

## Usage and Storage Patterns for PCM Oral Suspension during Consumption among Mothers in Aden City

Olfat Saleh Ahmed Mohammed<sup>1</sup>, Abd Al-Rahman Alawi Bin Yahya<sup>2</sup>, Mohammed Alshakka<sup>3</sup>,  
Mohamed Izham Mohamed Ibrahim<sup>4\*</sup>

<sup>1</sup>Department of Pharmaceutics, Faculty of Pharmacy, Aden University, Aden, Yemen

<sup>2</sup>Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Aden University, Aden, Yemen

<sup>3</sup>Clinical Pharmacy Section, Faculty of Pharmacy, Aden University, Aden, Yemen

<sup>4</sup>Professor of Social & Administrative Pharmacy, College of Pharmacy, QU Health, Qatar University, PO Box 2713, Doha, Qatar

**Abstract:** In most families, medicines are stored for various reasons, including treating chronic or severe ailments. Therapeutic effectiveness of medicines can be affected by prolonged storage. This study evaluated the in-home usage and storage of paracetamol (PCM) oral suspension during consumption among Aden city mothers. A cross-sectional study was conducted during four months (January to April 2019) using the distributed questionnaire. Mothers who had no children were excluded. The survey included 430 mothers. About 305 (70.9%) mothers stored PCM suspension in the refrigerator, and 260 (60.5%) kept it in the outer carton. Nearly 194 (45.1%) mothers store liquid PCM until it expires, while 23.7% regard the physical features of medicine. Over 208 (65.1%) mothers used the manufacturer's tools to withdraw the doses, however, 33 (7.7%) said syringes are easier to use. The study also found that although 242 (56.3%) users received medicine from a physician, 194 (45.1%) mothers did not get instructions on how to receive it from the practitioner. Only 97 mothers (22.6%) used PCM as an antipyretic and analgesic. Mothers are key persons in a household. However, they lack the knowledge of a common medicine used at home, such as PCM. Yemeni mothers' knowledge and practice about the usage and storage of PCM suspensions were concerned. Public education and awareness programs are important for enhancing the rational use of medicines.

**Keywords:** storage condition, mothers, rational use of medicines, paracetamol.

## 亚丁市母亲服用相变调制器口服混悬剂的使用和储存模式

**摘要：**在大多数家庭中，出于各种原因储存药物，包括治疗慢性或严重疾病。药物的治疗效果会因长期储存而受到影响。本研究评估了亚丁市母亲在家中使用和储存扑热息痛(相变调制器)口服混悬液的情况。使用分布式问卷进行了为期四个月(2019年1月至4月)的横断面研究。没有孩子的母亲被排除在外。该调查包括430名母亲。大约305位(70.9%)的母亲将相变调制器悬浮液存放在冰箱中，260位(60.5%)的母亲将其存放在外纸箱中。将近194位(45.1%)的妈妈会储存液体相变调制器直到过期，而23.7%的妈妈会考虑药物的物理特性。超过208位(65.1%)的母亲使用制造商的工具来取出剂量，但是，33位(7.7%)的母亲表示注射器更易于使用。该研究还发现，虽然有242名(56.3%)用户从医生那里获得了药物，但194名(45.1%)的母亲没有从医生那里得到如何服用药物的说明。只有97位妈妈(22.6%)使用相变调制器作为解热镇痛药。母亲是家庭中的关键人物。然而，他们缺乏家庭常用药物的知

Received: July 3, 2022 / Revised: August 1, 2022 / Accepted: September 5, 2022 / Published: October 30, 2022

About the authors: Olfat Saleh Ahmed Mohammed, Department of Pharmaceutics, Faculty of Pharmacy, Aden University, Aden, Yemen; Abd Al-Rahman Alawi Bin Yahya, Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Aden University, Aden, Yemen; Mohammed Alshakka, Clinical Pharmacy Section, Faculty of Pharmacy, Aden University, Aden, Yemen; Mohamed Izham Mohamed Ibrahim, Professor of Social & Administrative Pharmacy, College of Pharmacy, QU Health, Qatar University, Doha, Qatar

Corresponding author Mohamed Izham Mohamed Ibrahim, [mohamedizham@qu.edu.qa](mailto:mohamedizham@qu.edu.qa)

识，例如相变调制器。关注也门母亲对相变调制器混悬剂使用和储存的知识和实践。公共教育和宣传计划对于加强药物的合理使用非常重要。

**关键词：**贮存条件，准妈妈合理用药，扑热息痛。

## 1. Introduction

Any effective drug substance must have a high level of stability. While pharmaceutical molecules, like other chemicals, break down over time, drug product stability is more than just chemical breakdown. Any aspect of a drug product is changes in physical, chemical, or biopharmaceutical qualities could be classed as instability. Medicines must be stored properly to ensure their efficiency, potency, and physical integrity [1].

