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# COMPARATIVE QUALITY CONTROL TESTS FOR DIFFERENT MEDICINES SUPPLIED BY MEDICAL STORE DEPOT TO HEALTH FACILITIES AND SIMILAR GENERICS AVAILABLE IN THE MARKET

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**Abstract:**

***Aim:*** *To access the difference between the qualities of medicine purchased by the Medical Store Depot and the same generics available in the local market having same price.*

***Material and Methods:*** *Three different groups of medicines which are majorly used in the hospitals were selected i.e. anti-allergic, antibiotic and analgesic, two different groups were made based on purchased by MSD and similar brands available in the market, sufficient quantity of medicines were taken as per specification of Pharmacopeia and quality control tests were performed.*

***Results:*** *weight variation, thickness and hardness of both groups were within the Pharmacopeial range, friability results showed that MSD medicines had 0 – 0.20% and market medicines had 0 -0.35% loss in initial weight where, disintegration results revealed that majority of the MSD medicines had more time for disintegration as compared to market medicines. No marked difference was seen in drug release study i.e. 98.481 – 104.98%, 98.13 – 105.65% by MSD and present in the market respectively.*

***Conclusion:*** *Present study revealed that medicines purchased by the medical store depot have enough quality to be used in the patients and they are not substandard as compared to official standards. However, the same molecule presents in the market with different brand have much better quality and lie close to official standards as compared to the medicine purchased by the MSD.*

**Key Words:** *Quality Control, Medical Store Depot, Pharmacopeia*

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## INTRODUCTION:

Market of Pharmaceutical companies for their finished products varies from the government hospitals to private hospitals and the community pharmacies [1]. All those purchasers have different system of purchasing and mode of payment to the manufacturers [2]. As Government of Pakistan provides medicine to the community without any cost that's why tries to purchase the effective and cheap medicines to full fill the need of community [3]. Selection of appropriate drug at lower cost in a suitable quantity and provision to end user at right place and time is possible with a well-structured supply chain management system in health sector. After eighteenth amendment provincial Government is responsible to manage all health facilities in the province [4]. The Health department of Baluchistan is spending quite a budget to purchase health commodities to ensure adequate availability in the center and the peripheries by a stable administrative structure.

Government of Baluchistan purchase all the health commodities through Medical Store Depot (MSD) and the same is responsible to purchase quality medicine from the reputed manufacturers so that the end users get maximum benefit as far as their health is concern [5]. The safety, effectiveness and efficacy of pharmaceutical dosage form can be guaranteed when its quality is reliable and to confirm the quality of pharmaceutical dosage form it is required to perform the evaluation tests as per the official books like USP, BP etc [6-8]. Several In-vitro tests can be performed on the finished products to assess their quality e.g. Hardness test, thickness test, Weight variation, friability test, disintegration test and dissolution test [9]. In connection to what have said it is seen in the literature that numerous studies have been conducted on the finished products available in the market with different brands but none has been done on the medicine purchased by the MSD [10-12]. Therefore, the current study is designed to evaluate the quality of medicines purchased by MSD along with their comparison to the same generic available in the local market.

## METHODOLOGY

### Material:

Products from the Medical Store Depot (MSD) in appropriate quantity to conduct all the quality control tests on the basis of United States Pharmacopeia were taken along with the products from the market having save generic as that of the products opt from MSD in appropriate quantity to conduct all the quality control tests on the basis of United States Pharmacopeia [13]. Mettler AJ100, Switzerland weighing balance was used for weighing purpose, HQ40D pH meter was used for determination of pH, Phosphate and Acetate buffers for different analysis, Hardness Tester (Pharma test type PTB 301, Hainburg Germany), Friabilator (Pharma test type PTF1, Hainburg Germany), Vernier caliper, Disintegration apparatus (Pharma test type PTZ3, Hainburg Germany), Dissolution apparatus (Erweka TD6R, Germany), UV-Visible spectrophotometer and all other relevant lab apparatus to conduct the research.

### methods:

Six different generics of three different therapeutic classes was selected from MSD including Azithromycin, Ciprofloxacin, Diclofenac, Paracetamol, Chlorphenaramine and Citrizine, representing Antibiotic, Non-steroidal anti-inflammatory agents (NSAIDs) and Anti-Allergic respectively. Similar generics having same price was selected from the market for comparison. All those selected drugs were coded. Following tests were carried out according to the standards of official books.

