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Research Article

Evaluation Of Different Marketed Brands Of Aspirin Tablets Using Quality Control Tests

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ABSTRACT

Aspirin has an antiplatelet effect by inhibiting the production of thromboxane, which under normal circumstances binds with platelet molecules together to create a patch over damaged walls of blood vessels. Aspirin is also used long-term, at low doses, to prevent heart attacks, strokes, and blood clot formation in people at high risk for developing blood clots. The main undesirable side effects of aspirin are gastrointestinal ulcers, stomach bleeding, and tinnitus, especially in higher doses. So in order to minimize the side effects of aspirin in the gastric region these are coated with enteric material which causes the release of drug in intestinal region. The exposure of drug in the gastric region is almost prevented. The present study was carried out to assess the quality control parameters of three different brands of aspirin gastro resistant tablets marketed in Dindigul district. All the tablet brands were analysed for weight variation test, hardness, friability, disintegration studies and percentage drug release by in-vitro dissolution studies. Three different brands of aspirin tablets were passed the test for weight variation. The hardness of various brands of aspirin ranges from 5.5 kg/cm2 to 8.0 kg/cm2 and friability varies from 0.61 % to 0.76 %, hence found to be within the acceptable limits. They had shown the disintegration time varies from 2.15 to 2.75 minutes when placed in simulated intestinal fluid phosphate buffer at pH 6.8 and 93.4% to 96.6% of active drug was released within 1 hour in dissolution studies using acetate buffer pH4.5. Hence, it was concluded that all the tested formulations met the quality parameters of official specification and achieved optimum therapeutic efficacy.

INTRODUCTION

Aspirin, chemically acetylsalicylic acid (ASA), considered as one of the lives saving drug belongs to the class of NSAID, in conventional tablet form, is used to relieve pain, fever, and inflammation associated with many conditions, including the flu, the common cold, neck and back pain, dysmenorrhea, headache, tooth pain, sprains,

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fractures, myositis, neuralgia, synovitis, arthritis, bursitis, burns, and various injuries. It is also used for symptomatic pain relief after surgical and dental procedures. It causes gastric mucosal irritation resulting to gastric hemorrhage when it is administered as uncoated tablet. So the side effect of aspirin can be prevented by applying a thick enteric coat around the aspirin tablet. It blocks prostaglandin synthesis. It is non- selective for COX-1 and COX-2 enzymes. Inhibition of COX-1 results in the inhibition of platelet aggregation for about 7-10 days (average platelet lifespan). The acetyl group of acetylsalicylic acid binds with a serine residue of the cyclo oxygenase-1 (COX-1) enzyme, leading to irreversible inhibition. This prevents the production of pain-causing prostaglandins. This process also stops the conversion of arachidonic acid to thromboxane A2, which is a potent inducer of platelet aggregation Label. ASA binds to serine residue on the active site of COX-2 in the same fashion as its binding to the serine residue located on the active site of COX-1. The active site of COX-2 is, however, slightly larger than the active site of COX-1, so that arachidonic acid (which later becomes prostaglandins) manages to bypass the aspirin molecule inactivating COX-2. ASA, therefore, exerts more action on the COX-1 receptor rather than on the COX-2 receptor. Pharmaceutical manufacturers are focusing on development of new drug delivery systems for existing drug with more efficacy and bioavailability. The oral route of administration is the routine and most predominant method of administering drugs for systemic effects. Absorption of drug is monitored by physicochemical properties of drugs, their formulations, and routes of administration, when drug is administered orally. So the dosage forms can have a significant effect on the quality control parameters such as weight variation, hardness, friability, wetting time, disintegration time, dissolution profile etc. Also, these parameters are essential tools for maintaining batch to batch consistency during manufacturing process. This work mainly focus on the in-vitro quality control tests of three brands of aspirin marketed tablets and compared with pharmacopeial specifications1-3.

MATERIALS AND METHODS:

Chemicals

Three brands of aspirin tablets of different manufacturers with labeled contents of 150 mg were procured from various pharmacies of Dindigul district in Tamilnadu (Table 1). All the brands were properly checked for their physical appearance, manufacturer's name, batch number, manufacturing date, expiration date, manufacturing license number, and the maximum retail price at the time of purchase. The samples were properly coded with ASP-1, ASP-2 and ASP-3.

