DETERMINATION OF PARACETAMOL IN SOME MANUFACTURED TABLETS IN IRAQ MARKET USING UV – VISB SPECTROSCOPY

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Aim of the study:

The aims of this study were to investigate paracetamol from different pharmaceutical companies in Iraqi market to prove that:

1- The weight of each tablet is within the range of maximum difference allowed.

2 - Assay the active constituent of different samples using UV method & comparing the results to obtain the most potent one from the tested samples.

3 - To get the information about the manufactured tablet samples from different sources in Iraq market.

4 - To make control and comparing the results obtain from this study of the samples under consider.

Abstract:

This research was involving the determination of paracetamol drug in some manufactured tablets in Iraq market using UV spectroscopy method. The recovery of the drug from ten different samples of different company and country was carried out and compared with standard material of paracetamol. The recovery process was conduct using different new solvent (water, water-methanol mixture 95:5 v/v and water – ethanol mixture 95:5 v/v). The results of tablets weighing indicate that there is a significant difference in weight of tablets with RSD ranged between (0.53 – 4.89). The percentage of recovery was found to be ranged of (98.32 – 103.96) and RSD of (0.121 – 0.141) for water as solvent, (98.20 – 104.16) and RSD of (0.116 – 0.140) for methanol mixture as solvent and (98.87 – 103.68) and RSD of (0.117 – 1.28) for ethanol mixture as solvent.

1 – Introduction:

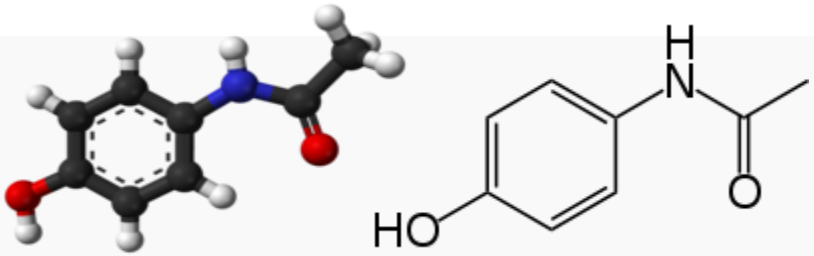
1.What is paracetamol?

Paracetamol, also known as **acetaminophen** or **APAP**, is a medication used to treat pain and fever.[1] It is typically used for mild to moderate pain. Evidence of benefit in fever for children is poor. It is often sold in combination with other ingredients such as in many cold medications. In combination with opioid pain medication, paracetamol is used for more severe pain such as cancer pain and after surgery.[2] It is typically used either by mouth or rectally, but is also available intravenously.

Paracetamol is generally safe at recommended doses. Serious skin rashes may rarely occur. Too high a dose can result in liver failure. It appears to be safe during pregnancy and when breastfeeding. In those with liver disease, it may still be used but lower doses should be taken.[3] Paracetamol is classified as a mild analgesic.

It does not have significant anti-inflammatory activity and how it works is not entirely clear.[4]

Paracetamol was discovered in 1877. It is the most commonly used medication for pain and fever in both the United States and Europe. It is on the WHO Model List of Essential Medicines, the most important medications needed in a basic health system. Paracetamol is available as a generic medication with trade names including Tylenol and Panadol among others.[5]

Paracetamol	
Systematic (IUPAC) name	
N-(4-hydroxyphenyl)ethanamide (N-(4-hydroxyphenyl)acetamide)	
Clinical data	
Pronunciation	Paracetamol (Acetaminophen)
Trade names	Tylenol, Panadol, others
Chemical data	
Formula	$C_8H_9NO_2$
Molar mass	151.163 g/mol
Physical data	
Density	1.263 g/cm^3
Melting point	169 °C (336 °F)
Boiling point	420 °C (788 °F)
Solubility in water	12.78 mg/mL (20 °C)

Medical uses:

1 – Fever.
2 – Pain.
3 – Osteoarthritis.
4 – Low back pain.
5 – Headaches.
6 – Postoperative pain.
7 – Other.

Adverse effects:

1 – Liver damage.
2 – Skin reactions.
3 – Asthma.
4 – Other factors.
5 – Overdose.
6 – Pregnancy.

How to store:

1- Keep this medicine out of the sight and reach of children.

2- Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

3 - Store your medicine in the original packaging in order to protect from moisture.

4 -Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Society and culture:

Naming:

Acetaminophen is the name generally used in the United States (USAN) and Japan (JAN); paracetamol is used in international venues (INN, AAN, BAN). In some contexts, such as on prescription bottles of painkillers that incorporate this medicine, it is simply abbreviated as APAP, for acetyl-para-aminophenol.

The word acetaminophen is also used in Canada, Venezuela, and Colombia.[36] Both come from a chemical name for the compound: para-acetylaminophenol and para-acetylaminophenol.

Paracetamol is available as:

Tablets, caplets, capsules, soluble tablets (these dissolve in water, which you then drink), an oral suspension (liquid medicine), suppositories.

