a volumetric analysis since the volume of the analyte, titrant, and even the indicator is crucial to the titration process. The complexometric titration makes use of indicators like calcein and Eriochrome black T, among others. (Bell-Young,2021).

Spectroscopy

The study and measurement of spectra formed by matter interacting with or producing electromagnetic radiation is known as spectroscopy. The study of the relationship between radiation and matter as a function of wavelength was the original definition of spectroscopy. Currently, any measurement of a quantity as a function of wavelength or frequency is referred to as spectroscopy. A sample containing molecules of interest is exposed to electromagnetic radiation of a certain wavelength range during a spectroscopy experiment, which causes absorption or emission. The sample takes in energy from the light source during absorption. The sample emits light at a wavelength that differs from the source's during emission. In UV spectroscopy, which is a form of absorption spectroscopy, a molecule absorbs light in the ultraviolet range (200–400 nm), which causes the electrons to be excited from their ground state to a higher energy state. It helps to clarify the structure of organic molecules by identifying heteroatoms and determining whether unsaturation is present or not.

Compounds that absorb UV radiation can be measured quantitatively using UV absorption spectroscopy. UV absorption spectroscopy can characterize the UV-absorbing chemicals that are used to determine the quality of compounds. By contrasting the absorption spectrum with the spectra of recognized substances, identification is accomplished.

Using this method, it is possible to determine if a chemical contains a functional group or not. The lack of a band at a specific wavelength is seen as proof that a certain group does not exist. UV spectroscopy can also be used to study the kinetics of reactions. The reaction cell is exposed to UV radiation, which causes changes in absorbance that may be seen. (Østergaard, 2018)

Chromatography

Chromatography is a method of physical separation. Due to the varied migration rates of the various components along the stationary phase's bed, chromatography is a technique for separating multicomponent mixtures into individual components. It enables the separation of compounds without the requirement for detailed knowledge about the type of substances to be separated, i.e., their number and their relative proportions in the mixture, as is required with other traditional separation procedures (such as crystallization, extraction, or distillation). Chromatography is a very effective analytical technique that is frequently utilized for scientific, industrial, and medicinal objectives due to its versatility and resolving power. It serves as a crucial component of many

scientific investigations' methodologies as well as a tool for monitoring the environment or the synthesis of pure substances in the chemical and pharmaceutical sectors. Pharmaceutical analysis accounts for 30% of chromatography's use, followed by biochemical and clinical chemistry (25%), environmental protection (15%), food and cosmetics (10%), and inorganic compounds (5%); 15% of chromatography's use is for analyses in other sectors. In turn, chromatography is utilized in approximately 75% of all analyses created by different pharmacopeias. (Pyka- pajak, et al.,2022) There are various chromatography techniques available. In this project, reverse phase HPLC and gas chromatography are discussed . Drugs are analyzed using high performance liquid chromatography (HPLC) in order to establish their identities and get quantitative data. (Nikolin et al., 2004)

Gas chromatography is a different well-liked chromatography technique. This is used, for instance, to assess the purity of numerous compounds in the food and pharmaceutical industries. This test can also be used to determine the drug's purity. The compounds must be gaseous in order to be tested here. The solvent is used to dissolve the test combination before it is added to the equipment. There is also a carrier gas introduced. Typically, helium or nitrogen, as they do not react with the combination. The chemicals go through a column that is kept at a specific temperature. The column is 200 m long and only a few millimeters thick. A detector that creates an external chromatogram is located at the end of the column. Components of the liquid mobile phase in column liquid chromatography interact to varied degrees with the solid stationary phase, sometimes referred to as the chromatography media or resin, as the liquid moves through the column. According to how they interact differently physiochemically with the stationary and mobile phases, molecules of interest in the mobile phase are divided.

Aim and objectives

The goal of this project is to create a database that will make it simple for researchers to identify the assay-type of drug substances. Additionally, students can benefit from this resource by using it. They can find out the assay type for an API, excipient, or reagent.

