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A Comparative Evaluation of Purity of Different Brands of Marketed Hydrochlorothiazide Tablets

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ABSTRACT: Hydrochlorothiazide is a short acting thiazide diuretic. Hydrochlorothiazide (HCTZ) is widely used to treat hypertension and oedema. This agent's metabolite appears to preferentially bind to and accumulate in red blood cells. This agent is primarily excreted by the kidneys.Ultraviolet and visible absorption spectrophotometry is the measurement of the absorption of monochromatic radiation by solutions of chemical substances, in the range of 185nm to 380nm, and 380nm to 780nm of the spectrum, respectively.The magnitude of the absorption of a solution is expressed in terms of the absorbance, A, defined as the logarithm to base of 10 of the reciprocal of transmittance (T) for monochromatic radiation

Here, we are studying the percentage labelled claim of different brands of the marketed hydrochlorothiazide tablets using UV Spectrophotometry.

KEYWORDS: Hydrochlorothiazide, spectrophotometry, monochromatic, transmittance.

I. INTRODUCTION

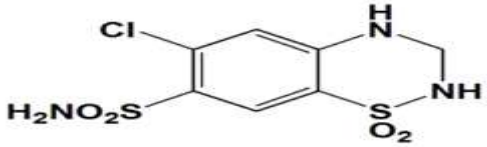
[1] Hydrochlorothiazide (HCTZ) is a thiazide-type diuretic that has been used clinically for more than half a century. The drug has been widely used to treat hypertension globally and is relatively very safe. Hydrochlorothiazide acts on the distal convoluted tubules and inhibits the sodium chloride co-transporter system. This action leads to a diuretic action that lowers blood pressure, but there is also a potassium loss in the urine.

Hydrochlorothiazide is a short acting thiazide diuretic. Hydrochlorothiazide (HCTZ) is widely used to treat hypertension and oedema. This agent's metabolite appears to preferentially bind to and accumulate in red blood cells. This agent is primarily excreted by the kidneys.

At the dose commonly prescribed in clinical practice of 12.5–25 mg/day, HCTZ was shown to modest effect on 24-hr ambulatory BP by 6.5/4.5 mmHg. This magnitude of reduction in BP was inferior to other drug classes, including angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), and calcium channel blockers (CCBs). The antihypertensive efficacy of HCTZ was found to be similar to other drug classes only at the higher daily dose of 50 mg.

[2] In a recent meta-analysis HCTZ the daily dose between 12.5–25 mg, caused a smaller reduction in clinic BP when compared to low dose CTD and Bendroflumethiazide. The estimated doses of Bendroflumethiazide, CTD, and HCTZ predicted to lower clinic systolic BP by 10 mmHg was 1.4, 8.6, and 26.4 mg, respectively. At the higher dose range, however, all three thiazide diuretics were shown to cause similar reduction in BP, suggesting difference in potency but not maximal efficacy. Another meta-analysis conducted by the British National Institute for Health and Clinical Excellence (NICE) group showed that indapamide was more potent than HCTZ in lowering BP.

II. CHEMISTRY



Hydrochlorothiazide

Figure 1: Chemical Structure of Hydrochlorothiazide

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IUPAC NOMENCLATURE: 6-chloro-1,1-dioxo-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide

[3] Hydrochlorothiazide is a benzothiadiazine that is 3,4-dihydro-2H-1,2,4-benzothiadiazine 1,1-dioxide substituted by a chloro group at position 6 and a sulphonamide at 7. It is diuretic used for the treatment of hypertension and congestive heart failure. It has a role as a xenobiotic, an environmental contaminant, a diuretic and an antihypertensive agent. It is a benzothiadiazine, a sulfonamide and an organochlorine compound.

STRUCTURE ACTIVITY RELATIONSHIP

General structure activity of thiazide diuretics can be summarized as:

- Chlorothiazide is the simplest member of the series.
- Hydrogen atom at the 2-N is most acidic due to presence of electron-withdrawing group.
- Sulfonamide group at C-7 position provides additional acidity to the drug.
- Electron withdrawing group is essential at position 6 for diuretic activity of the drug.
- Substitution of hydrogen at 6 position gives little diuretic activity, whereas, substitution with chloro and trifluoromethyl groups gives highly active compounds.
- Substitution of electron donating group at position 6 significantly reduces the diuretic activity.
- Replacement or removal of sulfonamide groups from position 7 significantly reduces the diuretic activity.
- Saturation of the double bond to give 2,4-dihydro derivative are 10-folds more active than the unsaturated compounds.
- Substitution of a lipophillic group at 3 position increases the potency.
- Substitution with the entities such as haloalkyl, aralkyl or thioether gives compounds with longer duration of action due to increased lipid solubility.
- Alkyl substitution at the 2-N position can increase the action duration.