Equipment's

Equipments utilized for this study were Electronic Balance (Wensar), Hardness Tester (Vinsyst), Friability Test Apparatus (Rolex India), pH meter (Infra Digi), Disintegration Test Apparatus (Rolex India), Dissolution Test Apparatus USP (Ceyone) and UV Visible Spectrophotometer (Sytronics).

Table 1: Brands of Aspirin Tablets

Brand Name	Manufacturer's	Sample Code	MRP (Rupees per strip)
Aspo 150 mg	Zeelab Pharmacy Pvt Ltd.	ASA-1	8.50
Ecospirin 150 mg	USV Pvt Ltd	ASA -2	10.98
Delispirin 150 mg	Aristo Pharmaceuticals Pvt. Ltd.	ASA -3	9.87

Preparation of the standard curve

About 100 mg of pure drug of aspirin was accurately weighed and dissolved in ethanol, then the volume was made up to the mark with distilled water in a 100 ml standard flask. It is said to be primary stock, 1 ml of this solution was pipetted out and transferred to 100 ml standard flask and the volume was made up to the mark with distilled water, named as secondary stock solution having the concentration of 10 µg/ml. From the secondary stock solution aliquots equivalent from 1 ml to 10 ml were pipetted out and transferred into a series of 10 ml standard flask and volume made up to the mark with distilled water. The absorbance of all the above solutions was measured against distilled water as blank at 227 nm using UV-Visible spectrophotometer. Then a calibration curve was plotted taking concentration in µg/ml on x axis and absorbance on y axis.

Evaluation of tablets4-8

Uniformity of Weight (Weight Variation)

Ten tablets were selected at a random and average weight was determined. Then each tablet was weighed individually and the individual weight was compared with an average weight (Wensar).

Weight Variation = ((Iw-Aw))/Aw ×100%

Where,

Iw is referred as Individual weight ,

Aw is referred as Average weight

Hardness

Tablet hardness test is also known as Crushing Strength Test and the tablet crushing load, which is the force required to break a tablet by compression in the radial direction, was determined using a VinSyst Manual Tablet Hardness Tester (Monsanto hardness tester).

Tablet hardness is checked to ensure that disintegration time and dissolution profile are within range or according to specifications. It is performed to ensure that tablets are strong enough to remain intact during coating, blistering, packing and transportation.

Limit:

Oral tablets have a hardness of 4 to 10 kg.

Friability

Friability of tablets was measured by using Roche Friabilator. Friability was evaluated from the percentage weight loss of 20 tablets tumbled in a friabilator at 25 rpm for 4 minutes. The tablets were dedusted, and the loss in weight caused by fracture or abrasion was recorded as the percentage weight loss (Rolex India).

Friability = ((Iw-Fw))/Iw ×100 %

Where,

Iw is referred as Initial weight and Fw is referred as Final weight

Limit:

Friability below 1% was considered acceptable.

Disintegration time9-11

The process of breakdown of a tablet into smaller particles is called as disintegration. A disintegration test is performed in-vitro to ensure that after taking medicine it will release active pharmaceutical ingredients in the stomach or intestine and will be absorbed to give pharmacological effect. This test is also performed to ensure the bioavailability of drugs. The in-vitro disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications. Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using 0.1 N HCl for 2 hrs and then phosphate buffer pH 6.8 for 1 hr. The assembly should be raised and lowered between 30 cycles per minute. The time in seconds/minutes taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

In vitro Dissolution Study12-15

The dissolution study was performed for marketed aspirin gastro resistant tablet formulation, by using digital dissolution apparatus, paddle method. The dissolution medium was 0.1 N HCl for 2 hrs and then phosphate buffer pH 6.8 for 1 hr (900 mL, 37

± 0.5°C). The dissolution rate was studied at 50 rpm using paddle method. Aliquot of dissolution medium was withdrawn at specific time interval, filtered off and the absorbance was measured spectrophotometrically at 227 nm by UV spectrophotometer.

RESULTS AND DISCUSSION16-21

Construction of Standard Curve

The aspirin pure drug was dissolved in ethanol and diluted suitably with distilled water to get the concentration of 1-10 µg/mL and the analysis of the sample was done using 1cm sample cell and scanning at 227 nm using double beam UV-Visible spectrophotometer (Table 2) and the calibration curve (Fig. 1) was constructed.

