Microbiological quality assessment of antacid suspensions available in Sudan

Rawaa E Biraima, Sabreen E Mohamed, Mona A Hajo, Anas M Elnazeer and Mohamed A Hussain

Abstract
Pharmaceutical products manufactured today must meet high microbiological specifications that the microbial content if not sterile should not exceed a minimum limit. Antacid suspensions are basic pharmaceutical multi-dose products that are used to neutralize gastric acid. They are highly susceptible to microbial contamination due to the neutral pH. In this study we attempted to assess the microbial quality of commercially available antacid suspensions in Sudan. Twelve batches belonging to four different companies were collected from different community pharmacies in Khartoum state; each company represented by three different batches which were represented by three products to compute the mean of the bioburden. The guideline of USP has been followed in all procedures and identification of the objectionable microorganisms. The testing conditions were examined by means of negative control. The enumeration of total viable count was done using pour plate method. We found that nine out of twelve of the tested batches exceed the USP limit for total microbial content (10³ CFU/ml), and five of which were found to be contaminated with objectionable microorganisms. This study is expected to benefit the manufacturers of these products to pay more attention for the microbial quality of their products.

Keywords: Microbiological quality, assessment, antacid suspension, Sudan

1. Introduction
Pharmaceutical products used in diagnosis, treatment and prevention of disease contain different kinds of compounds and ingredients most commonly in complex physicochemical states [1]. These products must be manufactured according to the code of good manufacturing practice in all aspects in order to ensure safety and quality [1-3]. The quality of pharmaceutical products is of great concern that it should not be tested at the end of the day but it should be built in the product [2, 4]. One of the most important features of pharmaceutical product quality is the level of its microbial content that is needed to be strictly controlled [4, 6]. Pharmaceutical products manufactured today must meet high microbiological specifications that the microbial content if not sterile should not exceed a minimum limit [1, 2, 7]. All these strict requirements are needed because of that, the consequences of microbial contamination of pharmaceutical products are highly serious particularly if the contaminating microorganisms have had the opportunity to multiply to high levels [1]. The assessment of such microbial quality is based on qualitative and quantitative tests that are used to enumerate the content of microorganisms as well as detection of specified objectionable ones [7, 8].

Antacid suspensions are basic pharmaceutical products that are used to neutralize hydrochloric acid in gastric secretions [9-14]; these products are multi-dose formulation in which the therapeutic agents are dispersed in an external phase in which they are not very soluble [5, 6, 15]. The antacid suspensions are more commonly preferred than tablets due to their rapid activity and ability to neutralize gastric acid [14]. The most common antacid preparations used contain mixture of aluminum hydroxide and magnesium Hydroxide [9-11, 14]. These elements when exist in the form of oral suspensions are highly susceptible for microbial contamination, not only because of the water content which is considered as important source of contamination but also due to the neutral pH which make it favorable environment for the growth of some microbes [4, 6] moreover, it’s pH affects the action of the preservative by changing in its ionization state that alter the proportion of the un-dissociated and dissociated form, which have different intrinsic antimicrobial activity and ultimately prevent the preservative from attaining an adequate protective concentrations [5, 6].
2. Materials and methods

2.1 Sample collection

This study was conducted on a sample of antacid oral suspensions that are collected from different community pharmacies in Khartoum state in Sudan. Thirty six products belonging to four different pharmaceutical companies were collected; each company was represented by three batches which were represented by three products to compute the mean of bioburden.

Table 1: The table illustrates the total viable count for three batches (A-1, A-2 and A-3) from same company and each batches represented by three products and the mean of total viable count was calculated for each batches.

<table>
<thead>
<tr>
<th>Batch No</th>
<th>Total viable count (cfu/ml)</th>
<th>Pseudomonas aeruginosa</th>
<th>Escherichia coli</th>
<th>Salmonella spp</th>
<th>Staphylococcus aureus</th>
<th>Candida albicans</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>1.5x10^3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>A-2</td>
<td>3.5x10^2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>A-3</td>
<td>5.01x10^4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2: The table illustrate the total viable count for three batches (B-1, B-2 and B-3) from same company and each batches represented by three products and the mean of total viable count was calculated for each batches.