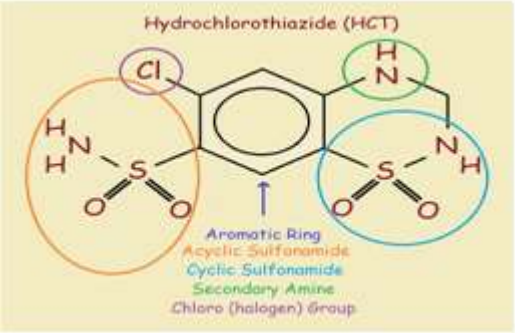

Figure 2: Structure of Hydrochlorothiazide for SAR

METHOD OF SYNTHESIS

Cyclization of 4,6-sulfonamido-3-chloroaniline by using paraformaldehyde and simultaneous reduction of double bond at C3-C4 to get the drug hydrochlorothiazide.

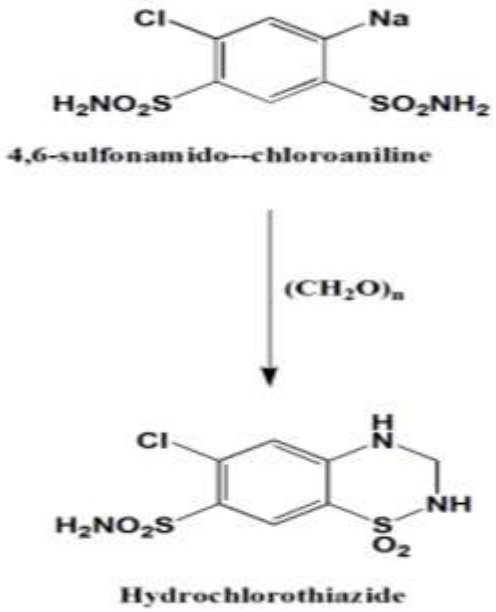

Figure 3: Synthesis of Hydrochlorothiazide

III. PHARMACOLOGY

CLASSIFICATION

Thiazide diuretics

MECHANISM OF ACTION

[4] Hydrochlorothiazide inhibits sodium chloride transport in the distal convoluted tubule. More sodium is then excreted in the kidney with accompanying fluid. Pharmacological effects begin

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in about 2 hours after an oral dose, peak in 4 hours, and lasts for about 6 to 12 hours. Hydrochlorothiazide is not metabolized, and a majority is excreted in the urine unchanged. It also causes a loss of potassium and bicarbonate.

The long-term actions of hydrochlorothiazide when it comes to reduction in blood pressure are not well understood. When administered acutely, the drug does lower blood pressure by promoting diuresis and decreasing plasma volume. However, following chronic use, hydrochlorothiazide appears to be reducing blood pressure by decreasing peripheral resistance. How the drug causes vasodilation is not known, but laboratory evidence suggests that it may be inhibiting the enzyme carbonic anhydrase, desensitizing the smooth muscle receptors to the rise in calcium, or preventing autoregulation in the kidneys.