Chapter2

Methods

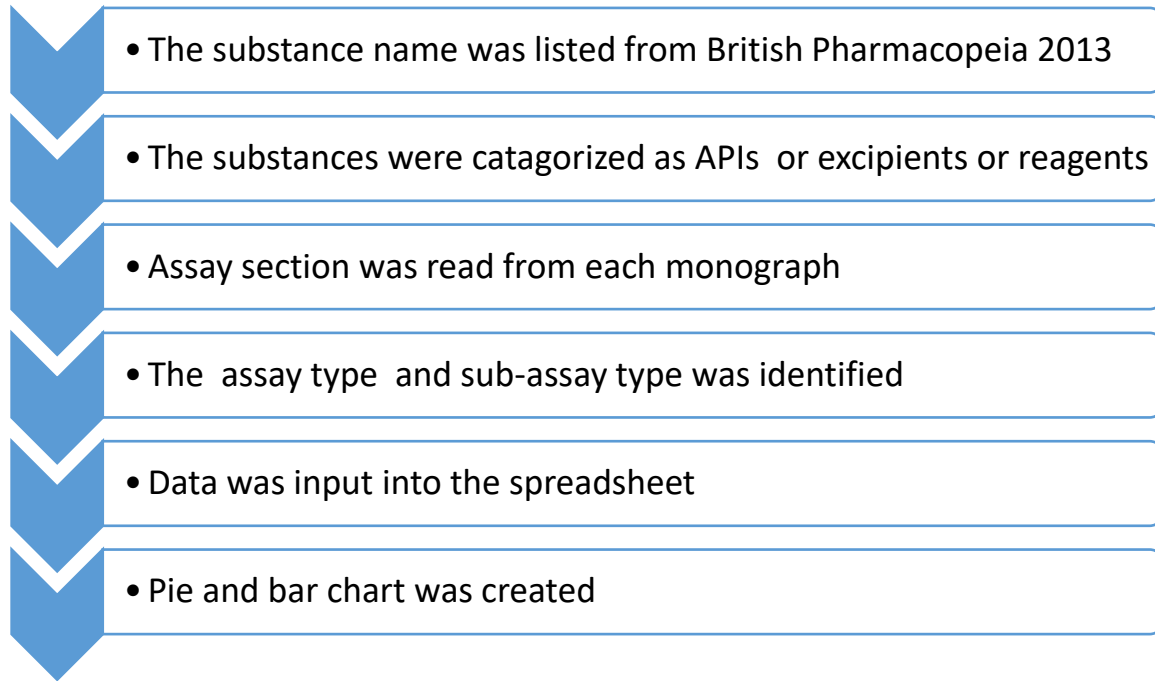


Figure 1: Flowchart of methodology

Chapter3

Result and discussion

Among 218 substances, titration is recommended for 136 of them, chromatography for 38, biological testing for 6, spectroscopy for 10, and gravimetry for 3 and Most often, titration is suggested here.

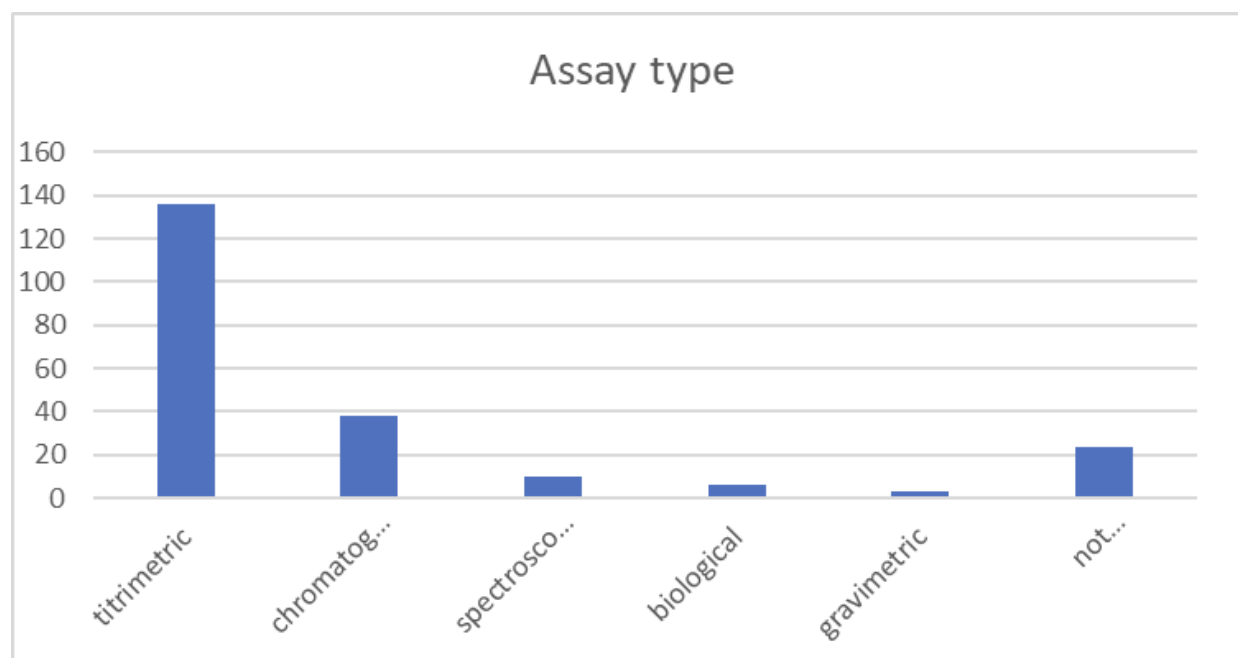


Figure 2: Different kinds of assay type recommended

Titration is primarily employed here since it offers various advantages.

