

## Microbial Assessment of Retention Samples and Impact in Monitoring Microbial Quality of Liquid Preparations in Pharmaceutical Industries

Stephen Dare Oloninefa\*<sup>1</sup>, Japhet Erasmus Aisoni<sup>2</sup>, Victor Chibueze Chukwu<sup>3</sup>, Victor Kolawole Fadayomi<sup>4</sup>, Jesse Innocent Apameio<sup>5</sup>

<sup>1</sup>Department of Biological Sciences, Kogi State University, Kabba, Nigeria  
 Email Address: [sdoloninefa@ksukabba.edu.ng](mailto:sdoloninefa@ksukabba.edu.ng)

<sup>2</sup>Department of Microbiology, Bayero University, Kano, Nigeria

<sup>3</sup>Department of Biological Sciences, State University of Medical and Applied Sciences, Igbo-Eno, Enugu, Nigeria  
 Email Address: [victor.chukwu@sumas.edu.ng](mailto:victor.chukwu@sumas.edu.ng)

<sup>4</sup>Department of Microbiology, Federal University, Lafia, Nigeria

Email Address: [fadayomiv@gmail.com](mailto:fadayomiv@gmail.com)

<sup>5</sup>Department of Biological Sciences, Taraba State University, Jalingo, Nigeria  
 Email Address: [jesseinnocent75@gmail.com](mailto:jesseinnocent75@gmail.com)

\*Corresponding Author's E-mail Address: [sdoloninefa@ksukabba.edu.ng](mailto:sdoloninefa@ksukabba.edu.ng); Telephone: 08038893341.

Received on: April, 2025

Revised and Accepted on: May, 2025

Published on: July, 2025

### ABSTRACT

The impact of retention samples in monitoring microbial quality of liquid preparations in pharmaceutical industries cannot be over-emphasized. The challenge of microbial contamination and monitoring microbial quality of liquid preparations call for the need to keep retention samples of liquid preparations in pharmaceutical industries. Seven (7) retention samples of registered liquid preparations (Mist Magnesium Trisilicate Mixture, Paracetamol Syrup, Cough Syrup, Vitamin C Syrup, Gentian Violet, Calamine Lotion and Hydrogen Peroxide) that were not less than two years inside the retention room were collected from two selected pharmaceutical industries and microbiology purity tests were carried out using standard methods. The results revealed absence of pathogenic bacteria in all the retention samples. The highest values of 46.67 cfu/ml and 30.00 cfu/ml obtained for total viable aerobic mesophilic bacteria plate count and fungi from Cough Syrup and Vitamin C Syrup respectively might possibly be due to the use of sugar and other excipients that support microbial growth. The results show that the microbial quality of the liquid preparations represented by the retention samples were satisfactory as they conformed to the British Pharmacopeia (BP) specifications for liquid specifications. This suggests that the liquid preparations produced followed current good manufacturing practice (cGMP) as shown in the results obtained from the retention samples. Therefore, retention samples play vital role in the monitoring of microbial quality of liquid preparations and subsequently contribute to drug development and annual product quality review in pharmaceutical industries.

**Keywords:** Impact, Microbial Quality, Retention Samples, Pharmaceutical Industries, Oral liquid preparations

### 1.0 INTRODUCTION

Liquid preparations in pharmaceutical industries due to the incorporation of water during compounding are more prone to microbial contamination compared to their counterparts, the solid dosage forms (Gandhi *et al.*, 2020; Rathore *et al.*, 2022). Therefore, the use of quality assurance systems involving the use of retention samples in pharmaceutical industries play vital roles in monitoring the microbial quality of liquid preparations because of the production environment and the quality of the raw materials. The preservation of liquid preparations (solutions, syrups and suspensions) from microbial growth is highly warranted because of the raw materials (active and non-active ingredients) used which are prone to microbial contamination because they support microbial growth as reported by Omoja and Adewale (2019). In order to avoid microbial contamination which can affect the shelf life of liquid pharmaceutical preparations coupled with the production of safe, efficacious and quality liquid

preparations, pharmaceutical industries are mandated to comply with Good Manufacturing Practice (GMP) and standards set in the pharmacopeias such as British Pharmacopeia (BP), United States Pharmacopeia (USP) and International Pharmacopeia (IP) during and after the production of the products (Li *et al.*, 2020; WHO, 2021).

Furthermore, the microbial assessment of retention samples which are held throughout the shelf life of the liquid preparations and one year after in the Retention Sample Room (RSR) assist greatly in the monitoring of the microbial quality of the liquid preparations, the potency of preservatives used, monitoring of storage conditions, customer complaints, deviations and recalls and annual product quality review (Khanna *et al.* 2019; Mohite *et al.*, 2020; Mahajan *et al.*, 2021; Adegboye *et al.*, 2022; Samad *et al.*, 2023).