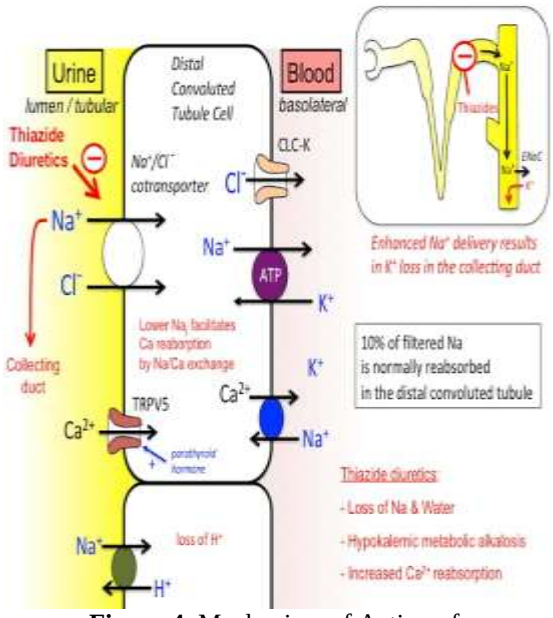

Figure 4: Mechanism of Action of Hydrochlorothiazide

USES

- [5] This medication is used to treat high blood pressure. Lowering high blood pressure helps prevent strokes, heart attacks and kidney problems. Use this medication regularly to get the most benefit.
- Hydrochlorothiazide belongs to a class of drugs known as diuretics/water pills." It works by causing you to make more urine. This helps your body get rid of extra salt and water.
- This medication also reduces extra fluid in the body (oedema) caused by conditions such as heart failure, liver disease or kidney disease.
- This can lessen symptoms such as shortness of breath or swelling in your ankles or feet.
- Hydrochlorothiazide may also be used treat patients with diabetes insipidus and to prevent kidney stones in patients with high levels of calcium in their blood. Talk to your doctor about the possible risks of using this medicine for your condition.
- It's also used to treat swelling that's caused by heart failure, liver damage (cirrhosis) and taking medication called corticosteroids and estrogens

ADVERSE DRUG REACTION

[6] If you experience any of the following symptoms, call your doctor immediately or get emergency medical treatment:

- dry mouth; thirst; nausea; vomiting; weakness, tiredness; drowsiness; restlessness; confusion; muscle weakness, pain, or cramps; fast heartbeat and other signs of dehydration and electrolyte imbalance
- blisters or peeling skin
- hives
- rash
- itching
- difficulty breathing or swallowing
- fever, sore throat, chills, and other signs of infection
- unusual bleeding or bruising
- ongoing pain that begins in the stomach area, but may spread to the back
- Hypokalaemia, or low blood levels of potassium are an occasional side effect. It can be usually prevented by potassium supplements or by combining hydrochlorothiazide with a potassium-sparing diuretic
- Hyperglycaemia, high blood sugar
- Hyperlipidaemia, high cholesterol and triglycerides

DOSAGE

In a double-blind, randomized study, the effects of 25 mg/day vs. 50 mg/day of hydrochlorothiazide were evaluated in geriatric patients (n = 51) with isolated systolic hypertension. Both dosages were associated with similar reductions in blood pressure; however, the higher dose (50 mg/day) caused a greater decline in serum potassium concentration. For this reason

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12.5 mg/day is most often initiated for the antihypertensive effects.

Senior dosage (ages 65 years and older)

There are no specific recommendations for senior dosing. Older adults may process drugs more slowly. A normal adult dosage may cause levels of this drug to be higher than normal in your body. If you're a senior, you may need a lower dosage or a different dosing schedule.

Dosage for edema

Adult dosage (ages 18 to 64 years)

- **Typical dosage:** 25 to 100 mg each day, taken by mouth as a single or divided dose.
- **Intermittent therapy:** Many people respond to intermittent therapy. This means that you may need to take this drug every other day or for three to five days each week. Taking the drug this way lowers your risk of an imbalance in your electrolytes.

Child dosage (ages 12 to 17 years)

- **Typical dosage:** 25 to 100 mg each day, taken by mouth as a single or divided dose.
- **Intermittent therapy:** Many people respond to intermittent therapy. This means your child may need to take this drug every other day or for three to five days each week. Taking the drug this way lowers your child's risk of an imbalance in their electrolytes.

Child dosage (ages 3 to 11 years)

- **Typical dosage:** The usual dosage is 0.5 to 1 mg per pound per day, taken in a single dose or two divided doses.
- **Maximum daily dosage:** 100 mg.

INTERACTIONS

Hydrochlorothiazide oral tablet can interact with several other medications. Different interactions can cause different effects. For instance, some can interfere with how well a drug works, while others can cause increased side effects.

Barbiturates: If you take these drugs with hydrochlorothiazide, your blood pressure may be lowered too much. You may have symptoms such as feeling dizzy when you stand up after sitting or lying down. Examples of these drugs include:

- phenobarbital
- pentobarbital

Lithium: In general, **lithium** shouldn't be taken with hydrochlorothiazide. That's because hydrochlorothiazide slows the clearance of lithium from your body. This increases your risk of high levels of lithium in your body, which can cause dangerous side effects.

