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Evaluation of Physical and Chemical Properties of Paracetamol (500mg) Tablets Marketed in Syria

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ABSTRACT

Paracetamol is medicine in all country and accessible without a prescription. Many commercial types of paracetamol tablets (500mg) are available in the Syrian drug market. The objective of this article is to evaluate the physicochemical characterizes for five commercial types of paracetamol (500 mg) tablets marketed in Syria. Paracetamol was evaluated for mass uniformity, friability, hardness, content uniformity, and dissolution rate. All the groups complied with the pharmacopieal specifications for mass uniformity and friability tests. Two brands (B, D) passed the USP requirements for content uniformity with values (90-110%) while the remaining groups failed. Three tested groups released more than 80% drug in 30 minutes except group A and group C.

KEY WORDS: Paracetamol, Hardness, Friability, Weight Variation, Content Uniformity, Dissolution Test.

1. INTRODUCTION

Quality control of drugs is considered important subject in the field of giving drug since the existing of many pharmaceutical industries that produce the same form for paracetamol. The examinations for considered solid dosage form involve tests for physical properties. Tablets should pass this tests to ensure that patient will receive the required therapeutic efficacy, and the drug is safe for the patient throughout the expiration date (Kohler, 2009; Ansel, 2000).

Paracetamol and acetaminophen are commonly used names for drug that is chemically derived from N-acetyl-para-aminophenol (Figure.1). It is accessible without a prescription. The main use of paracetamol is analgesic and antipyretic. It was discovered since about 95 years ago, but until now the mechanism that it affects in the body is unknown. Its pharmacological effects similarly to NSAIDs, but it doesn't have any anti-inflammatory activity (MARTA JB, 2014). The absorption of paracetamol occurs quickly from the gastrointestinal tract and reaches to its peak plasma after about 30 minutes from oral doses. The distribution happens into most body tissues. Paracetamol is excreted in the urine after the metabolism in the liver by cytochrome p450. The elimination half-life is about 2 hours. Paracetamol traverses the placenta and exhibits in breast milk (van der Marel, 2003; Prescott, 1993; Prescott, 1996; Prescott, 1989). Paracetamol is available in many dosage forms like as tablets, syrups, suppositories, injections, oral drops.

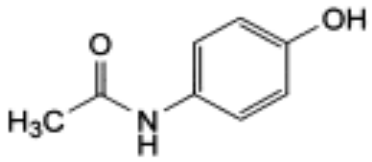

Figure.1. Structure of paracetamol

In Syria, most of pharmaceutical companies manufacture different forms of paracetamol. The main idea of this study is to test the physicochemical characterizes for five commercial types of paracetamol (500 mg) tablets marketed in Syria.

2. MATERIALS AND METHODS

We concentrate in this study on five commercial brands (A, B, C, D, E) of paracetamol tablets. The samples were chosen arbitrarily from registered pharmacies in Lattakia, Syria and have the strength of 500 mg. All the examinations had done during the product expiration dates. Plus to Freshly distilled water, many chemical reagents were used in our study like as sodium hydroxide, and potassium dihydroorthophosphate.

Mechanical resistance tests: This include hardness and friability tests.

Mass uniformity: this test is necessary in tablets evaluation. We took sample from 20 tablets for each commercial type.The deviation of weight each tablet from the average weight shouldn't left over ±5% according to USP.

Uniformity of content: 10 tablets were taken from each brand. Each tablet should contain not less 90% and not more than 110% of the active substance (proxy USP specification for drug content).

Dissolution test: For passing the test all paracetamol immediate release tablets must release 80% of drug within 30 minutes.

3. RESULTS AND DISCUSSION

Mechanical resistances tests: According to BP all commercial types passed the test.

Table.1. hardness and friability of metformin tablets

Brand	Hardness (KP±SD) N=10	Friability (%) N=20
A	7.12 ±0.14	0.76
B	6.56 ±0.65	0.65
C	5.87 ±0.46	0.91
D	6.23 ±0.79	0.54
E	7.24 ±98	0.82

Mass uniformity: As a result all commercial types passed the pharmacopeia requirements for weight variation (table.2).