In assessing the microbial quality of retention samples, tests for pathogenic bacteria (such as *Escherichia coli*, *Salmonella typhimurium*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Shigella dysenteriae*), total viable aerobic mesophilic bacteria plate count and fungi (yeasts and moulds) count are carried out and compared with the pre-set standards/limits in the pharmacopeia (such as BP) to determine whether they comply or not (Patel *et al.*, 2020). Satisfactory results obtained from microbial testing of retention samples help to validate the effectiveness of the preservatives used during the production of liquid preparations and also provide valuable information for product development (Patel *et al.*, 2020). Therefore, this study focuses on the microbial assessment of retention samples and impact in monitoring microbial quality of liquid preparations in pharmaceutical industries.

## 2.0 MATERIALS AND METHODS

### 2.1 Study Area

The study area covered two selected pharmaceutical industries within Minna, Niger State, Nigeria.

### 2.2 Sample Collection

Seven retention samples comprising 4 oral liquid preparations (Mist Magnesium Trisilicate Mixture, Paracetamol Syrup, Cough Syrup and Vitamin C Syrup) and 3 external liquid preparations (Gentian Violet, Calamine Lotion and Hydrogen Peroxide) that have spent at least 2 years inside the Retention Room were randomly collected from registered products from two selected pharmaceutical industries, labelled accordingly and analysed microbiologically.

### 2.3 Media Preparation

The culture media used for the isolation of pathogenic bacteria (*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella typhimurium*, *Shigella dysenteriae*) comprised of Eosin Methylene Blue Agar, Cetrimide Agar, Mannitol Salt Agar, Salmonella-Shigella Agar, Lactose Broth and Nutrient Broth. The total viable aerobic mesophilic bacteria plate count and fungi were isolated using Nutrient Agar, Sabouraud Dextrose Agar, Nutrient Broth and Sabouraud Dextrose Broth. The media were prepared according to the manufacturers' specifications

### 2.4 Preparation of Serial Dilution

The 10-fold serial dilution was prepared as reported by Oloninefa *et al.* (2020). Three millilitres were withdrawn from each of the retention samples and 1 ml each was aseptically delivered into 9 ml already sterilized Nutrient Broth, Lactose Broth and Sabouraud Dextrose Broth to obtain a dilution factor of  $10^{-1}$ .

### 2.5 Inoculation and Incubation

The inoculation and incubation were carried out as reported by Oloninefa *et al.* (2020). The inoculation of the sterilized culture media (Eosin Methylene Blue Agar, Mannitol Salt Agar, Salmonella-Shigella Agar) was carried out by withdrawing a loopful from the  $10^{-1}$  Lactose Broth using a sterilized wire inoculating loop whereas the Nutrient Agar and Sabouraud Dextrose Agar were inoculated through the withdrawal of a loopful from the  $10^{-1}$  Nutrient Broth. The incubation of these inoculated culture media (Eosin Methylene Blue Agar, Mannitol Salt Agar, Salmonella-Shigella Agar and Lactose Broth) were done at  $37^{\circ}\text{C}$  for 24-48 h while that of inoculated Nutrient Agar, Nutrient Broth, Sabouraud Dextrose Agar and Sabouraud Dextrose Broth were carried out at  $37^{\circ}\text{C}$  for 24-72 h.

### 2.6 Enumeration of the Organisms

The enumeration of the incubated culture media were done at the end of the incubation period. This was achieved through the multiplication of visible, viable and distinct colonies by the reciprocal of the dilution factor. The results were expressed the outcome in colony-forming unit per ml (cfu/ml). The results were compared with the pre-set standards in British Pharmacopeia (BP, 2009; Cheesbrough, 2010; Oloninefa *et al.*, 2020).

## 3.0. RESULTS

### 3.1 Microbiology Purity Test of Magnesium Trisilicate Mixture (MM)

Table 1 shows that pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*) were not present in all the selective media used. The total colonies obtained from Magnesium Trisilicate Mixture samples for total viable aerobic mesophilic bacteria plate count (TVAMBPC) and fungi were between 10.00-36.67 cfu/ml and 0.00-13.33 (Table 1).