Cholesterol-lowering drugs: Taking hydrochlorothiazide with certain drugs that lower cholesterol levels may make hydrochlorothiazide less effective. This means it may not work as well to treat your blood pressure or swelling. Examples of these cholesterol drugs include:

- cholestyramine
- colestipol

Corticosteroids: Hydrochlorothiazide can lower your electrolyte levels. Taking corticosteroids with hydrochlorothiazide can cause further loss of electrolytes (especially potassium). Low potassium levels can lead to constipation, fatigue, muscle breakdown, and weakness. Examples of these drugs include:

- prednisone
- methylprednisolone

Diabetes drugs: Hydrochlorothiazide can cause high blood sugar levels. If you take hydrochlorothiazide with diabetes drugs, your doctor may increase your dosage of your diabetes medications. Examples of these drugs include:

- insulin
- oral diabetes drugs, such as:
  - metformin
  - glimepiride
  - pioglitazone

[10]**Narcotics:** Taking hydrochlorothiazide with narcotics can make your blood pressure drop too low. You may have symptoms such as feeling dizzy when you stand up after sitting or lying down. Examples of these drugs include:

- morphine
- codeine

Nonsteroidal anti-inflammatory drugs (NSAIDs): Taking NSAIDs with hydrochlorothiazide can make hydrochlorothiazide less effective. This means it may not work as well to treat your blood pressure or swelling. Examples of these drugs include:

- ibuprofen
- naproxen

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IV. ULTRAVIOLET AND VISIBLE ABSORPTION SPECTROSCOPY

[7] Ultraviolet and visible absorption spectrophotometry is the measurement of the absorption of monochromatic radiation by solutions of chemical substances, in the range of 185nm to 380nm, and 380nm to 780nm of the spectrum, respectively.

The magnitude of the absorption of a solution is expressed in terms of the absorbance, A, defined as the logarithm to base of 10 of the reciprocal of transmittance (T) for monochromatic radiation:

$$A=\log_{10}(I_o/I)$$

Where,

I_o= the intensity of the incident radiation

I= the intensity of the transmitted radiation

The absorbance depends on the concentration of the absorbing substance in the solution and the thickness of the absorbing layer taken for measurement.

For convenience of reference and for ease of calculations, the specific absorbance of a 1%w/v solution is adopted in this Pharmacopoeia for several substances unless otherwise indicated, and it refers to the absorbance of a 1%w/v in a 1cm cell and measured at a defined wavelength. It is evaluated by the expression,

$$A(1\%,1cm) = A/cl$$

Where,

c is the concentration of the absorbing substance expressed as percentage w/v

l is the thickness of the absorbing layer in cm

The value of A(1%,1cm) at a particular wavelength in a given solvent is a property of the absorbing substance.

Unless otherwise stated, measure the absorbance at the prescribed wavelength using a path length of 1cm and at 24° to 26°. Unless otherwise stated, the measurements are carried out with reference to the same solvent or the same mixture of solvents.

APPARATUS

[8] A spectrophotometer, suitable for measuring the ultraviolet and visible ranges of the spectrum consists of an optical system capable of producing monochromatic light in the range of 200 nm to 800 nm and a device suitable for measuring the absorbance.

The two empty cells used for the solutions under examination and the reference liquid must have the same spectral characteristics. Where double-beam-recording instruments are used, the solvent cell is placed in the reference beam.

Figure 5: UV Spectrophotometer

CONTROL OF WAVELENGTHS

[7] Verify the wavelength scale using the absorption maxima of holmium perchlorate solution, the line of hydrogen or deuterium discharge lamp or the lines of a mercury vapour are tabulated below. The permitted tolerance is ±1 nm for the range 200 nm to 400 nm and ±3nm for the range 400 nm to 600 nm

241.15 nm (Ho)	404.66 nm (Hg)
253.70 nm (Hg)	435.83 nm (Hg)
287.15 nm (Ho)	486.00 nm (Db)
302.25 nm (Hg)	486.10 nm (Hb)
313.16 nm (Hg)	536.30 nm (Ho)
334.15 nm (Hg)	546.07 nm (Hg)
361.50 nm (Ho)	576.96 nm (Hg)
365.48 nm (Hg)	579.07 nm (Hg)

Table 1: Control of Wavelength

CONTROL OF ABSORBANCE

Check the absorbance using suitable filters or a solution of potassium dichromate UV at the wavelengths indicated in table, which gives for each wavelength the exact values and permitted limits of the specific absorbance. The tolerance of the absorbance is ±0.01.