Many medications have good solubility in organic solvents but are insoluble or only partially soluble in water. Solvents like alcohols, ethers, or chloroform can be used in non-aqueous titration because they can dissolve a greater variety of medicines and their derivatives. This guarantees complete medication dissolution, enabling precise and accurate titration. In an aquatic environment, certain medications may hydrolyze or engage in other chemical interactions that provide incorrect results. Non-aqueous titration offers a more stable and regulated environment, reducing the possibility of unintended reactions and ensuring the specificity of the titration

technique. Methods of non-aqueous titration frequently provide higher drug selectivity. The method's selectivity can be improved by adjusting the non-aqueous solvent and titrant selection to the medication under study. This is crucial when the medicine sample has a number of active ingredients or contaminants.

Titration also has the benefit of stability. Some medications can disintegrate in the presence of water or dissolved oxygen because they are susceptible to moisture or oxidation. Non-aqueous titration methods offer a dry setting that reduces the danger of drug degradation and ensures the stability of the substance during analysis.(FERNANDEZ-MAESTRE, 2020)

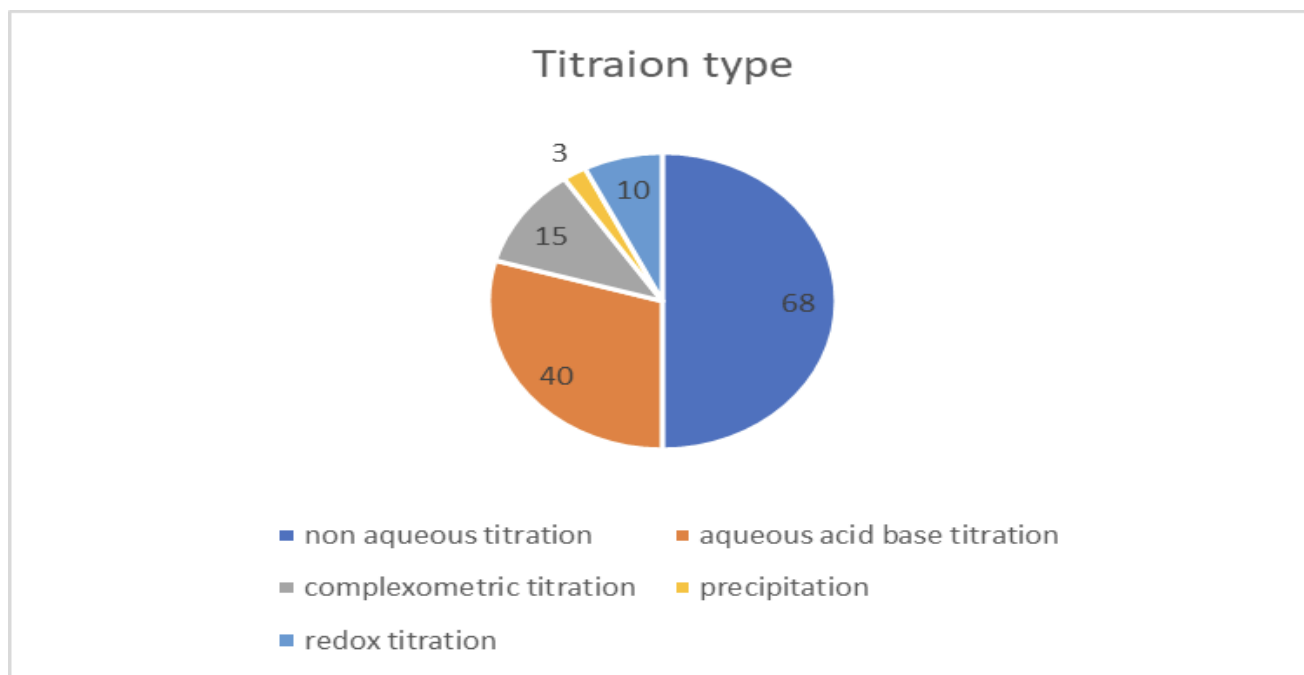


Figure 3: Five different types of titration techniques

Five different types of titration techniques are recommended in the collected database. These include non-aqueous, aqueous, complexometric precipitation, redox titration. Non-aqueous is recommended most. It is beneficial for titrating extremely weak acids or bases. It is possible to dissolve many organic acids that are notsoluble in water using non-aqueous solvents. As a result,

titration of these organic acids is simple. There are 40 compounds that may be assayed by aqueous acid base titration which is the second highest number.