Some types of paracetamol, such as liquid forms of paracetamol, are aimed specifically at children.

The common adult dose is 500 mg to 1000 mg. The recommended maximum daily dose, for adults, is 4000 mg. In recommended doses, paracetamol is generally safe for children and infants, as well as for adults, although rare cases of acute liver injury have been linked to amounts lower than 2500 mg per day.[37]

Paracetamol is commonly used in multi-ingredient preparations for migraine headache, typically including butalbital and paracetamol with or without caffeine, and sometimes containing codeine.

Determination of paracetamol in different types of manufactured tablets:

The raw material that used for preparation of stock solution obtained from SDI, Iraq. But the samples (paracetamol tablets) were taken from the Iraq pharmaceutical market. Table 2.3, tabulated the data obtained concerning the proprietary name, source, M.D, E.D and paracetamol quantity.

This study was conduct out as following:

1 - Weigh and grind three tablets of each type or source of the drug (Table 3.1)

2 - Transfer an accurately weighed portion, equivalent to about 0.01g of sample powder, to 100 ml volumetric flask.

3 - Add about 50 ml of solvent, and shake by mechanical means for 20 min.

4 - Dilute with same solvent to volume, and mix.

5 - Pass the solution through a filter having 0.5 μm or finer porosity.

6 - Each one of the samples is tested using the same conditions that used in the standard in the UV system at the same wave number applied for standard measurements.

7 - Then the equation of straight line is applied to calculate Paracetamol concentration & its weight.

Table.2.3 – List of samples under study.

Name of sample	company	country	M.D	E.D	Paracetamol mg
Paracetamol	Haditha	Iraq	2/2015	2/2018	500
Panadol	gsk	China	4/2105	4/2018	500
Paracetamol	MEHECO	China	12/2014	11/2017	500
Panda	JOSWE	Jordan – Sweden	3/2014	4/2017	500
Pmol	Oman	Jordan	8/2014	8/2017	500
Piodol	Pioneer	Iraq	8/2015	8/2018	500
Paracetamol	SDI	Iraq	8/2015	8/2018	500
APMOL	NKD	India	12/2014	11/2017	500
adol	Julphar	U.E.A	3/2015	3/2018	500
Paracetamol	TROGE	Germany	10/2013	10/2017	500

Results and Discussion:

3.1 – Weighing of tablets samples:

Three tablets from each sample were weight (one, one), the mean of weight and RSD are illustrated in (Table 3.1). The results revealed that there is a significant difference in the weight off the tablets of the same company due to the high values of standard deviation.

Table.3.1 – The results of tablets weighing.

Name of sample	Company	Country	Mean of weight mg	Standard deviation	Coefficient of variation	R.S.D
Paracetamol	Haditha	Iraq	650	10.0	0.0178	1.785
Panadol	gsk	China	583	0.031	0.0053	0.530
Paracetamol	MEHECO	China	550	9.0	0.0163	1.630
Panda	JOSWE	Jordan – Sweden	557	11.0	0.0197	1.970
Pmol	Oman	Jordan	600	12.0	0.0200	2.000
Piodol	Pioneer	Iraq	547	3.5	0.00639	0.639
Paracetamol	SDI	Iraq	629	10.1	0.0160	1.600
APMOL	NKD	India	600	10.0	0.0166	1.660
adol	Julphar	U.E.A	630	10.0	0.0158	1.580
Paracetamol	TROGE	Germany	593	29.0	0.0489	4.890

3.2 – Preparation of calibration graph:

A serious solutions have a different paracetamol concentration rang of (1, 3, 5, 8, 10 mg/L) were prepared by simple dilution of stock solutions which were prepared in 2.1.1.Figurs 3.1 – 3.3, shown the plots of calibration graph for a solutions at different concentrations with R^2 of (1, 0.9999, 0.9999) for water, methanol and ethanol respectively.

