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# Chewable Tablets: Is this Dosage Form Well Evaluated by Palestinian Health Professionals?

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**Abstract:**To evaluate the scientific knowledge and attitudes of health professionals in Palestine regarding the advantages of chewable tablets in comparison with other related dosage forms**. Methods:** Data was gathered from a questionnaire that was handed out to community pharmacists & Physicians. Pharmaceutical industry decision makers were also enrolled in this study. Data was analyzed using SPSS statistical software program version 11.0**. Results:** Both the 149 pharmacists and 111 physicians who participated in this study, had very close opinions with regard to the superiority of chewable tablets over the corresponding liquid dosage forms, especially when issues of palatability, stability, dose precision, ease of administration, portability and safety were mentioned. Pharmacists and physicians were uncertain about the higher effectiveness of chewable tablets in comparison with other related dosage forms, (i.e syrups and suspensions), which contain the same active ingredients. All industrial decision makers thought that the number of chewable tablet formulations present in Palestine is relatively low. One third of them believed that this dosage form is not fully evaluated nor well appreciated by pharmacists and doctors. About half of them thought that the lack of technology or specialized personnel is the reason behind the poor development of this dosage form**. Conclusion**: The importance of chewable tablets is not completely understood and appreciated by the Palestinian health personnel. Pharmaceutical manufacturers should pay more attention to the development and production of chewable tablets due to the obvious advantages of this dosage form. Clear and complete information about this dosage form must be provided to pharmacists and physicians by medical representatives.

**Key words:** chewable tablets, portability, palatability, safety.

# الأقراص القابلة للمضغ: هل هذا الشكل الصيدلاني مقيم بشكل جيد من قبل العاملين في القطاع الصحي الفلسطيني؟

**الملخص:هدف البحث:** هدف هذا البحث هو تحديد معرفة أعمدة النظام الصحي الفلسطيني( صيادلة، أطباء، صانعي القرار في المصانع) بأهمية و فوائد الأقراص القابلة للمضغ بالمقارنة مع الأشكال الصيدلانية الأخرى ذات الصلة (محاليل و معلقات). **منهجية البحث:** تم تحضير و توزيع استبانة على الصيادلة و الأطباء العاملين في القطاع الصحي الفلسطيني، كما تم استقتاء اراء صانعي القرار في مصانع الأدوية الفلسطينية. **النتائج:** كان لدى كلا" من الأطباء و الصيادلة المشاركين في تعبئة الاستبانة (111 طبيب و 149 صيدلاني ) تقارب في المعلومات من ناحية تفوق الأقراص القابلة للمضغ بالمقارنة مع المحاليل و المعلقات و ذلك من النواحي المتعلقة بالطعم، الثباتية، دقة الجرعة، سهولة التناول، سهولة النقل و الأمان. غالبية الصيادلة و الأطباء لم تكن لديهم معلومات واضحة أو صحيحة عن تفوق هذه الأقراص من ناحية الكفاءة مقارنة مع نظائرها من المحاليل التي تحتوي على نفس المادة الفعالة.اتفق جميع صانعي القرار في المصانع على أن هذا الشكل الصيدلاني غير متوفر بما يكفي في السوق الصيدلاني الفلسطيني، يعتقد ثلثهم أن السبب هو عدم المعرفة و بالتالي الاقتناع الكافيين للصيادلة و الأطباء باهمية هذا الشكل الصيدلاني بينما يعتقد 50 %منهم أن السبب في عدم وجوده بكثرة هو النقص في المهارات و التكنولوجيا الكافية لتحضيره. **الاستنتاج:**أهمية الأقراص القابلة للمضغ في النظام الصحي الفلسطيني غير مفهومة وواضحة بالكامل. على صانعي القرار في مصانع الأدوية الفلسطينية الاهتمام بهذا الشكل الصيدلاني و الدفع باتجاه إنتاجه، نظرا" للفوائد العديدة التي يتمتع بها بالمقارنة مع نظائره ذات الصلة.