Chromatography has advantages. It is feasible to separate and analyze complicated mixtures using chromatography because of its remarkable separation properties. Drugs are frequently combined with other compounds in biological samples, however chromatography allows for precise separation and differentiation of individual drug components. Because chromatographic methods are so sensitive, it is possible to identify and measure chemicals even at very low quantities. This is crucial for pharmaceutical analysis since precise measurements are required to evaluate the potency, purity, and safety of medicines. (Coskun, 2016)

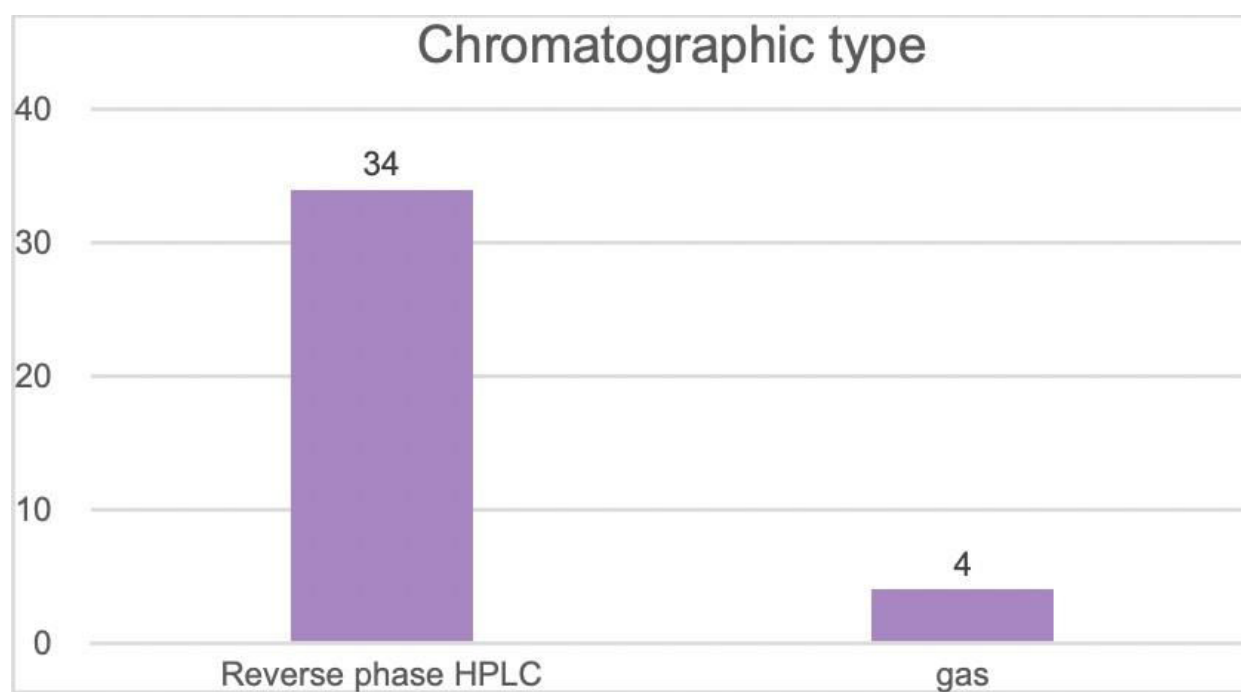


Figure 4: A bar chart of chromatography type

This graph shows that reverse phase HPLC is more commonly used than gas chromatography. In comparison to other chromatographic methods, it is a cost-effective approach. Water can be used with various solvents in the mobile phase of an RP-HPLC study. Reversed-phase Chromatography also has the benefit of accurately producing results from small amounts of sample.

On the other hand, the fundamental drawback of gas chromatography is that it can only separate volatile and thermally stable chemicals.

Spectroscopy is also used here. It is possible to quantify a qualitative property using a spectrophotometer. For instance, the concentration of a specific chemical in a solution can be determined by measuring the absorbance of light by that solution. This is helpful for determining the concentration of active components in liquid medications or the purity of pharmaceuticals.

