Analysis and Metaphysics
ISSN: 1584-8574, e-ISSN: 2471-0849
Vol 20 (1), 2021
pp. 33–37

Quality Control Analysis of Marketed Multivitamin Syrups Using Spectrophotometric Techniques

Dr. A. Kishore Babu, Associate Professor, A. M. Reddy Memorial College of Pharmacy, Petlurivari palem, Narasaraopet, A.P., India, Pin 522601. Email: drakbau@gmail.com

K. Narasimha rao, Dept. of Ph. Analysis, Assistant Professor, A. M. Reddy Memorial College of Pharmacy, Petlurivari palem, Narasaraopet, A.P., India, Pin 522601. Email: narasimharao1@gmail.com

Dr. K. Jagadeesh, Associate Professor, A. M. Reddy Memorial College of Pharmacy, Petlurivari palem, Narasaraopet, A.P., India, Pin 522601. Email: ashokchakravarthi928@gmail.com

B. Mallikarjuna Rao, Assistant Professor, Dept. of Ph. Analysis, A. M. Reddy Memorial College of Pharmacy, Petlurivari palem, Narasaraopet, A.P., India, Pin 522601. Email: maalikarjuna87@gmail.com

ABSTRACT

The microbiological contamination of seven (7) different brands of multivitamin syrups sold in Maiduguri, Borno state, was examined in this research. The purpose of the research is to assess the microbiological quality of several multivitamin preparation brands sold in Maiduguri by different producers. The pour plate technique was used. One of the seven samples included harmful organisms, according to preliminary analysis, which made it necessary to do more research to identify the organism. After testing for Salmonella, Staphylococcus, and Escherichia coli, only Salmonella was shown to be present. Although they were below the threshold count established by the microbiological quality of the syrups, the other six samples also included non-pathogenic organisms.

This result demonstrated that the majority of multivitamin syrups sold in Maiduguri adhered to Pharmacopoeia standards for microbiological purity.
Key words: multivitamin syrup, contamination, pathogenicity, and brands.

INTRODUCTION

Only with the use of a microscope can one observe microorganisms that are invisible to the human eye. These are tiny living forms that are dispersed across the environment, even inside the human body. Anthony Van Leeuwenhoek, a Dutch draper, discovered them for the first time in 1675 when he used his microscope to see small "animalcules" in raindrops. He later learned that they were found in feces, dental plague, and a variety of other materials [1]. The majority of microorganisms are benign or even helpful to humans. While many more may do so in individuals with compromised immune systems, just a small percentage in healthy persons cause illness. Twelve years or so after Van Leeuwenhoek's discovery, it was shown that these microscopic organisms might also act as disease agents in certain situations. Agostino Bassi first proved this for a bacterial infection of silkworms in 1835 [1]. In 1876, German scientist Robert Koch became the first to demonstrate that a bacteria could produce anthrax, a disease that affects humans. Naturally, there was a great deal of public and scientific excitement in the finding, but there were also individuals in the scientific and lay sectors who resisted the new idea of infection.

Microbiology is the study of microorganisms, and it should come as no surprise that a large portion of the research is focused on the organisms that actually cause illness in humans. It is now understood that microorganisms may be involved in a variety of disorders, including cervical cancer, angina pectoris, and peptic ulcers, in addition to the diseases that are traditionally classified as infectious. It is genetically possible for bacteria to spread and develop resistance to medications that are utilized as therapeutic agents [2]. Without a doubt, many more non-infectious disorders will be linked to microorganisms in the future. But they are also necessary for human existence. Many thousands of organisms live on every square inch of our body, helping to keep other potentially dangerous species from invading. Antibiotics, for example, may destroy this natural "flora," making it easier for dangerous organisms to take root and establish themselves.

The most practical dose form for infants, kids, and the elderly is a syrup, which is a non-sterile liquid that contains active medications [3].
Since children cannot readily or comfortably take pills or capsules, syrups are mostly manufactured for oral administration [4].