The manufacturing and storage environments of pharmaceutical items can significantly impact their quality. Some monographs give specific instructions on preserving a medicine (for example, the temperature or humidity). Such instructions apply unless the medicine label specifies different storage settings based on stability tests. Medicine must be protected from moisture, freezing, severe heat, and, if necessary, light during shipping and distribution if no particular guidelines or limitations are stated on the labeling [2].

The United States Pharmacopeia has defined various temperature labeling terminology [3]:

✓ *Freezer*: A place in which the temperature is maintained thermostatically between  $-20^{\circ}\text{C}$  and  $-10^{\circ}\text{C}$ .

✓ *Cold*: Any temperature not exceeding  $8^{\circ}\text{C}$ . A refrigerator is a cold place where the temperature is maintained between  $2^{\circ}\text{C}$  and  $8^{\circ}\text{C}$ .

✓ *Cool*: Any temperature between  $8^{\circ}\text{C}$  and  $15^{\circ}\text{C}$ .

✓ *Room temperature*: The temperature prevailing in a working area.

✓ *Warm*: Any temperature between  $30^{\circ}\text{C}$  and  $40^{\circ}\text{C}$ .

✓ *Excessive Heat*: Any temperature above  $40^{\circ}\text{C}$ .

✓ *Dry place*: A place that does not exceed 40% average relative humidity at  $20^{\circ}\text{C}$  or the equivalent water vapor pressure at other temperatures.

Liquid dosage forms are important pharmaceutical preparations that include active and non-active drug ingredients (excipients). They are most commonly found in multi-unit containers. Liquid formulations are complicated and prone to physical, chemical, and stability issues because of the additional adjuncts such as sweetening, flavoring, suspending, stabilizing, and preserving agents [4]. Orally delivered suspensions are among the most likely products to get contaminated with microorganisms after consumption [5].

PCM is among the most popular and most commonly used analgesic and antipyretic drugs worldwide. It is commonly available as an over-the-counter medication in various dosage forms such as solutions, suspensions, tablets, capsules, and

suppositories. PCM suspension is available as a ready-to use (not required reconstitution) multiple-unit [6]. PAP is the most significant impurity in PCM, and it can occur during storage or the manufacture of the drug [7-9]. PAP is a recognized nephrotoxic metabolite of PCM that is seen in the urine. The nephrotoxicity of PAP has been reported in animal studies [10]. Additionally, it was found that PAP, could cause acute hepatotoxicity in mice [11]. Thus, the quantity of 4-AP must be strictly controlled [12].

According to the product literature Summary of Product Characteristics [13], PCM suspension must be saved below  $25^{\circ}\text{C}$ , the bottle should be kept in the outer carton to protect from light, and preserved liquid medicines should have a 6-month in-use shelf-life. However, a local decision could be made to reduce this to 3-months for internal liquids [14].

In most families, medicines are stored for various reasons, including emergency usage and treatment of chronic or severe ailments. These medications are either prescribed by doctors or purchased over the counter at local pharmacies [15]. Most people do not consider how liquid medications are stored or how long they last, other than keeping them out of the reach of youngsters. Depending on the expiration date, they may keep pharmaceuticals for extended periods after opening the bottle. Because of easy access and improper storage, drug storage at home is a risk factor for irrational drug use. If the storage instructions are not followed, the drug's stability may be compromised, resulting in an ineffective medication.

Formulation and stability issues are more common with liquid medication than solid dosage forms. As a result, drugs in liquid form often have a significantly shorter shelf life than solid preparations [16]. Furthermore, the shelf life of a container relies on storage and care once it is opened. During storage, adverse effects owing to the production of small degradation products have been recorded [17].

Several studies have examined the storage patterns of several drugs [15-16, 18-20]. However, to our knowledge, none have mainly addressed PCM oral suspension usage and storage patterns in homes after the bottles have been opened. Therefore, this study aimed to determine how mothers used PCM oral suspension and how they stored it while they were using it. The findings of this study will raise awareness of the necessity of appropriate liquid pharmaceutical use and storage and reduce pediatric risk of side effects by degradation of products formed during storage.