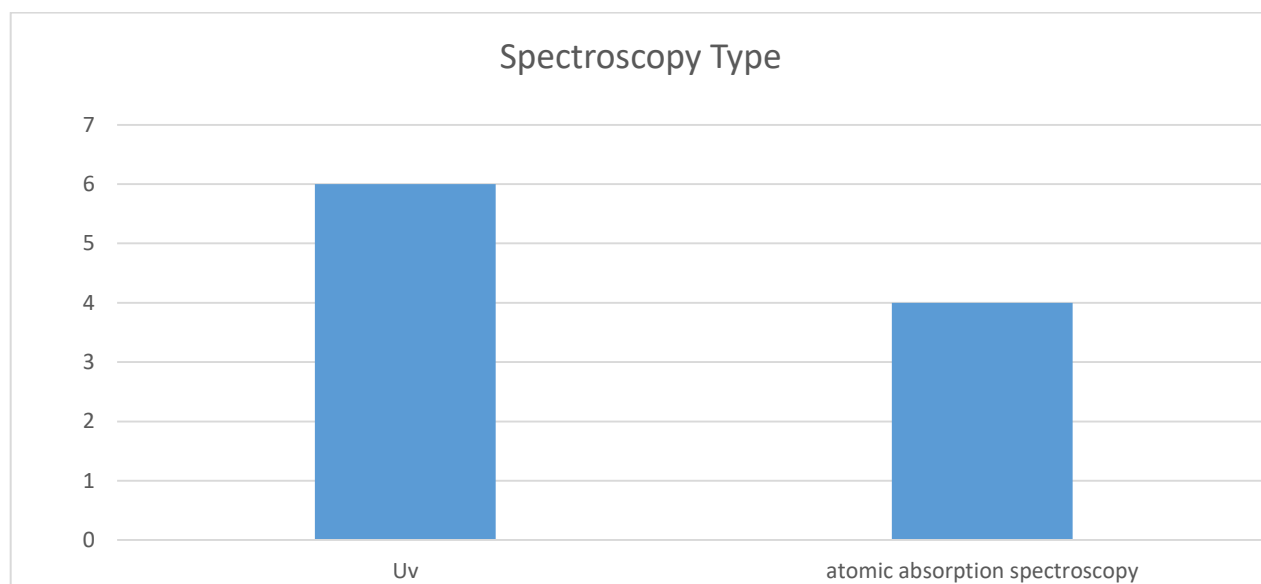


Figure 5: Ratio of UV spectroscopy and atomic absorption

In this graph, it can be seen that UV spectroscopy and atomic absorption spectroscopy were recommended for the drugs included in the database at similar frequency. (M et al., 2021)

On the other hand, gravimetric is less used. It has some limitations. Like, Low amounts of medications cannot be measured accurately using this method. The method is less sensitive than other analytical methods, making it challenging to detect and evaluate small amounts of drugs

Chapter 4

Conclusion

In a nut shell, the objective of this effort was to build a database that would help students and researchers to determine the assay type for various drugs. Gravimetry, chromatography, titration, and spectroscopy were some of the techniques used in the study. Because of its benefits in terms of solubility, stability, and selectivity, titration was the assay type that was most frequently advised among these techniques. Overall, the database developed for this project offers useful data on assay types for a variety of drug substances, assisting pharmaceutical research, development, and quality control. It is possible to gain a thorough understanding of the characteristics of drugs through the use of several analytical techniques, which also makes it easier to determine the purity, concentration, and stability of drugs. Researchers and students will gain from having an easily accessible resource for determining the right assay type for APIs, excipients, or reagents in pharmaceutical formulations when this material has been consolidated. The project has limitations, despite the fact that it is useful for teaching purposes. This list includes 218 monographs out of 1450. As a result, this is not a complete set of database. The entire picture cannot be understood from this database.

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Appendix A.

Constructed Database of assay type and subtype

Substance	Substance type	Assay type	Assay subtype		
Acacia	excipient			Not mentioned	
Spray dried acacia	excipient			Not mentioned	
Acamprosate calcium	API	titrimetric	aqueous acid base titration		
Acarbose	API	chromatographic	reverse phase HPLC		
Acebutolol Hydrochloride	API	titrimetric	aqueous acid base titration		
Aceclofenac	API	titrimetric	aqueous acid base titration		
Acemetacin	API	titrimetric	aqueous acid base titration		
Acenocoumarol	API	titrimetric	aqueous acid base titration		
Acesulfame Potassium	excipient	titrimetric	non aqueous titration		
Acetazolamide	API	titrimetric	aqueous acid base titration		
Glacial Acetic Acid	excipient	titrimetric	aqueous acid base titration		
Acetic Acid (6 per cent)	excipient	titrimetric	aqueous acid base titration		
Acetic Acid (33 per cent)	excipient	titrimetric	aqueous acid base titration		

Substance	Substance type	Assay type	Assay subtype		
Acetone	reagent			Not mentioned	
Acetylcholine Chloride	API	titrimetric	aqueous acid base titration		
Acetylcysteine	API	titrimetric	redox titration		
Acetyldigoxin	API	chromatographic	reverse phase HPLC		
Acetyltryptophan	API	titrimetric	aqueous acid base titration		
Acetytyrosine	API	titrimetric	aqueous acid base titration		
Aciclovir	API	titrimetric	non aqueous titration		
Acitretin	API	chromatographic	reverse phase HPLC		
Adapalene	API	chromatographic	reverse phase HPLC		
Adenine	excipient	titrimetric	non aqueous titration		
Adenosine	API	titrimetric	non aqueous titration		
Adipic Acid	excipient	titrimetric	aqueous acid base titration		
Adrenaline / Epinephrine	API	titrimetric	non aqueous titration		
Adrenaline Acid Tartrate / Epinephrine Acid Tartrate	API	titrimetric	non aqueous titration		
Agar	excipient			Not mentioned	