Syrups have a thick viscosity and a sweet flavor. All syrups are transported by a concentrated aqueous solution of sucrose or another sugar.
Because they are tasty and readily absorbed by the body, medicated and flavor-infused syrups are the recommended dose forms of choice for both adults and children. Multidose syrups are often used by patients, and the majority of them have been shown to be effective. Preservatives should thus be used by producers to avoid unintentionally contaminating syrup bottles that have been opened. Preservatives are used extensively in several production sectors, including the pharmaceutical and cosmetics industries [5].

Both substances with established antibacterial action and substances that might either directly or indirectly support antimicrobial activity are included in the preservatives [6]. By lowering the population and preventing the development of microorganisms that can be unintentionally introduced during repeated usage, antimicrobial preservatives function [7]. The kind and intrinsic preservative activity of certain formulative materials, the quantity of water accessible for development, and the preservative's own capabilities all affect how much of a preservative is needed. Therefore, minimizing microbial contamination and delaying microbial development and activity are the main goals of all handling and storage techniques [8].

93 samples of non-sterile pharmaceutical preparations from 34 different manufacturers, including 18 multivitamin syrups and 31 cough syrups, were examined in an effort to get general data on their microbial composition. The findings showed that one of the 18 multivitamins was contaminated, but all samples were free of Salmonella, Pseudomonas aeruginosa, and Escherichia coli. Three of the 31 cough syrup samples were contaminated with gram-positive bacilli, but the total aerobic count was not greater than 1x100org/ml [9].

A study conducted in Nigeria on the microbiological quality of a few commercially available syrups and suspensions revealed that 40% of them did not meet the regulatory standards for syrup microbiological quality. All except one of the syrups had bacterial loads < 103 cfu/ml, the maximum amount of germs that may be present in non-sterile medications. The most common contamination of syrup, Bacillus, was also the most common contaminant of medications, according to this research [11].

Five cough syrups had bacterial loads of less than 10 x 3cfu/ml, indicating that they complied with the official requirement for the microbiological quality of syrups. The other five were heavily contaminated and therefore did not meet the official limit, according to the microbiological quality analysis of 20 pediatric antimalarial and cough preparations [4]. Before a drug product is approved for use, the US Food and Drug Administration (FDA) mandates that it undergo testing for purity, identification, strength, quality, and stability. Process control and pharmaceutical validation are thus crucial [12].
The purpose of the research is to assess the microbiological quality of several multivitamin preparation brands sold in Maiduguri by different producers.

MATERIALS AND METHOD

Materials

- Drug samples (multivitamin syrup)
- Autoclave (Dixons CE model type ST 195, made in U.K)
- Incubator (Genlab, made in Cheshire)
- Foil paper
- Syringes
- Conical flask
- Beakers
- Cotton wool
- Disposable Petri dishes
- Mac Cartney bottles
- Hand gloves

- Spatula
- Air condition
- Weighing machine (Mettler pj 3600, made in Switzerland)
- Test tubes
- Measuring cylinder (Pyrex)
- Colony counter (Stuart sc6, made in U.K)
- Air filter (Hunter, made in China)
- Ultra violent lamp
- Laminar flow (Former scientific,inc made in U.S.A)

Media Used
- MacConkey agar (Darmstadt, Germany)
- MacConkey broth (Darmstadt, Germany)
- Nutrient agar (Darmstadt, Germany)
- Nutrient broth (Darmstadt, Germany)
- Sabourauds dextrose agar (Darmstadt, Germany)
- Sabourauds dextrose broth (Darmstadt, Germany)
- Baird parker agar (Darmstadt, Germany)
- Xylose lysine deoxycholate agar (Darmstadt, Germany)

others
- Distilled water
- Peptone water
- Methylated spirit.

Sample collection
Seven different brands of multivitamin syrups marketed in Maiduguri, Nigeria were purchased from three different pharmacies and corded with numbers 1-7. Each had NAFDAC registration status, shelf life, manufacturing and expiry date.