Table.2. Weight variation of metformin tablets

Brand	Measured weight mean (mg) N=20	Deviation Range (%)	RSD (%)
A	543	-2.76 – 4.32	4.13
B	572	-1.12 – 3.78	2.97
C	555	-3.32 – 3.35	4.09
D	545	-4.09 – 4.76	4.67
E	560	-3.45 –4.21	4.89

Content uniformity: Firstly, there was a linearity relationship in the range of 0.12-0.3mg/100ml when standard curve for paracetamol in sodium hydroxide was prepared. The regression equation is Y= 2.6515X-0.0104 and the correlation coefficients (r) of the linear regression of the calibration curves is 0.9998.

The results presented that two brands (B, D) passed the USP requirements for content uniformity with values between the range (90-110%) (table.3).

Table.3. Content uniformity of metformin tablets

Brand	Measured drug content mean (mg) N=10	Percent of content range (%) N=10	RSD (%)	Outside of proxy USP specification
A	431	84.32-88.54	3.45	10
B	465	91.78-95.77	2.15	0
C	445	86.05-91.11	4.76	8
D	476	92.43-97.19	4.98	0
E	427	82.79-87.09	5.02	10

Dissolution test: All formulations excluding formulation A and C passed this acceptance pharmacopeia criterion (USP).

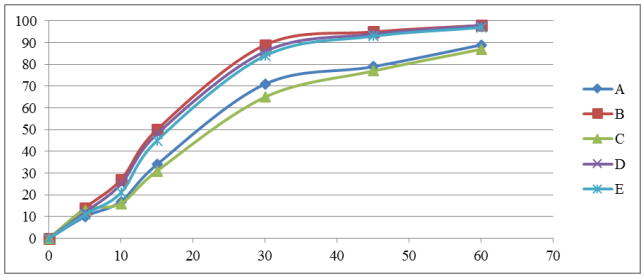

Figure.2. Dissolution profiles of paracetamol tablets

4. CONCLUSION

On the whole, all studied commercial types passed the non-official test of hardness and passed the pharmacopeial requirements for friability (less than 1%), and weight variation tests (deviation less than ±5%). Two groups (B, D) passed the USP requirements for content uniformity, while groups (A, C, E) failed the test with values outside of proxy USP specification. In this article, as expected for highly soluble compound, paracetamol, it was observed that for all products, at least 80% release within half an hour took place except brand A and brand C.

REFERENCES

Ansel HC, Popovich NG, Allen LV, Formas farmacêuticase sistemas de liberacao de farmacos, Sao Paulo, 6, 2000, 568.

Kohler LF, Nascimento HC, Schwengber ELL, Bandeira ZMP, Pazin GV, Machado SRP, Avaliacao biofarmacotecnica e perfil de dissolucao de comprimidos de dipirona: equivalências farmaceutica entre medicamentos de referencia, genericos e similares, Rev Bras Farm, 90 (4), 2009, 309-315.

Marta jewiak-b benista and jerzy z, nowakacta, Paracetamol, mechanism of action, applications and safety concern poloniae pharmaceutica ñ drug research, 71 (1), 2014, 11-23.

Papadopoulou V, Valsami G, Biopharmaceutics classification systems for new molecular entities (BCS-NMEs) and marketed drugs (BCS-MD): theoretical basis and practical examples, Int. J. Pharm, 361 (1-2), 2008, 70-77.

Prescott LF, Impaired absorption of paracetamol in vegetarians, Br J Clin Pharmacol, 36, 1993, 237–240.

Prescott LF, Paracetamol (acetaminophen): a critical bibliographic review, London, Taylor & Francis, 1996.

Prescott LF, Paracetamol disposition and metabolite kinetics in patients with chronic renal failure, Eur J Clin Pharmacol, 36, 1989, 291–297.

Van der Marel CD, Paracetamol and metabolite pharmacokinetics in infants. Eur J Clin Pharmacol, 59, 2003, 243–251.