Table 2: Data for Standard Curve

Concentration (µg/ml)	Absorbance (at 227 nm)
0	0
1	0.115
2	0.241
3	0.341
4	0.456
5	0.563
6	0.679
7	0.786
8	0.896
9	0.995

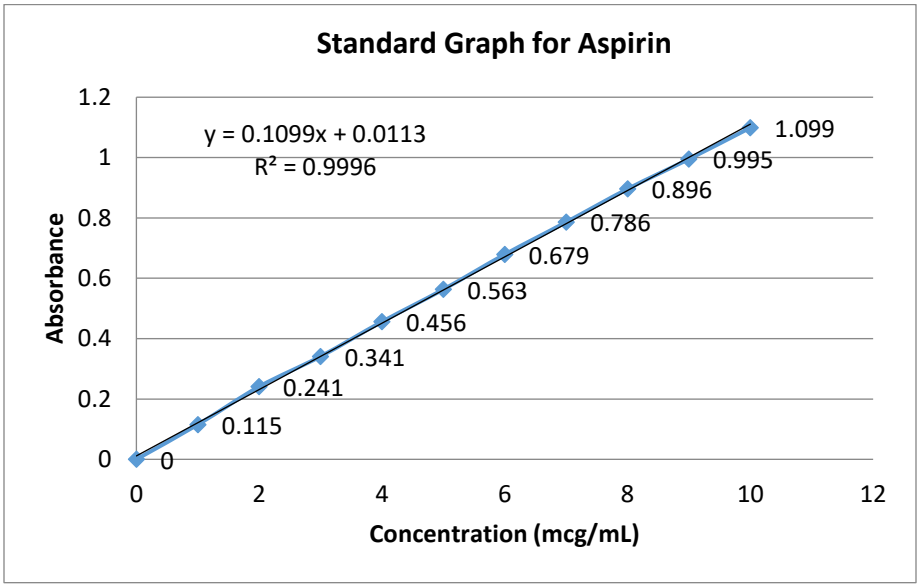

Fig 1: Standard Curve for Aspirin

Comparative Study Data for Evaluation of Tablets

The evaluation tests for all the brands of Aspirin tablets were determined and the observed results were shown on Table 3.

Weight Variation

The weight variation of three marketed brand was ranges from 0.3841% to 0.3654%. Hence all brands have been passed with the weight variation test as per IP limit.

Hardness Test

The hardness of presently studied aspirin tablets was ranges from 5.5 kg/cm2 to 8.0 kg/cm2and all the brands have been adhered to the IP specification.

Friability Test

The friability of marketed brands aspirin tablets was ranges from 0.61 % to 0.76 %. So the above brand tablets have agreed the friability test as per Pharmacopeial limit.

Disintegration Test

There is no disintegration was found in first 2 hrs in 0.1N HCl acid medium and the medium was changed in to phosphate buffer (pH 6.8). Hence, the disintegration time of 3 different marketed brands was ranges from 2.15 minutes to 2.75 minutes and complied with the disintegration test limit as per IP specification.

In vitro Dissolution Study

Comparison of in-vitro dissolution profiles (Table 4) of the three brands of aspirin gastro resistant tablets were illustrated in Figure 2. The in vitro dissolution in 0.1N HCl acid media for 2 h discovered no indication of drug release, whereas more than 85 % of drug released in all the brands evaluated within 1 hr, which complies with USP and BP specifications of more than 80 %. Such above observation and report is predicted, as these enteric coats have revealed the similar effect in previous reports.

Table 3: Comparative data for Weight variation, Hardness, Friability and Disintegration

Our BrandName	Weight variation (%)	Hardness (kg/cm^2)	Friability (%)	Disintegration (Minutes)
ASA-1	0.3841	5.5	0.61	2.15
ASA-2	0.7458	5.7	0.68	2.43
ASA-3	0.3654	8.0	0.76	2.75

Table 4: Dissolution study data

TIME (in min)	% Drug Release ASA-1	% Drug Release ASA-2	% Drug Release ASA-3
0	0	0	0
60	0	0	0
120	0	0	0
130	4.6	4.4	4.0
140	16.5	19.4	16.5
150	33.2	34.2	30.1
160	50.1	54.6	45.6
170	71.8	74.8	68.7
180	90.4	93.3	88.6
240	96.6	97.2	93.4

