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Comparative Study of Different Brands of Ranitidine Available in India

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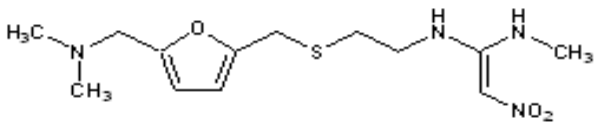
Abstract:- It can be challenging to choose the safest, most cost-effective, and effective brand of ranitidine because it is used to treat peptic ulcers and is marketed under numerous names. The purpose of this study is to determine whether the various brands of ranitidine HC pills sold in Karachi, Pakistan, are comparable to one another. For the study, four different brands of (150 mg) were used. Six quality control measures were carried out according to USP specifications, including weight variation test, hardness test, thickness test, friability disintegration test, and dissolving test. In terms of hardness, weight fluctuation, thickness friability, disintegration, and dissolution, the results showed that all brands are within tolerances. All brands' disintegration times were under 15 minutes, which was commendable according to the USP. Within 45, all brands displayed Q values more than 80%.

Introduction:

In accordance with BP. & USP guidelines, a comparative analysis is conducted to examine, assess, and compare the quality standards of commercially available local pharmaceutical brands of tablets with those of global pharmaceutical brands in India. The physical and chemical characteristics of local and international medicine brands were compared(1). Marketed oral medications are rumoured to have favourable physiochemical qualities in terms of absorption, metabolism, and distribution.



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In addition to being used to treat gastrointestinal reflux illness and duodenal and gastric ulcers brought on by helicobacter pylori infection, ranitidine is an H2 receptor antagonist that reduces the generation of stomach acid [3]. Pentagastrin (an enzyme), food, and histamine 4 enhance the release of acid, which is inhibited by this substance.

Methodology:-
Various brands of ranitidine were purchased from various Baramati retail pharmacies, and their qualitative and quantitative tests were conducted.

Evaluation parameters, Quantitative and Quantitative test

Price fluctuations:-

Sr No	Brand Name	Mfg By	Batch No	Mfg Date	Exp Date	Price/10 tablets
1	Rantac 150	J. B. Chemicals and Pharmaceuticals	TR322100	June 2022	November 2023	40.75 Rs
2	R-Loc 150	Zydus Cadila	I103989	August 2021	February 2024	36.96Rs
3	Aciloc 150	Cadilla Pharmaceutical	LD22517	September 2022	February 2025	40.94Rs

The best local brands with affordable costs and no health risks help raise awareness for allergy patients in our neighbourhood. Table 1 provides label information and pricing variations for various brands of Ranitidine

Thickness and diameter:-
A tablet's thickness can vary without affecting its weight due to variations in the granulation's density, the pressure with which the tablets are compressed, and the rate at which the tablets are compressed.

Hardness test:-
Hardness of the tablet is controlled by compression machine by applying the degree of pressure in Kg/cm2 during granules compression. This parameter is very important because it effects disintegration time and dissolution profile. A hardness tester is used for 20 tablets randomly and mean standard deviation S. D.

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Weight variation:-
To determine the correct dosage of the active component in the tablet, the weight of the dosage form is measured.

Disintegration test:-
Disintegration testing is one of the quality control procedures used to check if tablets or capsules dissolve in a fluid medium within the permitted amount of time. On CURRO MODEL NO. DS-0701, a disintegration test for all brands was conducted. Distilled water was added to a 900 ml beaker, which was kept at a constant 37 2°C temperature. Six pills from each brand were randomly chosen, added to the basket rack assembly, and then connected to the disintegration device. Each brand's disintegration time is compared to the Bp-specified Pharmacopoeial limit.

Friability test:-
The friability test is intended to assess the tablet's resistance to fracture during handling, transportation, and packaging. Ten tablets are weighed after a physical examination and dusting, then put in the friability apparatus where they experience rolling and repeated shocks as they drop 6 inches in each tern. The weight of the pills is measured after 100 rotations, and the result is contrasted with the original weight. Tablet friability is determined by the loss through abrasion. The maximum weight loss is no more than 1% of the tablet's original weight.

Assay:-
Determine by liquid chromatography

Test solution:-
Tally and powder 20 pills. To create a solution containing the equivalent of 0.01 percent w/v of ranitidine, mix a quantity of the powder containing 300 mg of ranitidine with 60 ml of the mobile phase for 10 minutes, dilution to 100 ml with mobile phase, filter, and dilution of the filtrate with mobile phase.