## 1. Introduction:

Oral dosage forms are the most popular pharmaceutical dosage forms available nowadays and this among other matters is mainly due to the ease of their administration. In some patients, however, oral dosage forms are not necessarily a convenient option. The difficulty encountered in swallowing tablets and capsules is one reason, while the fact that some patients find it inconvenient to take large amounts of water with the medication is another [1]. Conversely, many patients are not able to tolerate the taste of many drugs when formulated as liquid dosage forms, thus leading to poor patient compliance in those cases. Lately, recent developments in dosage form technology are concentrating on presenting the patient with viable dosage alternatives which provide good palatability and ease of administration at the same time [2,3,4]. This is especially valid when the preparation is to be administered to an infant or to an elderly patient. In such cases, powders for reconstitution, suspensions, syrups, elixir solutions and chewable tablets are considered to be suitable alternatives which solve the above-mentioned problem in some cases and satisfy the needs of such patients**.** It is worth

mentioning, though, that some patients still find inconvenience in taking the liquid dosage forms, in measuring the exact dose accurately or in carrying the package along while traveling [5-10]. All the mentioned reasons make chewable tablets one of the excellent alternative choices as an easy method of drug administration for these patients. In fact, the FDA has invited pharmaceutical manufacturers to develop and produce proper dosage forms especially for pediatric patients. Up until 1999, more than 60 chewable tablet medications were approved for patient use in the U.S.A. The list includes a wide range of medications such as analgesics, cold preparations, vitamins, anti-infectives, anti-convulsants and antacids [11-13]. In this context, chewable tablets are known to be advantageous over liquid dosage forms in many aspects, such as higher palatability, better availability, stability, dose precisions, portability and ease of administration especially during traveling [13]. As for the situation in the Palestinian market, a total of only 11 active ingredients are present as chewable tablets where all these active ingredients are manufactured by foreign pharmaceutical companies, while six out of these 11 were reproduced by Palestinian pharmaceutical companies. In the light of what was mentioned above re this dosage form, we decided to undertake the following study with the aim of evaluating the attitudes of Palestinian health professionals and their assessment of chewable tablets as a pharmaceutical dosage form.

## 2. Materials and Methods

This is a cross-sectional questionnaire-based study. The questionnaire which was used as a tool for the study was validated before starting the project. The validation was carried out by testing the questionnaire on a group of health professional as a pilot study. The questionnaire was modified and corrected based on the results of the pilot study. The questionnaire (appendix 1) was composed of three sections. The first part was a table where health professionals were asked to fill it with trade names of chewable tablet products present in the Palestinian market, their manufacturing companies, the active ingredients contained in each and the lower age limit they thought was approved for the drug. The second part was also a table where the health professionals were asked to comment on a statement regarding the superiority of chewable tablets over the corresponding liquid dosage forms with regard to palatability, stability, dose precision, portability and effectiveness. A general statement regarding the safety of chewable tablets should also be commented on. The third part of the study was designed to be answered only by industrial decision makers where 18 personnel in the four local pharmaceutical companies (Birzeit

Palestine Pharmaceutical company, Beit Jala Pharmaceutical company, Pharmacare Pharmaceutical company, Jerusalem Pharmaceutical company) were asked to encircle the appropriate answer to a question asking them what they thought the reasons behind his company's lack of development of chewable tablets. The questionnaire was handed out during the period of 15th of June till the 15th of September 2005. The questionnaire was distributed to both community pharmacists and industrial personnel by third year trainee students who were trained at various sites in the west bank, while the majority of physicians were approached by medical representatives who visited them frequently and thus were able to collect the filled questionnaires. Table (1) lists in detail, the setting where the study has taken place [14,15]. After collection of the filled forms, the data was entered and descriptively analyzed using statistical software program version 11.0 (SPSS).