**Table 1: Microbiology Purity Test of Magnesium Trisilicate Mixture (MM)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
MM1	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>a</sup>	0.00±0.00 <sup>a</sup>
MM2	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>a</sup>	10.00±0.00 <sup>b</sup>
MM3	0.00±0.00 <sup>a</sup>	26.67±3.33 <sup>b</sup>	0.00±0.00 <sup>a</sup>
MM4	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>a</sup>	13.33±3.33 <sup>b</sup>
MM5	0.00±0.00 <sup>a</sup>	36.67±3.33 <sup>c</sup>	10.00±0.00 <sup>b</sup>

The results showed the mean ± standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

#### KEY:

1: Expected/Limit- Nil or 0 cfu/ml

2: Expected/Limit-  $\leq 1 \times 10^3$  cfu/ml

3: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml

### 3.2 Microbiology Purity Test of Paracetamol Syrup (PS)

There was absence of pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*) from all the selective media used whereas the total colonies obtained from Paracetamol Syrup samples for both TVAMBPC fungi were 0.00-13.33 cfu/ml respectively (Table 2).

**Table 2: Microbiology Purity Test of Paracetamol Syrup (PS)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
PS1	0.00±0.00 <sup>a</sup>	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>b</sup>
PS2	0.00±0.00 <sup>a</sup>	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>b</sup>
PS3	0.00±0.00 <sup>a</sup>	0.00±0.00 <sup>a</sup>	0.00±0.00 <sup>a</sup>
PS4	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>b</sup>	0.00±0.00 <sup>a</sup>
PS5	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>b</sup>	0.00±0.00 <sup>a</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

#### KEY:

1: Expected/Limit- Nil or 0 cfu/ml

2: Expected/Limit-  $\leq 1 \times 10^3$  cfu/ml3: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml

### 3.3 Microbiology Purity Test of Cough Syrup (CS)

No pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*) in all the selective media whereas the total colonies obtained from Cough Syrup samples for TVAMBPC were between 13.33-46.67 cfu/ml while fungi recorded between 0.00 and 20.00 cfu/ml respectively (Table 3).

**Table 3: Microbiology Purity Test of Cough Syrup (CS)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
CS1	0.00±0.00 <sup>a</sup>	23.33±6.67 <sup>a</sup>	10.00±0.00 <sup>b</sup>
CS2	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>a</sup>	20.00±0.00 <sup>c</sup>
CS3	0.00±0.00 <sup>a</sup>	46.67±3.33 <sup>b</sup>	0.00±0.00 <sup>a</sup>
CS4	0.00±0.00 <sup>a</sup>	13.33±3.33 <sup>a</sup>	16.67±3.33 <sup>c</sup>
CS5	0.00±0.00 <sup>a</sup>	16.67±3.33 <sup>a</sup>	10.00±0.00 <sup>b</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

#### KEY:

1: Expected/Limit- Nil or 0 cfu/ml

2: Expected/Limit-  $\leq 1 \times 10^3$  cfu/ml3: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml

### 3.4 Microbiology Purity Test of Vitamin C Syrup (VC)

Table 4 reveals absence of pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*) in all the selective media. The total colonies obtained from Vitamin C Syrup samples for TVAMBPC ranged between 10.00 and 20.00 cfu/ml while fungi had colonies between 10.00 and 30.00 cfu/ml respectively (Table 4).

**Table 4: Microbiology Purity Test of Vitamin C Syrup (VC)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
VC1	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>a</sup>	10.00±0.00 <sup>a</sup>
VC2	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>a</sup>	13.33±0.00 <sup>a</sup>
VC3	0.00±0.00 <sup>a</sup>	16.67±3.33 <sup>b</sup>	30.00±0.00 <sup>b</sup>
VC4	0.00±0.00 <sup>a</sup>	20.00±0.00 <sup>b</sup>	13.33±3.33 <sup>a</sup>
VC5	0.00±0.00 <sup>a</sup>	10.00±0.00 <sup>a</sup>	16.67±3.33 <sup>a</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

**KEY:**

- 1: Expected/Limit- Nil or 0 cfu/ml
- 2: Expected/Limit-  $\leq 1 \times 10^3$  cfu/ml
- 3: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml

**3.5 Microbiology Purity Test of Gentian Violet (GV)**

No pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*), TVAMBPC and fungi (Table 5).

**Table 5: Microbiology Purity Test of Gentian Violet (GV)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
GV1	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
GV2	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
GV3	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
GV4	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
GV5	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

**KEY:**

- 1: Expected/Limit- Nil or 0 cfu/ml
- 2: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml
- 3: Expected/Limit-  $\leq 1 \times 10^1$  cfu/ml

**3.6 Microbiology Purity Test of Hydrogen Peroxide (HS)**

No pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*), TVAMBPC and fungi (Table 6) from all the Hydrogen Peroxide samples examined microbiologically (Table 6).