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Use solutions of potassium dichromate UV which has been previously dried to constant weight at 130°. For the control of absorbance at 235 nm, 257 nm, 313 nm and 350 nm, dissolve 57.0-63.0 mg of potassium dichromate UV in 0.005 M sulphuric acid and dilute to 1000.0 ml with the same acid. For the control of absorbance at 430 nm, dissolve 57-63 mg of potassium dichromate UV in 0.005 M sulphuric acid and dilute to 100.0 ml with the same acid.

Wavelength (nm)	Specific Absorbance	Maximum Tolerance
235	124.5	122.9 to 126.2
257	144.5	142.8 to 146.2
313	48.6	47.0 to 50.3
350	107.3	105.6 to 109.0
430	15.9	15.7 to 16.1

Table 2: Control of Absorbance

LIMIT OF STRAY LIGHT

Stray light may be detected at a given wavelength with suitable filters or solutions; for example, absorbance of a 1.2%w/v solution of potassium chloride in a 1 cm cell should be greater than 2.0 at about 200 nm when compared with water as reference liquid.

RESOLUTION POWER

When stated in a monograph, record the spectrum of 0.02%v/v solution of toluene in hexane UV. The ratio of the absorbance at the maximum at about 269 nm to that at the minimum at about 269 nm is not less than 1.5 unless otherwise specified in the monograph.

SPECTRAL SLIT WIDTH

When measuring the absorbance at an absorption maximum spectral slit width must be small compared with the half width of the absorption band otherwise errorneously low absorbance will be measured. Particular care is needed for certain substances and the instrumental slit width used should always be such that further reduction does not result in an increased absorbance reading.

CELLS

The absorbance of the cells intended to contain the solution under examination and the reference liquid, when filled with the same solvent should be identical. If this is not the case, an appropriate correction must be applied. The tolerance on the path length of the cells used is ±0.005 cm. Cells should be cleaned and handled with great care.

SOLVENTS

In measuring the absorbance of a solution at a given wavelength, the absorbance of the reference cell and its contents should not exceed 0.4 and should preferably less than 0.2 when measured the reference to air at the same wavelength. The solvent in the reference cell should be of the same lot as that used to prepare the solution and must be free from fluorescence at the wavelength of measurement. Ethanol (95%), ethanol, methanol, and cyclohexane, used as solvents should have an absorbance measured in a 1 cm cell at about 25 nm with reference to water not exceeding 0.10.

DETERMINATION OF ABSORBANCE

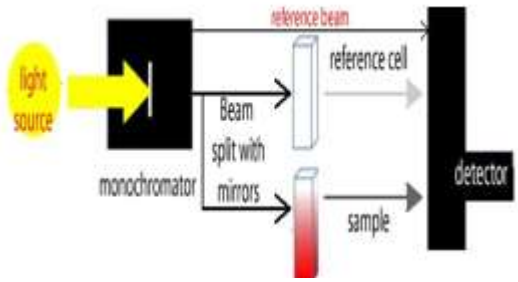

Figure 6: Schematic Diagram of Determination of Absorbance

Unless otherwise directed, measure the absorbance at the prescribed wavelength using a path length of 1 cm at 24° to 26°. If necessary, the path length may be varied provided that compliance with Beer`s Law has been shown over the range in question.

[9] A statement in a assay or test of the wavelength at which maximum absorption occurs implies that the maximum occurs either precisely at or within ±2 nm of the given wavelength. Likewise, a statement in a test of the absorbance, A, at a given wavelength or at the maximum at about a specified wavelength implies that the measured absorbance is within ±3% of the stated value.

When an assay or test prescribes the use of a Reference Substance, make the spectrophotometric measurements with the solution prepared from the Reference Substance by the official directions and then with the corresponding solution prepared from the substance under examination. Carry out the second measurement as quickly as possible after the first, using the same cell and experimental conditions.

Unless otherwise specified, the requirements in the monographs for light absorption in the tests and assays apply to the dried

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or anhydrous material, where a standard is given for loss on drying of content of water, respectively. Similar considerations apply where standards are given for solvent content. In calculating the result, the loss on drying or contents of water or solvent, determined by the method specified in the monograph, are taken into account.