### Hardness test:

Hardness of the tablet determines its disintegration thus sufficient hardness is desired for the tablet. Hardness Tester (Pharma test type PTB 301, Hainburg Germany) was used to perform the test. Ten tablets were taken and their hardness was determined and compared with the official standards [14].

### Thickness test:

Thickness of the tablets was measured with the help of Micrometer (M&W sheffild, England). Thickness of the tablets needs to be measured for the uniformity in the batch. Ten tablets were taken and their thickness were measured and compared with the standards [15].

### Weight Variation test:

This test identifies uniformity of the batch which reflects drug content uniformity. Twenty tablets were selected and weighed, average was calculated and difference in individual and average was considered and compared with official standards [16].

### Friability Test:

To assess the wear and tear in the products this test is performed, it also gives the idea of the possible loss in the tablet during transportation. Ten tablets were taken and their weight was recorded after that the same was placed in the Friabilator and it was rotated at 25 rpm for 4 minutes, those tablets were weighed

again for the loss and percentage was calculated, the result was compared with the official standards [17].

**Disintegration test:**

It is the process in which the tablets break down into smaller particles and can pass through mesh size 10. Basket rack assembly was used for this test, distilled water was used as solvent, and temperature was set at 37±2 ° C, motor was derived at 28-32 cycle/min. time taken by all the tablets to disintegrate was noted and compared with the standards [18].

**Dissolution test:**

This test indicates the drug release pattern of the tablets along with their efficacy. It is designed closely to the body conditions to predict the in-vivo release of the tablet. USP dissolution apparatus II was used, buffer of optimum pH was prepared, sampling time was adjusted, temperature was controlled at 37±0.5°C, apparatus was set at 50 rpm, after withdrawing the sample fluid was replaced. UV-Visible spectrophotometer was used to calculate drug release [19].

## RESULTS:

Table no 1. Comparative values for Weight variation, Hardness and Thickness along with their standard error of mean *(SEM)*

| Physical Parameters | Diclofenac Potassium | | Paracetamol | | Ofloxacin | | Ciprofloxacin | | Citrizine | | Chlorphenaramine | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** |
| **Weight variation** | 0.157 *±0.00* | 0.314 *±0.00* | 0.614 *±0.00* | 0.590 *±0.00* | 0.564 *±0.00* | 0.382 *±0.00* | 0.419 *±0.00* | 0.379 *±0.00* | 0.145 *±0.00* | 0.113 *±0.00* | 0.136 *±0.00* | 0.150 *±0.00* |
| **Hardness** | 61.29 *±0.63* | 64.43 *±0.09* | 110.63 *±1.64* | 92.98 *±2.52* | 161.07 *±1.25* | 75.1 *±1.10* | 140.8 *±2.88* | 69.35 *±0.99* | 45.01 *±2.96* | 62.99 *±0.46* | 40.16 *±1.18* | 44.86 *±3.47* |
| **Thickness** | 2.90 *±0.02* | 5.206 *±0.01* | 4.482 *±0.01* | 4.46 *±0.02* | 5.582 *±0.03* | 4.439 *±0.01* | 4.526 *±0.06* | 4.309 *±0.01* | 3.583 *±0.01* | 2.926 *±0.01* | 2.658 *±0.04* | 2.969 *±0.06* |

Table no 2. Comparative values for Friability and Disintegration

| Physical Parameters | Diclofenac Potassium | | Paracetamol | | Ofloxacin | | Ciprofloxacin | | Citrizine | | Chlorphenaramine | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** | **MSD** | **Market** |
| **Friability (%)** | 0.12% | 0.00% | 0% | 0.35% | 0.07% | 0.00% | 0.05% | 0.23% | 0.20% | 0.17% | 0.00% | 0.00% |
| **Disintegration (minutes)** | 20 | 7 | 2 | 1 | 2 | 5 | 5 | 4 | 5 | 9 | 3 | 2 |