Analysis of samples
Pour plate method was used for the estimation in accordance with [13]. The culture media (agar and broth) were prepared according to the manufacturers instructions. MacConkey, nutrient and Sabourauds dextrose were used for this analysis. One millilitre was withdrawn aseptically from each sample into corresponding labelled bottle PW1-7, thus comprising of peptone Water and drug sample. The screw caps were tightly covered and shaken well to ensure complete dissolution of the drug sample, 1ml from each bottle was transferred aseptically into duplicate medium plate (agar) and bottles (broth), kept in an incubator set at 37ºC. Bacterial colonies were counted and the number of colony forming units per ml of each plate was calculated [14].

Identification of isolated microorganisms
The sample of the syrups were plated on various selective media such as MacConkey for (*Escherichia coli*), Sabourauds dextrose agar for (*moulds and yeasts*), Baird parker agar (for *Staphylococcus*) and Xylose lysin Deoxycholate for *(Salmonella*) and then incubated.

TABLE 1 Labels present on the various drug samples investigated.

SAMPLES	MANUFACTURING DATE	EXPIRY DATE	BATCH NUMBER	NAFDAC NUMBER
1	10/2010	09/2013	+	+
2	07/2010	07/2012	+	+
3	10/2010	10/2012	+	+
4	06/2009	06/2011	+	+
5	02/2011	02/2014	+	+
6	06/2010	05/2012	+	+
7	06/2009	05/2011	+	+

+ = INDICATED

RESULTS AND DISCUSSION

Table 1 shows the different drug samples used indicating their manufacturing and expiry dates, batch numbers and NAFDAC registration numbers. These labels confirmed their authenticities and their free circulation in market are

fully accepted and recognised. It also reveals that their respective active ingredients are still valid as they were within their shelf-lives

Majority (table 2) of the contamination came from the nutrient agar. The least number of contaminations came from MacConkey agar which had two pathogenic organisms in contrast to MacConkey broth which had no contaminant. Only samples 1, 2 and 5 indicated the absence of growth in nutrient broth while samples 3, 4, 6 and 7 had growth in both nutrient agar and nutrient broth respectively.

TABLE 2: number of organisms recorded per millilitre

SAMPLES	NA	MCA	SDA	NB	MCB	SDB
1	80	_	4	_	_	_
2	60	_	2	_	_	_
3	60	2	1	+	_	_
4	50	_	2	+	_	_
5	40	_	2	_	_	+
6	60	_	_	+	_	_
7	40	_	_	+	_	_
CONTROL	_	_	_	_	_	_

NA = *NUTRIENT AGAR*
MCA = *MacConkey AGAR*
SDA = *SABOURAUDS DEXTROSE AGAR*
NB = *NUTRIENT BROTH*
MCB = *MacConkey BROTH*
SDB = *SABOURAUDS DEXTROSE BROTH*
\+ = *PRESENT*
_ = *ABSENT*

TABLE 3: shows the distribution pattern of isolated contaminants suspected in sample 3 under the influence of MacConkey agar.

MEDIA	ORGANISM	QUANTITY
MCA	E.COLI	NIL
BPA	STAPH	NIL
XLD	SALMONELLA	2

MCA = MacConkey agar
BPA = Baird parker agar
XLD = xylose – lysine deoxycholate agar

Furthermore, samples 1 through 4 showed that there was growth in the Sabouraud dextrose agar alone, not in the broth; sample 5 demonstrated that there was growth in both the broth and the Sabouraud dextrose agar; and samples 6 and 7 showed no growth in either the broth or the Sabouraud dextrose agar. It was discovered that the third sample had more harmful microorganisms than the official specified limit. This led to more research to look for Salmonella, Staphylococcus, and Esherichia coli. Salmonella was detected, while Escheichia coli and Staphylococcus were both negative (missing) (table 3). This pollution raises the possibility that water is the source.

The sugar concentration of the syrups, which produces strong osmotic pressure that inhibits many microorganisms, may be the cause of the reduced count seen in the other syrups [15]. Additionally, syrups are often filtered before being bottled. Salmonella contamination may also occur from an infected worker operating under unsanitary conditions or from significant microbial contamination of the production equipment [16]. Esherichia coli are a perfect indicator organism to check environmental samples for fecal contamination since they are not necessarily restricted to the gut and may live for short periods of time outside the body [17].