Substance	Substance type	Assay type	Assay subtype		
Medical Air				Not mentioned	
Synthetic Air				Not mentioned	
Alanine	API	titrimetric	non aqueous titration		
Albendazole	API	titrimetric	non aqueous titration		
Alcuronium Chloride	API	titrimetric	non aqueous titration		
Alfacalcidol	API	chromatographic	reverse phase HPLC		
Alfadex	API	chromatographic	reverse phase HPLC		
Alfentanil Hydrochloride	API	titrimetric	aqueous acid base titration		
Alfuzosin Hydrochloride	API	titrimetric	non aqueous titration		
Alginic Acid	excipient	titrimetric	aqueous acid base titration		
Alimemazine Tartrate	API	titrimetric	non aqueous titration		
Allantoin	API	titrimetric	aqueous acid base titration		
Allergen Products				not mentioned	
Allopurinol	API	chromatographic	reverse phase HPLC		
Almagate	API	titrimetric	complexometric titration	Al	

Substance	Substance type	Assay type	Assay subtype		
Almagate	API	titrimetric	complexometric titration	Mg	
Almagate	API	chromatographic	gas	Carbonic acid	
Aloxiprin	API	gravimetric		Al	
Aloxiprin	API	spectroscopic	UV	salicylates	
Alprazolam	API	titrimetric	non aqueous titration		
Alprenolol Hydrochloride	API	titrimetric	aqueous acid base titration		
Alprostadil	API	chromatographic	reverse phase HPLC		
Alteplase for Injection	API			Not mentioned	
Altizide	API	chromatographic	reverse phase HPLC		
Alum	API	titrimetric	complexometric titration		
Aluminium Chloride Hexahydrate	API	titrimetric	complexometric titration		
Aluminium Glycinate	API	titrimetric	complexometric titration		
Hydrated Aluminium Hydroxide for Adsorption	excipient	titrimetric	complexometric titration		
Dried Aluminium Hydroxide	API	titrimetric	complexometric titration		

Substance	Substance type	Assay type	Assay subtype		
Aluminium Magnesium Silicate	excipient	spectroscopic	atomic absorption spectroscopy	Al	
Aluminium Magnesium Silicate	excipient	spectroscopic	atomic absorption spectroscopy	Mg	
Dried Aluminium Phosphate	API	titrimetric	complexometric titration		
Aluminium Phosphate Gel	API	titrimetric	complexometric titration		
Aluminium Powder	API	titrimetric	redox titration		
Aluminium Sodium Silicate	excipient	spectroscopic	atomic absorption spectroscopy	Al	
Aluminium Sodium Silicate	excipient	spectroscopic	atomic absorption spectroscopy	Na	
Aluminium Stearate	excipient	titrimetric	complexometric titration	Al	
Aluminium Stearate	excipient	chromatographic	gas	stearic acid	
Aluminium Stearate	excipient	chromatographic	gas	palmitic acid	
Aluminium Sulfate	API	titrimetric	complexometric titration		
Alverine Citrate	API	titrimetric	non aqueous titration		

Substance	Substance type	Assay type	Assay subtype		
Amantadine Hydrochloride	API	titrimetric	non aqueous titration		
Ambroxol Hydrochloride	API	titrimetric	non aqueous titration		
Amfetamine Sulfate	API	titrimetric	non aqueous titration		
Amidotrizoic Acid Dihydrate	API	titrimetric	precipitation		
Amikacin	API	chromatographic	reverse phase HPLC		
Amikacin Sulfate	API	chromatographic	reverse phase HPLC		
Amiloride Hydrochloride	API	titrimetric	non aqueous titration		
Aminobenzoic Acid	API	titrimetric	aqueous acid base titration		
Aminocaproic Acid	API	titrimetric	non aqueous titration		
Aminoglutethimide	API	titrimetric	non aqueous titration		
Aminophylline	API	titrimetric	aqueous acid base titration	Ethylenediamine	
Aminophylline	API	titrimetric	aqueous acid base titration	Theophylline	
Aminophylline Hydrate	API	titrimetric	aqueous acid base titration	Ethylenediamine	
Aminophylline Hydrate	API	titrimetric	aqueous acid base titration	Theophylline	