Reference solution:-
Dissolved in a 0.0112% w/v solution With a little heat, dissolve the residue from the test for sulphated ash in 5 ml of sulfuric acid, then let it cool. then cautiously incorporate 0.2 ml of the 10 volumes of hydrogen peroxide solution. When using glossy fibre varieties, the solution does not change colour, but when using matt fibre varieties, an orange-yellow colour is produced, with ranitidine hydrochloride RS in the mobile phase increasing its intensity.

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Chromatographic system:-
A 25 centimetre by 4.0 mm stainless steel column filled with porous silica (5 um) and octadecylsilane (4 um). a mobile phase consisting of 85 volumes of methanol and, depending on the amount of titanium dioxide present, 15 volumes of 0.1 Mammonium Acetate, with a flow rate of 2 ml/min.

spectrophotometer with injection volume set to 322 nm. 20 nanoliters

Inject the benchmark mixture. If the relative standard deviation for replicate injection is greater than 2%, the test is not valid.

Inject both the reference and test solutions.

Determine how much C13H22N4O3S is present in the tablets:

Dissolution:-
The experiment for the dissolution used the USP apparatus I (Paddle).There were six vessels in use at once. 900ml of distilled water was added to each vessel. It was 37.50.5°C outside. The RPM setting was 100. To get to the desired temperature, the machine was preheated. When the timer started, one tablet was put in each vessel. At intervals of 10, 20, 30, 40, and 50 minutes, 5 mL of sample was removed from each vessel, and the solvent loss was reduced by adding fresh distilled water. Before measuring absorbances, each sample was filtered and diluted ten times. At the conclusion of the dissolution test, 314nm absorbance measurements were made.

Requirements for proposed study:-
Spectrum analyzer (). Disintegration tool (0). Magnetic hot plate stirrer () tester for hardness 0). Friability instrument (). For this work, we used a weighing scale, a micropipette, hydrochloric acid (), and freshly made distilled water. A medication must be reasonably accessible and meet a patient's therapeutic demands for a sufficient amount of time at the least expensive possible cost to the patient and their community. To test the various brands of cetirizine hydrochloride tablets available, a number of pharmaceutical criteria were used as per IP 31 (2008), L. e. thickness, hardness, weight variation, friability, disintegration, and dissolution.

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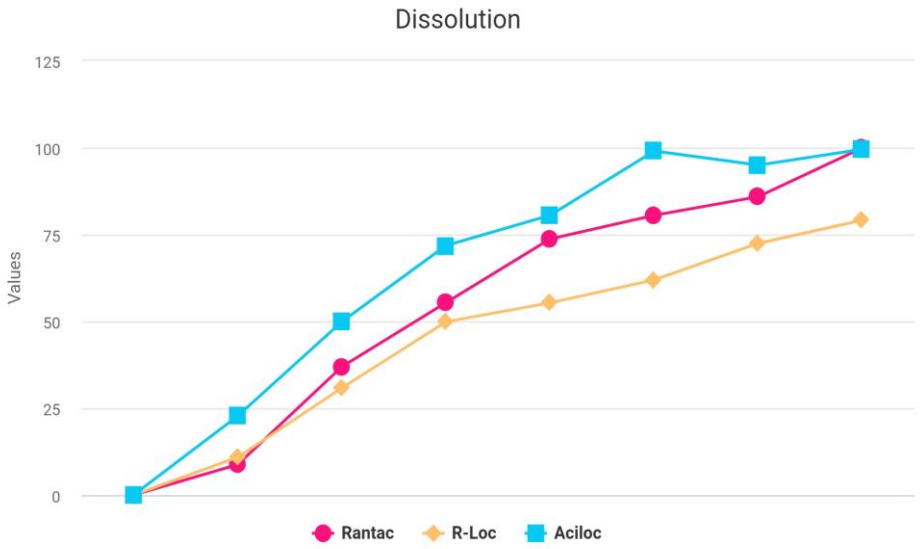
Result and discussion:- Dissolution Profile

Sr. No	Time in min.	Rantac	R-Loc	Aciloc
1	0	0	0	0
2	5	8.75±0.09	10.86±0.08	22.73±0.06
3	10	36.9±0.10	30.80±0.10	49.87±0.09
4	15	55.34±0.12	49.85±0.12	71.80±0.08
5	20	73.68±0.14	55.32±0.14	80.50±0.11
6	25	80.5±0.14	61.9±0.07	99±0.03
7	30	85.86±0.16	72.44±0.09	94.95±0.12
8	40	99.93±0.15	79.1±0.15	99.50±0.17



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	Thickness	Diameter	Hardness	Disintegration	Friability	Weight(gm)
ACILOC	4.24	3.8	4.48	3.50	1.45	0.15
R-LOC	4.25	4.2	4.01	8.3	1.60	0.16
RANTAC	4.23	3.9	5.33	4.57	1.32	0.16

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