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Weight Variation Test for Different Brands of Metformine 850 mg Tablets

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ABSTRACT

Quality of medicines is a very important aspect in drug manufacturing since it guarantees that the produced pharmaceutical products comply with pharmacopeial standards of safety, purity and quality. In this paper a quality control examination in terms of weight variation test has been performed for three brands of the antidiabetic tablets Metformin which were purchased from private pharmacies in Derna city. Weight variation test has been conducted according to the method and specification of the United States Pharmacopoeia (USP). The brands tested are Metformal[®] by Guidotti S.p.A, an Italian company, Metformin by Bristol-Myers Squibb, an American pharmaceutical company and Mefor[®] by TERIAK. a Tunisian pharmaceutical company. The results showed that Metformal[®] of Guidotti, Italy had the lowest mean of percentage deviation of 0.04% followed by Metfor[®], Teriak of Tunisia and Metformin[®] Bristol of USA with a mean percentage deviation of 0.37% and 0.44% respectively. It is important to note that official quality control tests for pharmaceutical tablets comprise weight variation test, uniformity of contents, disintegration test, dissolution test and friability test. It is important to run all official tests mentioned in the official pharmacopeia but limitation due to lack of instruments and chemicals was the main reason not conduct these tests in this paper. From this work, it is highly recommended that a quality control lab or center should be available in Derna city to be able to conduct all quality control tests in order to ensure quality of pharmaceutical products.

1. Introduction

The Quality of pharmaceutical products is a huge effort that ensures the appropriateness of drugs and medicines for their intended use based on their safety and quality according to the label claim introduced by the manufacturing company (Mittal A et al, 2015). For this reason, the activities of quality should be built into production of pharmaceutical products. (Gupta VN et al, 2015). The Pharmaceutical Industry has advanced in such a way that requires deep quality control to ensure that the produced pharmaceutical products meet the International pharmacopeial standards of efficacy and quality. (Linda A. Felton) The International Standard of Organization (ISO) defines quality control as “the operational techniques and activities that are useful to fulfil requirements for quality”.