V. METHODOLOGY

AIM OF THE STUDY

To compare the percentage purity of different brands of marketed hydrochlorothiazide tablets.

REAGENTS REQUIRED

- 0.1M Sodium hydroxide
- Distilled water

APPARATUS REQUIRED

- Standard volumetric flask (1000 ml) -1
- Standard volumetric flask (100 ml) – 3
- Measuring cylinder
- Beaker
- UV Spectrophotometer

SAMPLES

Hydride 25mg tablet
Aquazide 25mg tablet
BPZIDE 25mg tablet
Hydrazide 25mg tablet
Generic form

INSTRUMENT

UV Spectrophotometer
Model: Smart UV-VIS Double Beam Spectrophotometer 2203

- Micro controller based Double beam
- Graphic LCD
- Automatic source optimisation, baseline calibration and cell optimisation
- 200-1100 nm range
- 2.0 nm bandwidth
- Single wavelength, multi wavelength, scan and time scan operating modes
- Printer interface for 80 column D.M. Printer
- Automatic 5 position sample changer
- Single position 50/100 mm cuvette holder

Figure 7: Smart UV-VIS Double Beam Spectrophotometer 2203

METHODOLOGY

[7] Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of $C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

$$\text{Percentage Labelled Claim} = \frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$$

Percentage labelled claim is represented in: W/W

Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled water

VI. ASSAY OF HYDROCHLOROTHIAZIDE (HYDRIDE 25mg) TABLET

Brand name: Hydride-25
Manufactured by: Microlabs Limited
Type: Tablets
Unit:25mg
Price:18.00rs
Purchased from: Mullackals Medicals, Parassala, Trivandrum

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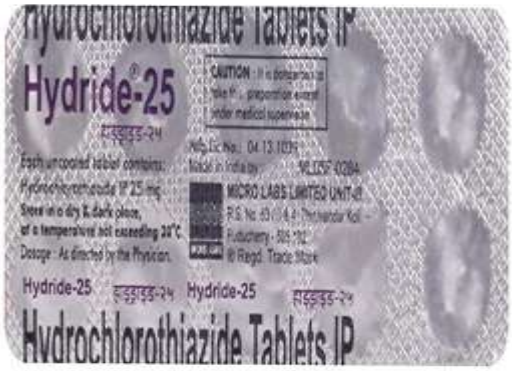

Figure 8: Hydride-25 Tablet

PROCEDURE

Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of $C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$

Percentage labelled claim is represented in: W/W

Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled wate

CALCULATION

Weight of 20 tablets = 2.8410 g

Average weight = 0.1420 g

Weight to be taken = $\frac{Average\ Weight}{Labelled\ claim} \times Weight\ required$

$= \frac{0.1420}{0.025} \times 0.02$

= 0.1136 g

Dilution Factor = $\frac{Weight\ taken}{100} \times \frac{5}{100} \times 100$

$= \frac{0.1136}{100} \times \frac{5}{100} \times 100$

= 0.00568%w/v

Absorbance = 0.511

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$

$= \frac{0.511 \times 0.1420}{520 \times 0.025 \times 0.00568} \times 100$

= 98.26%W/W

REPORT

The percentage labelled claim of the Hydride 25mg tablet was found to be 98.26%W/W

VII. ASSAY OF HYDROCHLOROTHIAZIDE (HYDRAZIDE-25mg) TABLET

Brand name: Hydrazide-25
Manufactured by: Cipla Ltd
Type: Tablets
Unit:25mg
Price:16.00rs
Purchased from: Kalra Medicals, Hari Nagar, New Delhi

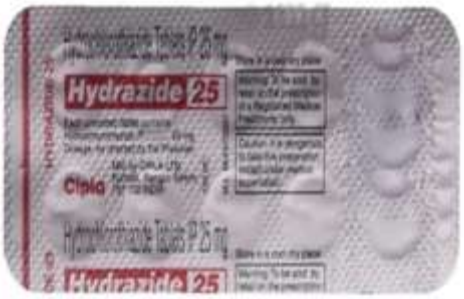

Figure 9: Hydrazide-25 Tablets

PROCEDURE

Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of$C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$