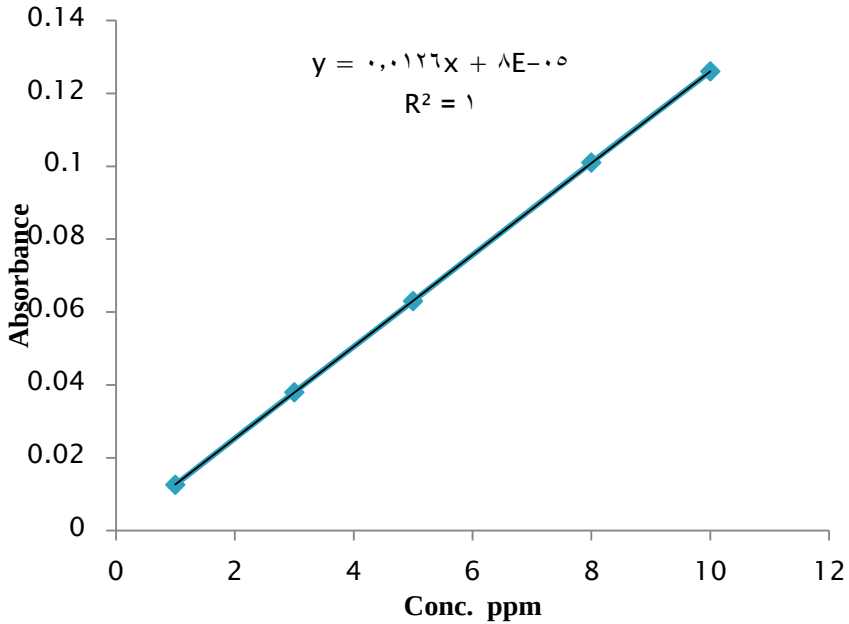


Fig:3.1:Calibration graph of paracetamol in water

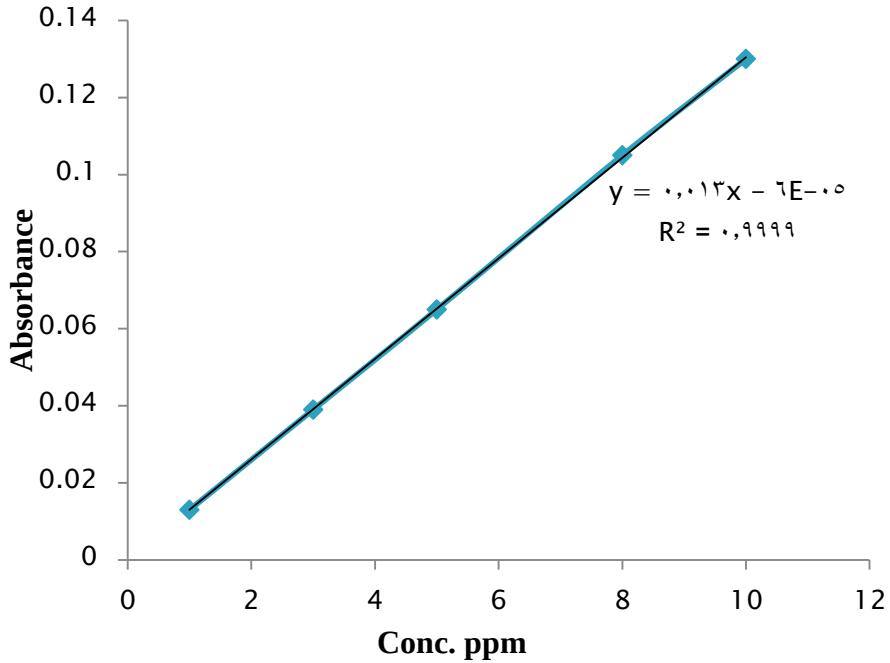


Fig: 3.2:Calibration graph of paracetamol in 5% methanol

3.3 – Estimated of paracetamol quantity in samples:

A 0.01 g from each sample powder was weight and dissolved in 100 ml of different solutions used for recovery of paracetamol in this study, the absorbance was measured in the same λ_{max} which was found to be (243 nm).Tables 3.2 – 3.4 tabulate the results obtained. The results indicate that the recovery percentages are with acceptable range of (98.45 – 103.93), and R.S.D range of (0.116 – 0.649) for all methods.

Table: 3.5: The final estimated quantity of paracetamol in tablets of different samples.

Company	Mean mg for water method	Mean mg for methanol method	Mean mg for ethanol method	Mean of mean mg for all methods	% of Mean found	Standard deviation	Coefficient of variation	R.S.D
Haditha	494.2	495.3	495.05	494.85	98.97	0.5766	0.00116	0.116
gsk	493.1	491.0	492.7	492.27	98.45	1.1151	0.00227	0.227
MEHECO	519.8	520.8	518.4	519.67	103.93	1.2055	0.00232	0.232
JOSWE	510.2	507.2	510.0	509.13	101.83	1.6773	0.00329	0.329
Oman	490.0	495.3	495.6	493.63	98.73	3.1501	0.00638	0.638
Pioneer	492.5	493.8	494.75	493.68	98.74	1.1295	0.00288	0.288
SDI	513.0	514.1	511.65	512.92	102.58	1.2270	0.00239	0.239
NKD	491.6	492.9	494.35	492.95	98.59	1.3757	0.00279	0.279
Julphar	495.5	498.7	496.75	496.98	99.40	1.6127	0.00324	0.324
TROGE	509.3	516.1	513.15	512.85	102.57	3.4099	0.00649	0.649

Conclusions:

The conclusions from this research are the following point:

1 – The researchers found that there is a significance different in the weight of tablets one from other in the same sample for all company.

2 – According to the first point the quantity of the active constituent will be different in the samples under study.

3 – The obtained results from this research indicate that the percentage of active constituent (paracetamol) was in acceptable rang for all samples.

4 – Finally and from the results obtained which are indicate that the applied method show a good recovery percentage for all samples, that mean we can applied the method for determination of paracetamol in different samples.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