## 2. Materials and Methods

### 2.1. Study Design

A cross-sectional study was conducted to evaluate the in-home usage and storage conditions of PCM oral suspension in Aden city. The study was carried out over four months (January to April 2019) (Figure 1).

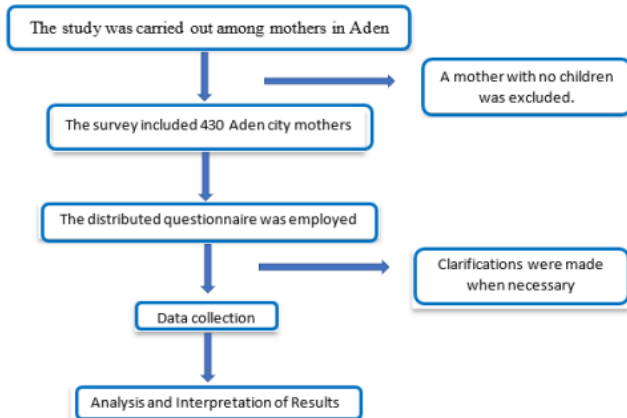


Fig. 1 Flowchart of the research methodology

### 2.2. Study Population

The study was conducted among mothers in Aden city. The mothers who had no children were excluded.

### 2.3. Sampling Technique and Sample Size

A probability sampling technique was used. A simple random sampling was performed to select the participants of this study. The sample size was calculated as per a 95% confidence level and a 5% error margin. Out of 222832 females 15-60 years old on the list of population 2017 obtained from the Health Office of Aden, we estimated a sample size of 383 according to the Raosoft sample size calculator [21]. Another 20% was added to the sample to become 425 participants in case of missing data. For the study, 430 participants were involved in the survey.

### 2.4. Data Collection Tools

This study was performed using a distributed questionnaire. Four academics assessed the survey items and were asked to remark on the face research instrument, including the appropriateness and context of the evaluated activities, to ensure the questionnaire validity. Their opinions and suggestions were considered before being put into the final edition of the questionnaire.

The participants were given the appropriate questionnaires to fill. These were collected after completion or, where necessary, were given out to have them the next or some other day. When clarifications were necessary, they were made. After that, the questionnaires were collated, and the data were coded, and checked for completeness.

### 2.5. Data Analysis

Statistical Package for the Social Sciences, SPSS

version 26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp) was used to enter and evaluate the data collected from the questionnaire. All variables were subjected to a descriptive analysis. Frequencies and percentages were used to summarize categorical variables.

### 2.6. Ethics Consideration

The Ethics Research Committee of the University of Aden, Faculty of Medicine and Health Sciences, approved the study procedure. After discussing the research's aims, importance, and advantages and the study's voluntary involvement, all participants who were willing to engage in the study gave their written informed permission. They were told that all information obtained would be confidential and used solely for research reasons.

## 3. Results

### 3.1. Socio-Demographic Characteristics of the Study Population

All the participants were female (100%). Regarding participants' level of education, the majority were high school graduates ( $n = 233$ , 54.2%). The socio-demographic characteristics are displayed in Table 1.

Table 1 Socio-demographic characteristics of the study population

| Characteristics          | No. respondents (N = 430) | %    |
|--------------------------|---------------------------|------|
| <b>Gender</b>            |                           |      |
| Female                   | 430                       | 100  |
| <b>Age</b>               |                           |      |
| 15-29 y                  | 182                       | 42.3 |
| 30-39 y                  | 179                       | 41.6 |
| ≥40 y                    | 69                        | 16   |
| <b>Education</b>         |                           |      |
| Non-educated             | 14                        | 3.3  |
| Primary educated         | 51                        | 11.9 |
| Secondary educated       | 132                       | 30.7 |
| Graduate educated        | 233                       | 54.2 |
| <b>Area of residence</b> |                           |      |
| Al-Manssora              | 154                       | 35.8 |
| AlShikh-Othman           | 56                        | 13.0 |
| Khormaksar               | 55                        | 12.8 |
| Kerater                  | 67                        | 15.6 |
| Al-Muala'a               | 31                        | 7.2  |
| Al-Buraika               | 52                        | 12.1 |
| Al-Memdara               | 3                         | 0.7  |
| Al-Tawahi                | 12                        | 2.8  |

### 3.2. PCM Storages Patterns at Homes during Consumption

The frequencies of mothers and storage patterns of PCM suspensions in homes are illustrated in Table 2. A high percentage of mothers (70.9%,  $n = 305$ ) mentioned keeping the liquid medicine in the refrigerator. About 14.7% ( $n = 63$ ) said they kept them in a room with air-conditioning, while 10.7% kept them as recommended in the patient information leaflet.