This definition means that every activity related to control, enhancement, management or assurance of quality might be accomplished by the quality control test (Mittal A et al,2015).The manufactured products are considered as “fit for use” only if they comply with the established quality standards mentioned in the official pharmacopeias such as the United States Pharmacopeia (USP),The British Pharmacopeia(BP) The European Pharmacopoeia (PhEur),The Indian Pharmacopoeia (IP), The International Pharmacopoeia (PhInt) and The Japanese Pharmacopoeia (JP). (Woodcock J. ,2004). These pharmacopeias have laid down the diverse specified limits to some extent within which the value should fall in order to be acceptable as per the standards. The introduction of the Food and Drug Administration (FDA) of the current good manufacturing practices (cGMP) resulted in magnification of the awareness and importance of the quality of medicinal products. (Mazumder B. et al,2011). Both production and quality control (QC) are brought under the roof of GMP (Fortunak JM et al,2014). The quality of all aspects involved in drug manufacturing, is analyzed by QC personnel to abolish errors at each step during manufacturing. For this reason, quality control must be built into medicines during production and designing of a process which is achieved by the proper spacing, ventilation, design of the plant, sanitation and hygiene during schedule fabrication of products (Rana TM et al, 2009).For confirming the quality of pharmaceutical dosage form, it is required to perform the quality control test as prescribed in various pharmacopoeias and guidelines (Aulton ME,2001).Quality control of medicinal products involve all measures taken, including the establishment of specifications, sampling, relevant testing and analytical clearance, to make certain that the starting materials, intermediates, packaging materials and finished pharmaceutical products conform with approved specifications or standard for identity, strength, purity and other attributes (World Health Organization,2011).Quality control focus attention on testing of products for pitfalls. This obligates the producer to refuse the releases of products or carry out the possible investigation to make products absolutely free of manufacturing errors prior to release into the market. (Teja CH et al,2011)In-Process Quality Control (IPCQ) ensures that the product complies with all the quality requirements, principally safety and efficacy and that all operations that are carried out before, during and after the manufacturing of a finished product, from receiving raw materials, processing, packaging and labelling until the end of the batch are controlled (Mazumder B et al,2011)In-process quality control represents the monitoring and evaluation of manufacturing process to produce medication of superior efficacy, safety and quality which assure the consumer that the products perform consistently and, in a manner, satisfactory for the purpose of its intended use (Levi L et al,2010). During Quality control of tablets During the manufacturing and formulation of tablets, a number of the procedures are employed to assess the quality of tablets. (Levi L et al,2010). Some tests are regarded as official tests and described in pharmacopoeias which are traditionally concerned with content and in vivo release of active substances, while other than pharmacopoeias are known as non-compendia test concerning with quality attributes and need to be used in quality evaluation of tablets (Aulton ME,2001).Finished products are those dosage forms that have undergone every phase of production, including the packaging in its final container and labelling (World Health Organization,2011). The FPQC test with respect to qualitative and quantitative characteristics along with test procedures and their acceptance limits as described in specification by which the finished product should comply throughout its valid expiration date (Teja CH et al,2011). The specification of the finished product is determined by the quality attributes related to the process of production. During the developmental phase and at the time of validation of the manufacturing process, a suitable specification for every facet of the quality studied should be determined regularly (Vinay S et al,2011). During or after the manufacturing process, certain IPQC and FPQC assessment are performed where the acceptance criterion is the same or minimal than the release requirement, (e.g. size, shape, weight, hardness, thickness, disintegration, dissolution and other characteristics) which may serve as a foundation for quality evaluation when included in the specification (Teja CH et al,2011). Finished product quality control test for tablets are dimensions (thickness, diameter), assay, uniformity of content, weight variation, friability test, the content of active ingredients, hardness test, disintegration test, dissolution test etc. (WHO,2014) The four tests are likely to relevant to tablets dosage form and other pharmaceutical products are description, identification, assay and impurity (WHO,2014).

The aim of this study is to evaluate different brands names of Metformin tablet 850mg purchased from private pharmacies in Derna city in order to perform Finished product quality control in terms of Weight variation test according to the USP method and standard.

Weight variation test

Weight variation test is carried out for uncoated and coated tablets by weighing 20 tablets individually, the average weight of these 20 tablets is determined and then the standard deviation of each tablet from the average weight is determined The batch is regarded as accepted if the weight of not more than 2 of tablets deviates from average weight by greater than the percentage listed in table 1 and no tablet vary in weight by more than two-fold of that percentage .(14.15.16)

The result of this test is expressed in percentage and calculated from the given formula:

$$\text{Weight variation} = [WI - WA] / WA \times 100$$

Where,

WI = Individual tablet's weight

WA = Average tablet's weight

Table 1 Weight variation tolerance for uncoated and film-coated tablets as per IP, BP and USP

IP/BP	% Deviation	USP
80 mg or less	10	130 mg or less
More than 80 mg and less than 250 mg	7.5	More than 130 mg and less than 325 mg
250 mg or more	5	325 mg or more

2.Method

The materials used were 20 tablets of each brand of Metformin 850mg tablets and a digital balance.

Weight variation test has been performed according to the weight variation test which is described in the USP where 20 tablets are weighed individually then the average weight has been determined. The weight variation has been calculated from the given formula:

$$\text{Weight variation} = [WI - WA] / WA \times 100$$

Where,

WI = Individual tablet's weight

WA = Average tablet's weight

The USP standard for % deviation for each weight group is shown in table 2. Since Metformin tablets under investigation have the weight of 850mg (i.e., More than 325 mg), the % of deviation which is selected was 5% according to the USP standard. (14,15,16)

The batch is regarded as accepted if not more than 2 of the 20 tested tablets deviate from the average weight by more than 5% percentage, and no tablets vary in weight by more than two-fold of that percentage (i.e. 10%).

