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Microbiological quality assessment of antacid suspensions available in Sudan

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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 (10^2 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].

In order for the manufacturers to be able to manufacture pharmaceutical products that comply with compendial microbiological standards, they should be aware about the sources that are known to contribute to contamination of pharmaceutical products which are mainly the atmosphere, water, contaminated raw materials, equipment and personnel [1, 5, 6, 14, 16, 17].

Microorganisms that contaminate pharmaceutical products or raw materials may be considered either as a source of infection to human [1, 3-6, 12, 14, 17] or may lead to spoilage if the resultant products of degradation can be utilized by the contaminating microorganisms as a source for biosynthesis and energy production which is likely to cause physicochemical changes of product which may be organoleptic with the release of very unpleasant smelling and tasting [1, 5, 6, 12, 14, 18] and further attack many of the suspending agents used in pharmaceutical suspensions causing depolymerization which may lead to physical instability of suspensions and ultimately sedimentation [1].

Not all pharmaceutical products are equally susceptible to microbial spoilage. The overall rate of deterioration will depend on the chemical structure of the ingredient, type and quantity of microorganisms contaminating the product [1] presence and concentration of the antimicrobial agent [6] pH, and finally the presence of sweetening agent which in some instances constitute a ready substrate for microbial attack [17] unless if used in high concentrations where it inhibits microbial attack [2, 4, 15].

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.

2.2 Sample preparation and enumeration of total microbial count

Following the guidelines of USP and under aseptic condition and after vigorous shaking ten ML of each antacid suspension was added to ninety ML of sterile peptone water (Himedia Ltd, India) and by making two-fold serial dilutions, The total microbial count has been determined by using pour plate method, in which one ML of each dilution was mixed with 15-20 ML of sterile molten nutrient agar (Himedia Ltd, India) and 15-20 ML sterile molten Sabrouaud dextrose agar (Himedia Ltd, India) for enumeration of bacteria and fungi respectively, and then poured in sterile disposable petri dish. The plates of nutrient agar were incubated at 30-35 °C for 5 days where as the plates of Sabrouaud dextrose agar was incubated at 25 °C for 7 days.

2.3 Detection of specified microorganisms

For detection of objectionable microorganisms, from each antacids suspension ten ML was added to ninety ML of sterile peptone water, then 10 ML from this mixer was added to 90 MI sterile soybean casein digest broth and incubated at 30-35 °C for 18 to 24 hours, then 1 ML was taken from each sample and mixed with 16-20 ML of sterile molten mannitol salt agar (Himedia Ltd, India), cetramide agar (Himedia Ltd, India) and xylose lysein deoxycholate (Himedia Ltd, India) for detection of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella spp* respectively, the plate were incubated at 30-35 °C for 18-48 hours. For confirmatory tests of objectionable microorganisms, catalase (Bells, UK) and coagulase were done for *Staphylococcus aureus*, KIA (Himedia Ltd, India), urea fermentation (Himedia Ltd, India), citrate utilization (Himedia Ltd, India) and oxidase test (Himedia Ltd, India) were used to identify *E. coli*, *Pseudomonas aeruginosa* and *Salmonella*. Germ tube test were used to identify *Candida albicans*.

3. Results and Discussion

Total bacterial count and objectionable microorganisms isolated from products.

Table 1: The table illustrate 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.

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

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.

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

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.

Batch No	Total viable count (cfu/ml)	<i>Pseudomonas aeruginosa</i>	<i>Escherichia coli</i>	<i>Salmonella spp</i>	<i>Staphylococcus aureus</i>	<i>Candida albicans</i>
C-1	2.16X10 ¹	-	-	-	-	-
C-2	6X10 ¹	-	-	-	-	-
C-3	1.6X10 ⁴	-	-	-	-	-

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

Batch No	Total viable count (cfu/ml)	<i>Pseudomonas aeruginosa</i>	<i>Escherichia coli</i>	<i>Salmonella spp</i>	<i>Staphylococcus aureus</i>	<i>Candida albicans</i>
D-1	0.5X10 ¹	-	-	-	-	-
D-2	6X10 ²	-	-	-	-	-
D-3	2X10 ⁶	-	-	-	-	-

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 (10² 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.

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