Percentage labelled claim is represented in: W/W

Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled water

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CALCULATION

Weight of 20 tablets = 2.7601 g
Average weight = 0.1380 g

Weight to be taken = $\frac{Average\ Weight}{Labelled\ claim} \times Weight\ required$

$= \frac{0.1380}{0.025} \times 0.02$

= 0.1104 g

Dilution Factor $= \frac{Weight\ taken}{100} \times \frac{5}{100} \times 100$

$= \frac{0.1104}{100} \times \frac{5}{100} \times 100$

= 0.00552%w/v

Absorbance = 0.514

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$

$= \frac{0.514 \times 0.1380}{520 \times 0.025 \times 0.00552} \times 100$

= 98.84%W/W

REPORT

The percentage labelled claim of the Hydrazide 25mg tablet was found to be 98.84%W/W

VIII. ASSAY OF HYDROCHLOROTHIAZIDE (AQUAZIDE-25 mg) TABLET

Brand name: Aquazide-25
Manufactured by: Sun Pharma Laboratories Ltd
Type: Tablets
Unit:25mg
Price:18.00rs
Purchased from: Neo Medicals, Oninmoodu, Varkala

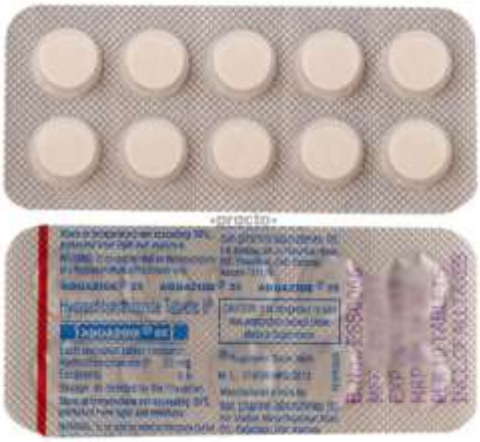

Figure 10: Aquazide-25 Tablets

PROCEDURE

Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of $C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilution\ factor} \times 100$

Percentage labelled claim is represented in: W/W

Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled water

CALCULATION

Weight of 20 tablets = 2.8020 g
Average weight = 0.1401 g

Weight to be taken = $\frac{Average\ weight}{Labelled\ claim} \times Weight\ required$

$= \frac{0.1401}{0.025} \times 0.02$

= 0.1120 g

Dilution Factor = $\frac{Weight\ taken}{100} \times \frac{5}{100} \times 100$

$= \frac{0.1120}{100} \times \frac{5}{100} \times 100$

= 0.00568%w/v

Absorbance = 0.522

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weight}{A1\% \times Labelled\ claim \times Dilutiopn\ factor} \times 100$

$= \frac{0.522 \times 0.1401}{520 \times 0.025 \times 0.00568} \times 100$

= 99.04%W/W

REPORT

The percentage labelled claim of the Aquazide 25mg tablet was found to be 98.84%W/W

IX. ASSAY OF HYDROCHLOROTHIAZIDE (BPZIDE-25mg) TABLETS

Brand name: BPZIDE-25 mg
Manufactured by: Stadmed Pvt Ltd
Type: Tablets
Unit:25mg
Price:17.00rs
Purchased from: PharmEasy (Online Pharmacy)

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Figure 11: BPZIDE-25 Tablets

PROCEDURE

Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of $C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

Percentage Labelled Claim = $\frac{Absorbance \times Average\ weig\ ht}{A1\% \times Labelled\ \ claim \times Dilution\ \ factor} \times 100$

Percentage labelled claim is represented in: W/W

Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled water

CALCULATION

Weight of 20 tablets = 2.8201 g

Average weight = 0.1410 g

Weight to be taken = $\frac{Average\ \ weig\ ht}{Labelle\ \mathrm{d}\ claim} \times Weight\ required$

$= \frac{0.1410}{0.025} \times 0.02$

$= 0.1128$ g

Dilution Factor = $\frac{\text{Weig ht taken}}{100} \times \frac{5}{100} \times 100$

$= \frac{0.1128}{100} \times \frac{5}{100} \times 100$

$= 0.00564\%w/v$

Absorbance = 0.513

Percentage Labelled Claim = $\frac{\text{Absorbance} \times \text{Average weig ht}}{\text{A1\%} \times \text{Labelled claim} \times \text{Dilution factor}} \times 100$