Table 2. The USP specification for weight deviation according to tablet weight

Weight of tablets (mg)	% Deviation
130mg or less	10
More than 130 mg and less than 325 mg	7.5
325 mg or more	5

3 Ethical Approvals

An ethical approval to conduct this study has been determined from the office of The Office of Ethics and The Office of Quality in the College of Medical Technology, Derna Libya.

4.Results

The results for weight variation test for the three Metformin 850mg brands are shown in tables 3,4 and 5

Table 3 The weight variation results For Metforal® from Guidotti company

Number of tablets	Weight of Tablet (mg)	Percentage Deviation (%)
1	959	1.62
2	936	-0.81
3	961	1.83
4	944	0.03
5	944	0.03
6	946	0.24
7	943	-0.07
8	949	0.56
9	956	1.30
10	934	-1.02
11	939	-0.49
12	952	0.87
13	941	-0.28
14	934	-1.02
15	937	-0.70
16	940	-0.39
17	927	-1.76
18	943	-0.07
19	941	-0.28
20	955	1.19
Mean	943.7mg	0.04%

Table 4. The weight variation results For Metformin® tablet 850 mg from Bristol-Myers Squibb, USA

Number of tablets	Weight of tablet (mg)	Percentage Deviation (%)
1	990	-0.93
2	977	-2.23
3	995	-0.43
4	999	-0.03
5	1010	1.07
6	1004	0.47
7	989	-1.03
8	987	-1.23
9	1006	0.67
10	1000	0.07
11	1006	0.67
12	995	-0.43
13	990	-0.93
14	999	-0.03
15	1013	1.37
16	1010	1.07
17	1007	0.77
18	981	-1.83
19	999	-0.03
20	1016	1.67
Mean	999.3 mg	0.44%

Table 5 The weight variation results for Mefor® for TERIAK company, Tunisia

Tablet No.	Weight of tablet (mg)	Percentage Deviation (%)
1	904	0.53
2	889	-1.13
3	908	0.97
4	892	-0.80
5	920	2.31
6	922	2.53
7	892	-0.80
8	905	0.64
9	901	0.20
10	891	-0.91
11	911	1.31
12	866	-3.6
13	907	0.86
14	899	-1.13
15	812	-9.69
16	899	-0.02
17	890	-1.02
18	902	0.31
19	909	1.08
20	887	-1.35
Mean	899.2 mg	0.37 %

5. Discussion

The results showed that all the tested Metformin brands have passed the weight variation test according to the USP standard which is 5% for this weight group above 325 mg. and for this reason they are regarded as accepted batches. The results also showed that Metformal® tablets of Guidotti, Italy had the lowest mean of percentage deviation of 0.04% followed by Metfor® Teriak of Tunisia and Metformin® of Bristol with a mean percentage deviation of 0.37% and 0.44% respectively.

6. Conclusion

From this work, it is concluded that all metformin tested batches under the tested brand names have complied with the USP standard of weight variation test and regarded to be accepted.

It is important to emphasize that further studies involving more brands of metformin to check their quality and compliance with pharmacopeial standards are needed.

7. Suggestions

It is highly recommended that a quality control center in Derna city is to be established to enable us to conduct all needed quality control tests for different pharmaceutical products.

This center will enable us to conduct all required quality control tests ensuring that all pharmaceutical products available in the markets comply with the international quality standards stipulated in the pharmacopoeias such as the United States Pharmacopeia (USP) and the British Pharmacopeia (BP).

By this way, we can guarantee that the patients are consuming high quality medications which are safe and effective and of high quality.

8. Limitations

Because of lack of materials and instruments, the whole FPQC of pharmaceutical tablets which include weight variation test, friability test, uniformity of content test, disintegration rate test and dissolution rate test, could not been carried out in this study.

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