**Table (1):** The population, approximate numbers of community pharmacies and physicians catering for the population in each of the cities of the West Bank where the study was conducted.

| West bank city | Population | Number of community pharmacies | Number of physicians |
|---|---|---|---|
| Nablus | 326.873 | 87 | 530 |
| Qalqilya | 94.210 | 23 | 57 |
| Ramallah | 280.508 | 50 | 410 |
| Jericho | 42.268 | 24 | 21 |
| Bethlehem | 174.654 | 45 | 200 |
| Tulkarm | 167.873 | 47 | 240 |
| Jenin | 254.216 | 30 | 265 |

## 3. Results:

### 3.1 Physcians' & Pharmacists' attitudes:

The questionnaire was distributed throughout the various cities of the west Bank where it was filled by 111 physicians and 149 community pharmacists. In addition, eighteen (18) decision makers have also responded by filling the specified part of the questionnaire. Twenty different trade names are found in the Palestinian market, 50% (10 products) of these were most frequently mentioned by health professionals, where 40% of the products mentioned were antacids, while the remaining products were analgesics (15%), anthelminitics (20%), vitamin supplements (15%) and antiepileptics (10%). All health professionals had no idea about the lower limit of patient age allowed to take chewable tablets. Among the participant pharmacists, 58.1% and 48.2% of the physicians thought that chewable

tablets demonstrated better palatability compared to the corresponding liquid dosage forms. The results obtained also showed that the majority of pharmacists (73.2%) and about half of the physicians (54.1%) regard chewable tablets as a dosage form with higher stability characteristics than the corresponding liquid dosage forms (Table 2).

It is always an important pre-requisite for the success of any treatment schedule to have a dosage form which provides the best attainable precision of dose. In this study, half of the physicians and pharmacists (53.1%, 51.9%) respectively agreed that chewable tablets can provide patients with higher dose precision than the corresponding liquid dosage forms (Table 2). Unfortunately 21.4% of the pharmacists and 15.7% of the physicians disagreed with this point. The majority of community pharmacists and physicians agreed that chewable tablets had better portability properties than the corresponding liquid dosage forms. As for the ease of administration, 68.2% of pharmacists agreed that chewable tablets can be administered easier than the corresponding liquid dosage forms while 54.1% of physicians agreed with this (Table 2). Almost equal numbers of pharmacists had opposite opinions regarding the effectiveness of chewable tablets compared to liquid dosage forms, with 24.2% believing that chewable tablets had better effectiveness profiles, while 26.8% thought otherwise. On the other hand, the highest percentage of physicians was uncertain of the higher effectiveness of chewable tablets, while a small percentage (15.6%) of physicians thought that chewable tablets were superior to liquid dosage forms in effectiveness. 32.1% believed the opposite (Table 2). As for the final statement of: "Chewable tablets are safe", very close results were obtained from both pharmacists and physicians who agreed with this statement which means that about half (50%) of the health professionals who participated do recognize this dosage form as a safe alternative to children than the corresponding available and widely used liquid dosage forms (Table 2).

**3.2 Industrial personnel viewpoints:**

As shown in table 3, 33.3% of the industrial pharmacists believed that this dosage form is not fully evaluated and accepted by pharmacists and physicians. All industrial personnel reported that their companies have developed chewable tablet formulations in the past, but that the number of products present now is still comparatively low. 55.6% of pharmaceutical decision makers thought that the reason behind the poor development of this dosage form was due to lack of technology or specialized personnel to develop this dosage form. Equal percentages of the participant personnel

(11.1%) believed that the poor development of this dosage form may be due to either strategic company decisions or to the high cost incurred by chewable tablets.