Substance	Substance type	Assay type	Assay subtype		
Amiodarone Hydrochloride	API	titrimetric	non aqueous titration		
Amisulpride	API	titrimetric	non aqueous titration		
Amitriptyline Embonate	API	titrimetric	non aqueous titration		
Amitriptyline Hydrochloride	API	titrimetric	non aqueous titration		
Amlodipine Besilate	API	chromatographic	reverse phase HPLC		
Strong Ammonia Solution				not mentioned	
Ammonio Methacrylate Copolymer (Type A)				not mentioned	
Ammonio Methacrylate Copolymer (Type B)				not mentioned	
Ammonium Bicarbonate				Not mentioned	
Ammonium Bromide	reagent	titrimetric	precipitation		
Ammonium Chloride	API	titrimetric	aqueous acid base titration		
Ammonium Glycyrrhizinate	excipient	titrimetric	non aqueous titration		

Substance	Substance type	Assay type	Assay subtype		
Amobarbital	API	titrimetric	non aqueous titration		
Amobarbital Sodium	API	titrimetric	non aqueous titration		
Amoxicillin Sodium	API	chromatographic	reverse phase HPLC		
Amoxicillin Trihydrate	API	chromatographic	reverse phase HPLC		
Amphotericin	API	biological			
Ampicillin	API	chromatographic	reverse phase HPLC		
Ampicillin Sodium	API	chromatographic	reverse phase HPLC		
Ampicillin Trihydrate	API	chromatographic	reverse phase HPLC		
Amylmetacresol	API	chromatographic	gas		
Antazoline Hydrochloride	API	titrimetric	non aqueous titration		
Apomorphine Hydrochloride Hemihydrate	API	titrimetric	non aqueous titration		
Aprotinin	API	biological			
Aprotinin Concentrated Solution	API	biological			
Arginine	excipient	titrimetric	aqueous acid base titration		
Arginine Aspartate	excipient	titrimetric	non aqueous		

Substance	Substance type	Assay type	Assay subtype		
			titration		
Arginine Hydrochloride	excipient	titrimetric	non aqueous titration		
Argon	excipient			not mentioned	
Articaine Hydrochloride	API	titrimetric	non aqueous titration		
Ascorbic Acid	API	titrimetric	redox titration		
Ascorbyl Palmitate	excipient	titrimetric	redox titration		
Asparagine Monohydrate	excipient	titrimetric	non aqueous titration		
Aspartame	excipient	titrimetric	non aqueous titration		
Aspartic Acid	excipient	titrimetric	aqueous acid base titration		
Aspirin	API	titrimetric	aqueous acid base titration		
Atenolol	API	titrimetric	non aqueous titration		
Atorvastatin Calcium Trihydrate	API	chromatographic	reverse phase HPLC		
Atracurium Besilate	API	chromatographic	reverse phase HPLC		
Atropine	API	titrimetric	non aqueous titration		
Atropine Sulfate	API	titrimetric	non aqueous titration		
Attapulgite	excipient			not mentioned	

Substance	Substance type	Assay type	Assay subtype		
Activated Attapulgite	API			not mentioned	
Azapropazone	API	titrimetric	non aqueous titration		
Azathioprine	API	titrimetric	non aqueous titration		
Azelastine Hydrochloride	API	titrimetric	non aqueous titration		
Azithromycin	API	chromatographic	reverse phase HPLC		
Bacampicillin Hydrochloride	API	chromatographic	reverse phase HPLC		
Bacitracin	API	biological			
Bacitracin zinc	API	biological		not mentioned	
Baclofen	API	titrimetric	non aqueous titration		
Bambuterol Hydrochloride	API	titrimetric	non aqueous titration		
Barbital	API	titrimetric	non aqueous titration		
Barium Sulfate	reagent			not mentioned	
Barium Sulfate for Suspension	reagent	gravimetric			
Anhydrous Beclometasone Dipropionate	API	chromatographic	reverse phase HPLC		
Beclometasone Dipropionate Monohydrate	API	chromatographic	reverse phase HPLC		
White Beeswax	excipient			not mentioned	

Substance	Substance type	Assay type	Assay subtype		
Yellow Beeswax	excipient			not mentioned	
Benazepril Hydrochloride	API	chromatographic	reverse phase HPLC		
Bendroflumethiazide	API	titrimetric	non aqueous titration		
Benorilate	API	gravimetric			
Benperidol	API	titrimetric	non aqueous titration		
Benserazide Hydrochloride	API	titrimetric	non aqueous titration		
Bentonite	API			not mentioned	
Benzaldehyde	excipient	titrimetric	non aqueous titration		
Benzalkonium Chloride	API	titrimetric	redox titration		
Benzalkonium Chloride Solution	API	titrimetric	redox titration		
Benzathine Benzylpenicillin	API	chromatographic	reverse phase HPLC		
Benzatropine Mesilate	API	titrimetric	non aqueous titration		
Benzbromarone	API	titrimetric	aqueous acid base titration		
Benzethonium Chloride	API	titrimetric	redox titration		
Benzocaine	API	titrimetric	redox titration		
Benzoic Acid	API	titrimetric	aqueous acid base titration		
Hydrous Benzoyl Peroxide	API	titrimetric	redox titration		