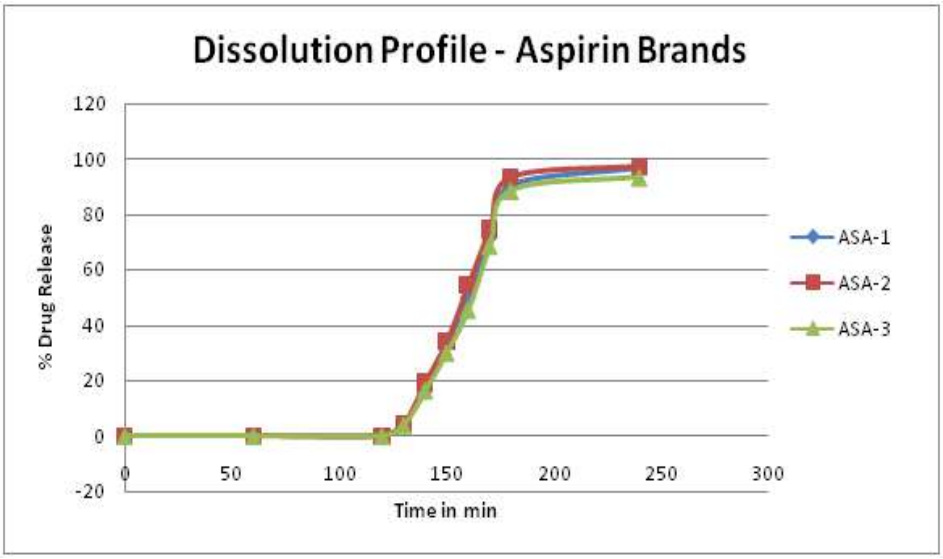

Fig 2: Graph for Dissolution Study

CONCLUSION:

From the above investigation, it was concluded that all of the brands of aspirin tablet met the limits of quality control tests in the official monographs for in-vitro evaluation. When some of the tablet properties are taken in to consideration, all the tested brands of aspirin tablets comply with official in-vitro quality standards. Also, quality standards of all the tested tablets were not significantly different to each other.

Percentage drug release on dissolution studies has been complied with specification which shows the increased therapeutic effectiveness of the product. The reported data in this study will be very useful and helps the pharmaceutical industry to improve and invest for quality control tests to give better pharmaceutical products to the patients. The efficacy of the drug formulations is based upon their analytical and quality control test which results to achieve therapeutic effectiveness and quality attributes.

REFERENCE:

1. Enma V Paez Espinosa, John P Murad and Fadi T Khasawneh. Aspirin: Pharmacology and Clinical Applications, Thrombosis (2012), 2012: 1-15.
2. Vane JR and Botting RM. The mechanism of action of aspirin, Thrombosis Research (2003), 110 (6): 255-258.
3. Bamidele Johnson Alegbeleye, Oke-Oghene Philomena Akpoveso, Rana Kahdim Mohammed and Bernard Yeboah-Asiamah Asare. Pharmacology, Pharmaceutics and Clinical Use of Aspirin: A Narrative Review, Journal of Drug Delivery & Therapeutics (2020), 10(5-s): 236-253.
4. Vinay S, Sudeendra Bhat R, Balamuralidhara V and Pramod Kumar TM. Comparative Study of In-process and Finished Products Quality Control Tests of IP, BP & USP for Tablet, International Journal of Pharmacy Teaching & Practices (2011), 2(4): 176-183.
5. Shabana Md. A Review on the Quality Control Analysis of Oral Dosage Form: Tablets, Research and Reviews: Journal of Pharmacy and Pharmaceutical Sciences (2016), 5(2): 108-114.
6. Mohammed S Alqahtani, Mohsin Kazi, Mohammad A Alsenaidy and Muhammad Z Ahmad. Advances in Oral Drug Delivery, Frontiers in Pharmacology (2021), 12: 1-21.
7. Felix Schneider, Mirko Koziolek and Werner Weitschies. In Vitro and In Vivo Test Methods

for the Evaluation of Gastroretentive Dosage Forms, Pharmaceutics (2019), 11(416): 1-29.