**Table 2**: Data obtained from health professionals regarding chewable tablets compared to other corresponding liquid dosage forms.

| comparison | Pharmacists (n=149) (%) | | | | Physicians (n=111) (%) | | | |
|---|---|---|---|---|---|---|---|---|
| | Agree | Disagree | Uncertain | Equal | Agree | Disagree | Uncertain | Equal |
| Better palatability | 58.1 | 19.6 | 16.2 | 6.1 | 48.2 | 26.4 | 14.5 | 10.9 |
| Higher stability | 73.2 | 6.7 | 16.8 | 3.4 | 54.1 | 15.6 | 23.9 | 6.4 |
| Better dose precision | 53.1 | 21.4 | 20 | 5.5 | 51.9 | 15.7 | 21.3 | 11.1 |
| Better portability | 68.7 | 9.5 | 17 | 4.8 | 78.5 | 10.3 | 9.3 | 1.9 |
| Easier administration | 68.2 | 14.2 | 11.5 | 6.1 | 54.1 | 19.3 | 19.3 | 7.3 |
| Better effectiveness | 24.2 | 26.8 | 31.5 | 17.4 | 15.6 | 32.1 | 36.7 | 15.6 |
| Safety | 53 | 16.1 | 18.1 | 12.8 | 46.2 | 20.8 | 25.5 | 7.5 |

## 4. Discussion:

The number of chewable tablet formulations found in the Palestinian market shows that this dosage form is not widely available in this country. An important point to mention here too, is that the critical situation of the Palestinian territories includes the constant presence of road blocks and check points which represent major obstacles for the freedom of movement

of individuals and transportation of goods including medical supplies which are in constant demand throughout the various areas of the country. Here, the stability and portability issues are highly important for the health care system efficiency.

**Table 3**: Data obtained from industrial personnel regarding the reasons of chewable tablets' poor development.

| Statements asked to industrial personnel (n=18) regarding the reason of not developing chewable tablets | Agree (%) |
|---|---|
| Very costly | 11.1 |
| Lack of technology or specialized personnel | 55.6 |
| Chewable tablets are not fully evaluated and accepted by physicians and pharmacists | 33.3 |
| They have not developed this dosage form before | 0 |
| The company has more important strategies | 11.1 |

About one half of the participating pharmacists and physicians, had different opinions than what we expected re the superiority of chewable tablets regarding their palatability compared to liquid dosage forms. This result might hinder the success of this dosage form in the Palestinian pharmaceutical market and thus reduce the success opportunities of the therapeutic treatment, since palatability plays a fundamental role in the improvement of drug compliance. In fact, palatability is a very important factor in the selection of an appropriate drug product and formulation where the preparation of palatable formulations is not necessarily an easy task. Regarding the stability of chewable tablets, 73.2% of the pharmacists and 54.1% of the physicians agreed that chewable tablets had superior stability than the corresponding liquid dosage forms. These results are expected since the pharmacists' background studies include a better understanding of the issues of stability of pharmaceutical dosage forms. With this advantage well understood by pharmacists, it is expected that a preferential attitude towards this dosage form is practiced when supplying certain medications in community pharmacies, especially when it comes to non-prescription drugs. On the other hand, the fact that only half of the physicians knew this fact may have a negative effect on the number of chewable products prescribed

by them, which may be one of the reasons behind the poor consideration of this dosage form among physicians.

Another very important result to be discussed is the dose precision of chewable tablets, where unfortunately only half of the pharmacists and physicians agreed that they are superior. In fact many problems in dose precision arise when liquid dosage forms are used for pediatric patients [5-7]. Lack of precision was also shown even in the use of oral droppers and this precision problem is particularly important when giving potent drugs with narrow therapeutic indices to pediatric patients [8]. These precision problems can be eliminated by the use of chewable tablets, since the weight uniformity of this dosage form is an essential characteristic and requirement of the official pharmacopeias [9,10]. Concerning the ease of swallowing or ease of administration of medication, most pharmacists (68%) and only one half of the physicians agreed with this issue. In fact, the ease of administration of medications to children presents a challenge for both health professionals and patients equally. For many adults, it is not always easy to swallow many drugs in the form of tablets and in a study conducted in Norway, it was showed that every third woman and every sixth man agreed to have problems with swallowing tablets [1]. This is also an important issue when it comes to choosing a suitable dosage form for pediatric patients and the search is always ongoing for the most acceptable and easiest one to administer. Therefore, compliance problems may result in a reduction in drug efficacy, which leads in some cases to complications of the disease being treated especially when the administered drug is an antibiotic which may be in the form of the emergence of resistant strains of the targeted bacteria. Because of this, many antibiotics were evaluated for their taste, smell and texture especially in pediatric patients to obtain good compliance, good prognosis and prevention of bacterial resistance development [2]. Parents usually present pharmacists with information regarding the acceptability of their children to a certain medication especially if it is a repeat prescription or a chronically used drug which might imply that pharmacists have better feedback regarding this issue than physicians [3,4]. In this context, it was surprising that only a very low percentage of physicians and pharmacists (15.6% and 24.2%) respectively claimed better effectiveness of this dosage form in comparison with other dosage forms containing the same active ingredients.