One of the basic necessities of life is water, and any unwanted chemical addition contaminates it and renders it unsuitable for human use [18]. Water, the manufacturing environment, workers, and packaging materials have historically been the main causes of pharmaceutical contamination [19]. To guarantee a decrease in the degree of microbiological contamination, appropriate consideration should be paid to the earlier treatment of these variables.

As only one sample was discovered to have pathogenic organisms above the recognized purity standard, it is also evident from the findings that the extent of microbial contamination in the various brands of multivitamin syrup samples utilized was quite low. Other non-pathogenic microorganisms, such as yeast and mold, were found to be within the acceptable range, suggesting that they meet the FIP working committee's 1975 official standards for the microbiological quality of syrups.

With only one (1) of the seven (7) samples tested exhibiting contamination above the acceptable level, the results of this study, which complement those of other studies, demonstrated that non-sterile pharmaceutical mixtures, such as pediatric preparations (syrups and suspensions), demonstrated compliance with the official requirement for microbiological quality of syrups. On the other hand, they might be quiet and unnoticed sources of illness for babies.

CONCLUSION

Although the other six multivitamin syrups met the regulatory standards for microbiological purity, it may be inferred that one of them was tainted. One of the multivitamin samples was discovered to have Salmonella, which might have come from contaminated water, industrial equipment, or diseased staff.

REFERENCES

[1] Angharad P D. Micro-organisms Oxford University Press London. **2003**.
[2] Amit P, Parul S. Asian J. Plant Sci. Res., **2011**, 1(2): 69- 80.
[3] Muhammed A, Umoh V J. Nigr. J. Pharm. Sci. **2009** 8(2) 126-134.
[4] Adeshina G O, Ajayi S, Onaolapo J A. Nigr. J. Pharm. Sci. **2009** 8(1): 109 - 117.
[5] Hugo W B, Russel A D. Pharm. Micr. Sec editn. **1980** Blackwell Scientific Publications.
[6] Spiegeleer B, Wattyn E, Sleggers G, Meeren V, Vlamick K. Vooren L. Pharm. Dev. Technol. **2006**. 11: 275-284.
[7] Rosenthal R A, Buck S L, Henry C L. Schlech B A. J. Ocular Pharmacol. Ther. **2006**. 22: 440-448.
[8] Ajiboye E A, Sani A, Adebayo R M, Kolawole M O, Oladosu O T. Adv. Appl. Sci. Res., **2011**. 2(4): 391-400.
[9] Dilnawaz S, Tasawar A J, Rafi S. Pakst. J. Pharm. Sci. **1998**. 61-66.
[10] Ibezim E C, Esimone C O, Ofeofule S I, Chah K F. J. Phytomed. Therap. **2002** 7(1&2): 18-25
[11] Maria del Carmen de la Rosa, Maria A M, Maria L G, Carlos P. J. Appl. Bacteriol. **1993**. 74: 570-577.
[12] Rajesh K. Parida. Der Pharmacia Sinica, **2010**, 1(1): 11-19.
[13] Collin C H, Lyne P M. Microbiology Methods 4th edition Butterworths, London **1976** pp 159-199.
[14] Conn H J, Manual of Microbiological Methods McGraw Hill, New York. **1975** pp 37-72.
[15] Cooper K E, Gunn C. Microbial Contamination of Non- Sterile Pharmaceuticals. In Cater, S.J. (ed) Dispensing for pharmaceutical Students 12th edition published by S. K. Jain Delhi India **1987** p 43-80.
[16] Okonko I O. Afric. J. Food Sci. **2009**. 3(2): 035-050
[17] Manaal Z, Chetan R, Pushpendra S, Sana I, Shumaila K, Akhilesh K. Euro. J. Exp. Bio., **2011**, 1(2):118-124.
[18] Alo M N, Anyim C, Elom M. Adv. Appl. Sci. Res., **2012**. 3(2): 887-894.
[19] Olutimeyin B, Onaolapo J A. J. pharm. Res. Dev. **1997**. 2(1): 35-43.