8. Cristina Maderuelo, Jose M Lanao and Aránzazu Zarzuelo. Enteric coating of oral solid dosage forms as a tool to improve drug bioavailability, Europian Journal of Pharmaceutical Sciences (2019), 138. doi: 10.1016/j.ejps.2019.105019.
9. Hanan Muzeyin Kedir, Eskinder Ayalew Sisay and Alfoalem Araba Abiye. Enteric-Coated Aspirin and the Risk of Gastrointestinal Side Effects: A Systematic Review, International Journal of General Medicine (2021), 14: 4757–4763.
10. Pawan Singh, Prevesh Kumar and Neelkant Prasad. Formulation and Evaluation of Aspirin Tablets by Using Different Lubricants in Combination for better Kinetic Drug Release Study by PCP, Research J. Pharm. and Tech. (2017), 10(9): 2934-2938. doi: 10.5958/0974-360X.2017.00519.4
11. Michele Dei Cas, Jessica Rizzo, Mariangela Scavone, Eti Femia , Gian Marco Podda, Elena Bossi, Monica Bignotto, Sabrina Caberlon, Marco Cattaneo and Rita Paroni. In-vitro and in-vivo metabolism of different aspirin formulations studied by a validated liquid chromatography tandem mass spectrometry method, Scientific Reports (2021), 11:10370. doi.org/10.1038/s41598-021-89671-w.
12. Toshihide Abe, Yoshitsugu Yanagihara, Tomonobu Uchino, Toyohito Oriyama, Mamoru Komatsu, Katsuyoshi Nakajima and Hiroshi Suzuki. Evaluation of the Pharmaceutical Characteristics of Various Enteric-Coated Aspirin Tablets under Different Storage Conditions, Chem. Pharm. Bull. (2014), 62(7): 617–626.
13. Amrajaa Y, Gadalmwla S, Alashiby A and Farhat N. Pharmaceutical Quality Control Testing of Different Brands of Aspirin Sold in AL-Bayda City Markets, Alq J Med App Sci. (20230, 6(2): 460-468. doi.org/10.5281/zenodo.8244723.
14. Fonso Urich JA, Fedorko A, Hölzer B and Khinast J. Evidence of Reliable Gastro-Resistance of Novel Enteric Ready-to-Fill Capsules Simplifying Pharmaceutical Manufacturing, Pharmaceutics (2023), 15: 2592. doi.org/10.3390.
15. Mate PC, Gokhale N, Jambhulkar Y and Singh G. A Comparative In-Vitro study for Evaluation of different Marketed brands of Metformin Hydrochloride (500 mg) Tablets, International Journal of Pharmacy & Life Sciences (2020), 11(7): 6738-6745.
16. Hettiarachchi TW, Wickramaratne DBM, Sudeshika SHT, Akshila Niyangoda, Sakeena MHF and Herath HMDR. Comparative In-Vitro Evaluation of Metformin HCl and Paracetamol Tablets Commercially Available in Kandy District, Sri Lanka, Int J Pharm Pharm Sci. (2014), 7(2): 520-524.
17. Fabio Seigi Murakami, Cassiana Mendes, Bernardi LS and Rafael Nicolay Pereira. Development and evaluation of 20 mg omeprazole gastro-resistant tablets, Latin American Journal of Pharmacy (2008), 27(4): 519-527.
18. Shravani Y, Hindustan Abdul Ahad, Chinthaginjala Haranath, Gamaa Birir Mohamed Musa, Adam Ali Omer Adam and Kethari Rushiketh Reddy. In vitro Relative examination of Dissimilar brands of Rabeprazole sodium Gastro-Resistant Tablets, International Journal of Life Science and Pharma Research (2020), 10(5): 1-5. doi.org/10.22376/ijpbs/lpr.2020.10.5.P1-5.
19. Yaa Asantewaa Osei, Elvis Oppong Boakye, Marcel T Bayor and Frederick William Akufo Owusu. Physicochemical Equivalence and Quality Assessment of Various Brands of Gastro-Resistant Omeprazole Capsules in the Kumasi Metropolis, Hindawi, The Scientific

World Journal (2022); Volume 2022: Article ID 7924600. doi.org/10.1155/2022/7924600.

20. Shaila Eamen, Sayful Islam M, Safinaj Arju Ara Alam, Moyen Uddin M, Golam Mucktady M, and Sultana S. In-Vitro Fundamental Assessment of Disintegration and Dissolution Profile of Enteric Coated rabeprazole Tablet Commercially Accessible in Bangladesh, British Journal of Pharmaceutical Research (2015), 6(6): 423-428.
21. Pranav Palshikar, Anshu Sharma, Chetan Singh Chauhan and Ravindra Kamble. Preparation and Evaluation of Enteric Coated Tablet of Sodium Valproate, International Journal of Research in Pharmacy and Chemistry (2013), 3(3): 583-590.

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