The safety issue of administering any type of medication to pediatrics is a major concern, not to mention chewable tablets which are solid dosage forms feared for possibilities of choking hazards particularly in children below 2 years of age. Due to the importance of chewable tablets and to

ensure a safe use in the pediatric field, Michele et al. (2002) have investigated their safety [13], where they demonstrated that chewable tablets are well tolerated in children of 2 years of age and older**.** This is due to the fact that chewable tablets are formulated in a manner which eventually leads to a reduction in the possibility of choking or aspiration. Among the considerations that are usually taken while formulating a chewable tablet is a near neutral pH, appropriate sizes and shapes which facilitate swallowing and ease of rotation in the trachea if aspirated, short disintegration and dissolution times which are important attribute to prevent airway obstruction. In this context one half of the interviewed pharmacists and physicians claimed the safety of this dosage form, which leaves the

remaining 50% with an opposing opinion must be well-informed and ensured about the safety issues of chewable tablets. Concerning the results of the questionnaire given to decision makers in the pharmaceutical industry, it was interesting to see that this category has identified precisely two reasons for the poor development of chewable tablets. In fact, 56% of them said that lack of technology or specialized personnel is the obstacle, while 33.3% said that the reason is that this dosage form is not fully understood and accepted by pharmacists and physicians. However, the first reason can be solved by well organized scientific cooperation between universities and the pharmaceutical industry as is the case in many industrial countries, whereby the expertise of university professors can be of great help in this field. The second reason can be overcome by well organized labors of medical representatives who must concentrate their efforts to educate and inform pharmacists and physicians about the obvious advantages of this dosage form.

## 5. Conclusion:

From the results obtained in the current study, we feel obliged to recommend some measures which may lead to a better outcome for both the pharmaceutical industry and the patient. The current situation in Palestine entails that Palestinian drug manufacturers should consider to reduce the size of their products in general which will result in lower bulk and weight of the transported goods. With this measure being taken, a reduction of transportation costs both on the local and international levels may be achieved as well as making the process a relatively smoother one. Secondly, the transformation of many liquid preparations for a number of drugs into chewable tablet formulations has many advantages such as better portability and physical stability-and this is especially important for patients traveling from one place to another while carrying their medications-as well as saving

space both in industry stores and pharmacy shelves. Moreover, the use of chewable tablets is expected to result in a reduction of compliance problems in many patients of different age groups. The reason behind this is the better palatability as compared to liquid dosage forms which will lead to better adherence to therapy. This is especially true when talking about antimicrobial agents where patient compliance is an essential aspect for a successful treatment and avoidance of emerging resistant strains in the future. Finally, and as has been documented, the safety issue of chewable tablets has been investigated thoroughly and this dosage form was found to be safe in children above 2 years of age and therefore this dosage form can be used safely in this category of patients. It is advisable that more attention be given to chewable tablets as a safe and effective dosage form for a wide variety of active ingredients. Pharmaceutical companies are also encouraged to re-evaluate this issue and to pay more public attention to it through condensed and scientific efforts of their medical representatives in order to change and improve the knowledge of many of the pharmacists and physicians who do not possess the proper information. Once this matter has been accomplished, there will be a marked rise in the numbers of sales of their marketed products.

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