Substance	Substance type	Assay type	Assay subtype		
Benzydamine Hydrochloride	API	titrimetric	non aqueous titration		
Benzyl Alcohol	API	titrimetric	aqueous acid base titration		
Benzyl Benzoate	API	titrimetric	aqueous acid base titration		
Benzyl Hydroxybenzoate	excipient	titrimetric	redox titration		
Benzylpenicillin Potassium	API	chromatographic	reverse phase HPLC		
Benzylpenicillin Sodium	API	chromatographic	reverse phase HPLC		
Betacarotene	API	spectroscopic	UV		
Betadex	excipient	chromatographic	reverse phase HPLC		
Betahistine Dihydrochloride	API	titrimetric	aqueous acid base titration		
Betahistine Mesilate	API	titrimetric	non aqueous titration		
Betamethasone	API	spectroscopic	UV		
Betamethasone Acetate	API	spectroscopic	UV		
Betamethasone Dipropionate	API	chromatographic	reverse phase HPLC		
Betamethasone Sodium Phosphate	API	spectroscopic	UV		
Betamethasone Valerate	API	spectroscopic	UV		
Betaxolol Hydrochloride	API	titrimetric	aqueous acid base titration		

Substance	Substance type	Assay type	Assay subtype		
Bezafibrate	API	titrimetric	aqueous acid base titration		
Bicalutamide	API	chromatographic	reverse phase HPLC		
Bifonazole	API	titrimetric	non aqueous titration		
Biotin	API	titrimetric	non aqueous titration		
Biperiden Hydrochloride	API	titrimetric	non aqueous titration		
Bisacodyl	API	titrimetric	non aqueous titration		
Bismuth Subcarbonate	API	titrimetric	complexometric titration		
Bismuth Subgallate	API	titrimetric	complexometric titration		
Heavy Bismuth Subnitrate	API	titrimetric	complexometric titration		
Bismuth Subsalicylate	API	titrimetric	complexometric titration		
Bisoprolol Fumarate	API	titrimetric	non aqueous titration		
Bleomycin Sulfate	API	biological			
Borax	API	titrimetric	aqueous acid base titration		
Boric Acid	excipient	titrimetric	aqueous acid base titration		
Botulinum Toxin Type A for Injection	API			not mentioned	
Botulinum Toxin				not mentioned	

Substance	Substance type	Assay type	Assay subtype		
Type B for Injection					
Bovine Serum				not mentioned	
Bretylum Tosilate	API	titrimetric	non aqueous titration		
Bromazepam	API	titrimetric	non aqueous titration		
Bromhexine Hydrochloride	API	titrimetric	aqueous acid base titration		
Bromocriptine Mesilate	API	titrimetric	non aqueous titration		
Bromperidol	API	titrimetric	non aqueous titration		
Bromperidol Decanoate	API	titrimetric	non aqueous titration		
Brompheniramine Maleate	API	titrimetric	non aqueous titration		
Bronopol	excipient	titrimetric	precipitation		
Brotizolam	API	titrimetric	non aqueous titration		
Buclizine Hydrochloride	API	titrimetric	non aqueous titration		
Budesonide	API	chromatographic	reverse phase HPLC		
Bufexamac	API	titrimetric	non aqueous titration		
Buflomedil Hydrochloride	API	titrimetric	non aqueous titration		
Bumetanide	API	titrimetric	aqueous acid base titration		
Bupivacaine	API	titrimetric	aqueous acid		

Substance	Substance type	Assay type	Assay subtype		
Hydrochloride			base titration		
Buprenorphine	API	titrimetric	non aqueous titration		
Buprenorphine Hydrochloride	API	titrimetric	aqueous acid base titration		
Buserelin	API	chromatographic	reverse phase HPLC		
Bupirone Hydrochloride	API	titrimetric	non aqueous titration		
Busulfan	API	titrimetric	aqueous acid base titration		
Butyl Hydroxybenzoate	excipient	chromatographic	reverse phase HPLC		
Butylated Hydroxyanisole	excipient			not mentioned	
Butylated Hydroxytoluene	excipient			not mentioned	
Cabergoline	API	chromatographic	reverse phase HPLC		
Caffeine	API	titrimetric	non aqueous titration		
Caffeine Hydrate	API	titrimetric	non aqueous titration		