Table No 3. Result obtained from percent (%) content of tablets

| Tablets for sampling | Diclofenac Potassium | | Paracetamol | | Ofloxacin | | Ciprofloxacin | | Citrizine | | Chlorphenaramine | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MSD | Market | MSD | Market | MSD | Market | MSD | Market | MSD | Market | MSD | Market |
| 1 | 99.03 | 100.312 | 100.52 | 103.02 | 99.419 | 100.424 | 102.47 | 102.24 | 99.677 | 100.701 | 100.469 | 100.455 |
| 2 | 98.16 | 100.318 | 102.64 | 102.31 | 98.429 | 100.43 | 100.19 | 101.73 | 100.699 | 99.687 | 98.481 | 100.462 |
| 3 | 98.31 | 100.299 | 100.85 | 101.81 | 98.428 | 100.422 | 100.73 | 100.73 | 99.681 | 100.713 | 99.478 | 99.475 |
| 4 | 100.66 | 103.65 | 100.40 | 98.13 | 99.58 | 100.00 | 102.19 | 102.19 | 96.99 | 100.42 | 100.61 | 98.37 |
| 5 | 104.98 | 105.64 | 102.49 | 101.66 | 101.17 | 101.41 | 100.42 | 100.39 | 100.00 | 98.42 | 101.10 | 99.31 |
| 6 | 102.99 | 99.33 | 101.25 | 102.36 | 100.94 | 99.52 | 102.39 | 102.39 | 97.56 | 102.14 | 101.43 | 100.29 |

## DISCUSSION:

Medical store depot (MSD) which is the drug distribution institution for whole Balochistan and it runs under the supervision of government, its duty is to purchase medicine and distribute to all government hospitals of the vicinity. As government has to serve huge number of people thus it tries to buy cheap drugs from local companies as compared to multinational companies which consumes more budget. To assess the quality of medicine purchased and supplied by the MSD three different groups of drugs were selected which were commonly in use i.e. Diclofenac potassium and Paracetamol representing NSAID group, Ofloxacin and Ciprofloxacin representing antibiotic group, Cetirizine and Chlorphenaramine representing anti allergic group respectively, their quality control tests were conducted and compared.

As far as the weight variation is concerned there is no marked difference between the medicine of MSD and that available in the market, according to United States Pharmacopeia (USP) “Not more than 2 tablets deviate from average weight by more than 7.5% deviation”. Whereas marked difference is noticed in the hardness of paracetamol, ciprofloxacin, cetirizine and chlorphenaramine respectively, as hardness represents resistance abrasion, chipping or breakage during transportation and storage determination of hardness is necessary, limits as per British Pharmacopeia (BP) is (4-6Kg). Noticeable difference is seen in the thickness of tablets supplied by the MSD and present in the market 0.63-2.96 Kg/cm2 purchased by MSD and 0.09-3.47 Kg/cm2 present in the market as shown in table no. 1. Thickness uniformity is necessary for consumer as well as for packaging. USP permits 5% variation. Our result is in line with the study conducted in India reviewing the evaluation of tablets[20].

Friability is another indicator to check strength of the tablet. 20 tablets were taken from each brand, as per USP tablets that lose 1% of their weight are considered acceptable. From our data as shown in table no.2 it is obvious that both medicines purchased by MSD and that available in the market comes in acceptable limit i.e. MSD having 0-0.20% and Market having 0-0.35% respectively. Our results are supported by another research [21].

For almost all the solid dosage forms it is necessary to breakup or disintegrate and convert into small particles to form solution. Therefore, sometimes this disintegration steps serves as rate limiting step in absorption. Formulation factors i.e. excipient used in the formulation and process of manufacturing may effect disintegration of tablets. The disintegration time was determined according to the method reported by USP [22]. To qualify for this test tablets must disintegrate within 1 hour. Our results revealed that diclofenac potassium, ciprofloxacin, chlorphenaramine and paracetamol purchased by MSD consumed more time as compared to tablets obtained from market, oflaxacin and citrizine of MSD had less disintegration time as that of present in the market. These facts are supported by the study [21].

Drug release study is a measure of amount of drug released into dissolution medium with respect to time. This study provides a clue of drug absorption

followed by oral administration. Poor dissolution results in poor availability of drug at the site of absorption leading to sub-therapeutic efficacy. Results of in-vitro release are described in table no.3. percent drug release for both purchased by MSD were 98.481 – 104.98% and market were 98.13 – 105.65% respectively. As per official book (IP) for each tablet tested for dissolution amount of Active ingredient in solution must not be less than 70% of the labelled amount. Our results describe that all medicines were within range, in concordance with another study [23].

## CONCLUSION:

Our study revealed that medicine purchased by the medical store depot has enough quality to be used in the patients and they are not substandard as compared to official standards. However, the same molecule presents in the market with different brand have much better quality and lie close to official standards as compared to the medicine purchased by the MSD. It is therefore, recommended that MSD must look into the quality of medicine before purchase along with the price so that more quality medicine can be utilized by the patients.

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