Only 3.7% (n = 16) kept the medicine in any place. The mothers who kept PCM suspension after the first use in the outer carton were 60.5% (n = 260), while 37.0% (n = 159) kept it without the outer carton.

The liquid medicine was stored after the first opening till expired date as expressed by 45.1% (n = 194) of mothers, 31.2% (n = 134) stored the medicine until finishing the bottle, and 23.7% (n = 102) according to the physical properties of medicine (Table 2).

Table 2 Patterns of PCM suspension storage in homes

| Characteristics                                                              | Frequency | %    |
|------------------------------------------------------------------------------|-----------|------|
| <b>Some mothers who keep the PCM suspension after the first opening</b>      |           |      |
| 1. In refrigerator                                                           | 305       | 70.9 |
| 2. In the air conditioning room                                              | 63        | 14.7 |
| 3. At a temperature recorded on the bottle of the drug                       | 46        | 10.7 |
| 4. any place                                                                 | 16        | 3.7  |
| <b>Storing the PCM suspension after the first use</b>                        |           |      |
| 1. Within outer carton                                                       | 260       | 60.5 |
| 2. Without outer carton                                                      | 159       | 37.0 |
| 3. Sometimes in the outer carton and others without the carton               | 11        | 2.6  |
| <b>Storing the PCM suspension after the first opening for the following:</b> |           |      |
| 1. The expired date                                                          | 194       | 45.1 |
| 2. Finishing the bottle                                                      | 134       | 31.2 |
| 3. According to the physical properties of the product                       | 102       | 23.7 |

### 3.3. Usage Patterns of PCM in Homes during Consumption

Various tools were used to withdraw the liquid medicine dose (table 3). Most mothers (n = 280, 65.1%) used manufacturer's tool (dosing spoon or dosing cup), (n = 111, 25.8% used any available spoon (e.g., spoon food), (n = 33, 7.7%) used a syringe and only (n = 6, 1.4%) reported that they used any tool.

It is important to investigate who advised the participants to use PCM. This study showed that about 56.3% (n = 242) of the mothers received the drug by prescription (after a suggestion from their physician), (n = 91, 21.2%) without prescription, while (n = 97, 22.6%) were according to the pharmacist's selection. Nearly 54.9% (n = 236) of all mothers received advice from the prescriber or dispenser about how to save the medicine, while 45.1% (n = 194) did not. Most of the mothers (n = 256, 59.5%) used PCM as an antipyretic (for fever) and 15.1% (n = 65) as an analgesic only while 22.6% (n = 97) used it as an antipyretic or analgesic.

Table 3 Usage patterns of PCM in homes during consumption

| Characteristics                                              | Frequency | %    |
|--------------------------------------------------------------|-----------|------|
| <b>Tools used for withdrawing the dose of PCM suspension</b> |           |      |
| 1. Use of manufacturer's tool (dosing spoon or dosing cup)   | 280       | 65.1 |
| 2. Use of any available spoon                                | 111       | 25.8 |
| 3. Syringe                                                   | 33        | 7.7  |
| 4. Other (any tool)                                          | 6         | 1.4  |

Continuation of Table 3

|                                                                      |     |      |
|----------------------------------------------------------------------|-----|------|
| <b>Way to obtain the medicine</b>                                    |     |      |
| 1. Prescription                                                      | 242 | 56.3 |
| 2. Without prescription                                              | 91  | 21.2 |
| 3. Pharmacist                                                        | 97  | 22.6 |
| <b>Advice from prescriber or dispenser about saving the medicine</b> |     |      |
| 1. Yes                                                               | 236 | 54.9 |
| 2. No                                                                | 194 | 45.1 |
| <b>Reasons for the use of a PCM suspension by mothers</b>            |     |      |
| 1. Antipyretic                                                       | 256 | 59.5 |
| 2. Analgesic                                                         | 65  | 15.1 |
| 3. Antipyretic and analgesic                                         | 97  | 22.6 |
| 4. Other uses                                                        | 12  | 2.8  |

## 4. Discussion

The current study was the first in Aden-city to assess the usage and storage of PCM oral suspension during consumption by mothers at home. The finding points to inadequate information about the expiry time of PCM liquid medications after the first opening of the bottles, as well as the risks of long-term storage adverse effects.