<table>
<thead>
<tr>
<th>Batch No</th>
<th>Total viable count (cfu/ml)</th>
<th>Pseudomonas aeruginosa</th>
<th>Escherichia coli</th>
<th>Salmonella spp</th>
<th>Staphylococcus aureus</th>
<th>Candida albicans</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-1</td>
<td>8.15x10^3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>B-2</td>
<td>2.33x10^2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>B-3</td>
<td>6x10^2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

Table 3: The table illustrate the total viable count for three batches (C-1, C-2 and C-3) from same company and each batches represented by three products and the mean of total viable count was calculated for each batches.

<table>
<thead>
<tr>
<th>Batch No</th>
<th>Total viable count (cfu/ml)</th>
<th>Pseudomonas aeruginosa</th>
<th>Escherichia coli</th>
<th>Salmonella spp</th>
<th>Staphylococcus aureus</th>
<th>Candida albicans</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-1</td>
<td>2.16X10^3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>C-2</td>
<td>6X10^4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>C-3</td>
<td>1.6X10^4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
4. Discussion
Antacid oral suspensions are highly susceptible to microbial contamination mainly due to its neutral pH. The present study was done in order to show if the commercially available antacid oral suspensions in Sudan comply with the compendial microbiological standards particularly the USP specifications. We found that nine out of twelve batches of the antacid suspensions tested were exceeded the USP limit for total microbial content (10^2 CFU/ml), and five of which were found to be contaminated with objectionable microorganisms namely *Staphylococcus aureus* and *Candida albicans*. In all mentioned previous studies on microbiological quality of antacid suspensions conducted in Bangladesh in (2004, 2012 and 2014) and the other one conducted in Nigeria in 2012 detected the presence of *staphylococcus aureus* with high load. Three batches out of twelve were found to be contaminated with *staphylococcus aureus*, two of them belonging to the same pharmaceutical company. It appears from these results that among the objectionable microorganisms *staphylococcus aureus* is the most common which indicate that either poor personal hygiene as the *staphylococcus aureus* is considered as part of the normal flora of human skin or production environment could also participate as a source of contamination with *staphylococcus aureus*. Presence of *Candida albicans* in three batches belonging to the same manufacturer is also indicative for inadequate personal hygiene, while the absence of *Pseudomonas aeruginosa*, *E. coli* and *Salmonella spp*. in our entire samples indicate lacking of fecal contamination.

5. Conclusion
With regard to this study and other similar studies made along the world about the microbiological quality of oral antacid suspensions, it appears that the manufacturers of these antacid suspensions really face problem with the microbial quality of these products which may be the cause behind the low number of these products in the market, this may be due to failure to implement efficiently all principles of GMP or failure to achieve effective preservation system. Further studies should be conducted to find out which type of preservatives would be effective against microorganisms native to manufacturer production environment. This study is expected to benefit the manufacturers of these products to pay more attention for the microbiological quality of their product, manufacturing environment and to give more training for the operating personnel about personal hygiene.

5.1 Declaration of interest
Authors declared that there is no conflict of interest in this study.

6. References
10. Martindale i. Martindal_e’s.
Microbiological quality assessment of antacid suspensions available in Sudan

Article - January 2016

5 authors, including:

Anas Elnazeer
International University of Africa

Some of the authors of this publication are also working on these related projects:

establishment of invitro culture of giardia sp from fecal sample of suspected patients View project
Piped water is available in Ciudad Juarez, Chihuahua, Mexico, but residual disinfectant is not reliably found in the public drinking water supply. Lack of confidence in the public supply leads many residents to rely on bottled water. To more. Piped water is available in Ciudad Juarez, Chihuahua, Mexico, but residual disinfectant is not reliably found in the public drinking water supply. Lack of confidence in the public supply leads many residents to rely on bottled water. Microbiological quality assessment of rural drinking water supplies in Iran. Save to Library. Download.