$= \frac{0.513 \times 0.1410}{520 \times 0.025 \times 0.00564} \times 100$

= 98.65%W/W

REPORT

The percentage labelled claim of the BPZIDE 25mg tablet was found to be 98.65%W/W

X. ASSAY OF HYDROCHLOROTHIAZIDE (Kerala Government Supply)

Brand name: Hydrochlorothiazide Tablets I.P. 25 mg (Generic Form)

Manufactured by: Unicure India Ltd (Kerala Government Supply)

Type: Tablets

Unit: 25mg

Price: Government Supply

Purchased from: Government Hospital, Kulathupuzha, Kollam

Figure 12: Hydrochlorothiazide Tablet I.P. Government Supply

PROCEDURE

Weigh and powder20 tablets. Weigh a quantity of powder containing 20mg of hydrochlorothiazide, add 50 ml of 0.1M sodium hydroxide, shake for 20 minutes and dilute to 100ml with 0.1M sodium hydroxide. Mix, filter, dilute 5ml of the filtrate to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 273nm.

Calculate the content of $C_7H_8ClN_3O_4S_2$ taking 520 as the specific absorbance at 273nm.

Percentage Labelled Claim = $\frac{\text{Absorbance} \times \text{Average weig ht}}{\text{A1\%} \times \text{Labelled claim} \times \text{Dilution factor}} \times 100$

Percentage labelled claim is represented in: W/W

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Preparation of 0.1 N NaOH

Weigh 4.2g NaOH and dissolve in 1000 ml distilled water

CALCULATION

Weight of 20 tablets = 2.9311 g

Average weight = 0.1465 g

$$\text{Weight to be taken} = \frac{\text{Average weig ht}}{\text{Labelled claim}} \times \text{Weight required}$$

$$= \frac{0.1465}{0.025} \times 0.02$$

$$= 0.1172 \text{ g}$$

$$\text{Dilution Factor} = \frac{\text{Weig ht taken}}{100} \times \frac{5}{100} \times 100$$

$$= \frac{0.1172}{100} \times \frac{5}{100} \times 100$$

$$= 0.00586\%w/v$$

Absorbance = 0.509

$$\text{Percentage Labelled Claim} = \frac{\text{Absorbance} \times \text{Average weig ht}}{\text{A1\%} \times \text{Labelled claim} \times \text{Dilution factor}} \times 100$$

$$= \frac{0.509 \times 0.1462}{520 \times 0.025 \times 0.00586} \times 100$$

$$= 97.88\%W/W$$

REPORT

The percentage labelled claim of the Hydrochlorothiazide tablet 25 mg (Kerala Government Supply) tablet was found to be 97.88%W/W.

XI. RESULT AND INTERPRETATION

After performing the study that is, the evaluation of purity of different brands of marketed hydrochlorothiazide the values obtained and mentioned below:

Different Brands of Hydrochlorothiazide Tablets	Percentage Labelled Claim of Different Brands of Hydrochlorothiazide Tablets (in %W/W)
Hydride-25	98.26%W/W
Hydrazide-25	98.84%W/W
Aquazide-25	99.04%W/W
BPZIDE-25	98.65%W/W
Generic Form (Government supply)	97.88%W/W

Table 3: Comparison of Percentage Labelled Claim

From the above table, we can see the percentage labelled claim of the different brands of marketed hydrochlorothiazide tablets.

From the results obtained it is clear that Aquazide-25 manufactured by Sun Pharma Laboratories Ltd was found to have the percentage labelled claim of 99.04%w/w, when compared to the other brands of marketed hydrochlorothiazide tablets.

The other brands showed the percentage labelled claim between the range 97-98%w/w.

The order of percentage labelled claim can be represented in the order:

Aquazide>Hydrazide>BPZIDE>Hydride>Generic Form (Government supply)

XII. CONCLUSION

The study on different brands of marketed hydrochlorothiazide tablets was performed and the conclusion obtained from the studies made that Aquazide-25 was found to be having the highest labelled claim of 99.04%w/w.

By performing the study, we can draw the percentage labelled claim of the different brands of the marketed hydrochlorothiazide tablets and can compare the results obtained of each of the marketed product. By comparing these results, the product having the highest labelled claim can be identified and reported.

These studies are done to find out the percentage labelled claim of the products marketed.

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