Since PCM is one of the most popular and most commonly used analgesics and antipyretic drugs worldwide, the knowledge of the various storage conditions for individual medicine products and the need to provide such optimal storage conditions is of prime importance. According to product literature [13], and a patient information leaflet [22], the suggested storage temperature for PCM suspension is below 25°C (cool location), and the container should be kept in the outer carton. However, Aden has a major problem with power outages, which cause the temperature to fluctuate. Furthermore, Aden has a hot desert climate according to the Köppen-Geiger climate classification system [23].

In this study, most mothers kept PCM suspensions in the refrigerator's outer cartons. Even though the refrigerator is a cold environment with a temperature range of 2° to 8° [3], it has become an alternate and adequate storage condition for the medicine since the intended storage temperature for PCM suspension was not feasible with the Aden climate. The time it takes to keep the liquid medicine after it has been opened is an important concern. The findings showed that most mothers keep the PCM suspension after the initial opening until the expiration date. However, liquid formulations are complicated and prone to physical, chemical, and microbiological instability since they include additional adjuncts such as sweetening, flavoring, suspending, and preservation agents [24]. Moreover, the expiry date may be dramatically shortened after opening the bottle of drugs due to improper storage conditions, unhygienic handling, or repeated opening and closing depending on storage and handling [16]. For preserved liquid medications, a 3-6-month in-use shelf-life is often recommended [14].

The dosing cups were the most used method for

measuring the doses in this study. These findings are similar to [19], which showed that droppers and dosing cups were the most commonly used devices in the home for measuring liquid medications. However, this study also found that syringes were more likely to measure an acceptable dose compared to a dosing cup. The dosage errors might be created by the confusion between teaspoons and tablespoons or by assuming that the whole dispensing cup represented the correct dose [25]. Furthermore, dosing syringes rather than cups may result in fewer dosage mistakes [26]. PCM is an over-the-counter medicine; therefore, prescriptions are not required. However, most mothers in this study acquired the drug via prescription (after a physician's recommendation). These findings differed from [27], who found that nearly half of those who received drugs did not receive them from a medical professional. During children's illnesses, the mothers commonly provide PCM medication. PCM is one of the world's most widely prescribed and used analgesics and antipyretics. The findings of this study are comparable to those of [28], who found that the most common reason for prescribing the drug was to treat fever; however, analgesic effects of treating headaches and earaches were also indicated.

Considering those mentioned above, purchasing medicinal products packed in small quantities is advisable to avoid long-term storage. Additionally, they must mark the date of opening on the bottle of the medicine. To enhance the survey's results, further practical work is needed to evaluate the stability of liquid medications stored after being consumed for a long time at home.

## 5. Conclusion

Yemeni mothers' knowledge and practice about the usage and storage of PCM suspensions are concerning. Mothers kept the PCM suspension for longer periods after opening the bottle as they were interested in the expiration date. The intended storage temperature could not be achieved in the Aden climate. Most mothers kept them in the outer carton. Many mothers used the manufacturer's tools to withdraw the doses. Almost half of the mothers did not get instructions on how to take it from the practitioner. Public education and awareness programs are important for enhancing the safe and rational use of medicines.

Even though the study has raised important issues with PCM, it has a few limitations. This study was performed in only one city. If the study had been conducted in diverse geographical locations of the country, the results would have been more significant and applicable to the country. The study was also restricted because it only assessed one type of liquid medicine. However, because PCM is one of the most widely prescribed over-the-counter medications, used as an analgesic and antipyretic worldwide, the current findings may provide general guidelines for the use and

storage of other liquid medications leading to more well-designed and larger studies on the topic.

This study has offered significant findings for relevant parties to consider regarding how liquid medicines should be stored at home during use to avoid pediatric adverse reactions. The finding will also raise awareness of mothers' safety issues related to medication use and storage in the home.

## Acknowledgment

The authors would like to thank all mothers who have spent their time participating in this study.

Mohammed Alshakka passed away after the completion of the study and writing the draft of the manuscript. We appreciate his contribution to pharmacovigilance activities in Yemen.

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