**Table 6: Microbiology Purity Test of Hydrogen Peroxide (HS)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
HS1	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
HS2	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
HS3	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
HS4	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
HS5	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

**KEY:**

- 1: Expected/Limit- Nil or 0 cfu/ml
- 2: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml
- 3: Expected/Limit-  $\leq 1 \times 10^1$  cfu/ml

**3.7 Microbiology Purity Test of Calamine Lotion (CL)**

No pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*), TVAMBPC and fungi (Table 7) from all the Calamine Lotion samples examined microbiologically (Table 7).

**Table 7: Microbiology Purity Test of Calamine Lotion (CL)**

Samples	<sup>1</sup> Pathogenic Bacteria (cfu/ml)	<sup>2</sup> Total Viable Aerobic Mesophilic Bacteria Plate Count (cfu/ml)	<sup>3</sup> Fungi (cfu/ml)
CL1	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
CL2	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
CL3	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
CL4	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>
CL5	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>	0.00 $\pm$ 0.00 <sup>a</sup>

The results showed the mean  $\pm$  standard error of mean while the values with the same superscript in the same column are not significantly different at  $p < 0.05$

**KEY:**

- 1: Expected/Limit- Nil or 0 cfu/ml



2: Expected/Limit-  $\leq 1 \times 10^2$  cfu/ml

2: Expected/Limit-  $\leq 1 \times 10^1$  cfu/ml

#### 4.0 DISCUSSION

The absence of pathogenic bacteria (*P. aeruginosa*, *S. aureus*, *E. coli*, *S. dysenteriae* and *S. typhimurium*) from the microbial assessment of the retention samples was in line with the previous findings by Ibrahim *et al.* (2022) and USP (2022) who reported that pharmaceutical products especially liquid preparations are expected to be free from specified pathogenic bacteria to guarantee the safety of the end users. No pathogenic bacteria recorded in all the samples also agree with the pre-set standards in the BP and WHO for non-sterile oral liquid preparations (WHO, 2020; BP, 2023; Eke *et al.*, 2023). In addition, the absence of the pathogenic bacteria also confirm that good manufacturing practices (GMP) were adequately and strictly followed during the manufacturing of the products by the manufacturers (Mourya *et al.*, 2021).

Furthermore, the low numbers of colonies recorded for total viable aerobic mesophilic bacteria plate count (TVAMBPC) and fungi were in line with the BP specifications even though both Cough Syrup and Vitamin C syrup had higher values which may possibly be due to the use of sugar and other raw materials in their preparations that can enhance and support the growth of microbes as reported by Ali *et al.* (2022) and BP (2023).

However, the absence of pathogenic bacteria, TVAMBPC and fungi obtained from external liquid preparations (topical products) such as Gentian violet and Calamine Lotion was in agreement with the previous studies by Hussein *et al.* (2020) who posited that both preparations contain antimicrobial agents. Hence, the absence of pathogenic bacteria, TVAMBPC and fungi. In the same vein, the results obtained from Hydrogen Peroxide were consistent with the BP (BP, 2023). Generally, the findings in this study revealed the manufacturer's compliance with the GMP and BP standards which boost the quality, efficacy of the products and guarantee the safety of the final users and by extension the public health (Singh *et al.*, 2024; Adeyemi *et al.*, 2024; BPC, 2024; WHO, 2025).

#### 5.0 CONCLUSION

The compliance of the results of the retention samples with the BP specifications show that the liquid preparations were manufactured by following good manufacturing practices (GMP), strict compliance to the standard operating procedures guiding the operations of pharmaceutical industries and maintenance of good storage conditions. Therefore, retention samples should regularly be taken for every batch of the product produced so that they can be used in the monitoring of microbial quality of liquid preparations which will eventually contribute

immensely in drug development and during the annual product quality review in pharmaceutical industries.

#### ACKNOWLEDGEMENT

The authors wish to acknowledge the support and cooperation of the personnel from the Quality Control Department of Jesil Pharmaceutical Industries Limited, Minna and LeyJay Pharmaceuticals Limited, Minna.

#### REFERENCES

- Adegboye, M. F., Yakubu, O. F. & Aliyu, A. A. (2022). Microbial quality assurance of liquid pharmaceutical preparations in Nigeria: A review. *African Journal of Pharmaceutical Research & Development*, 14 (2), 55–64.
- Adeyemi, S. T., Ogunleye, A. A. & Balogun, J. O. (2024). Evaluation of GMP compliance and its impact on pharmaceutical product quality in Nigeria. *Journal of Pharmaceutical Quality Assurance*, 15 (2), 102–115
- Ali, R., Khan, S., Farooq, U. & Ahmed, N. (2022). Assessment of microbiological quality of commercially available syrups in Pakistan. *Journal of Applied Pharmaceutical Science*, 12 (02), 113–118.
- British Pharmacopoeia- BP (2009). In: *Microbiological Quality of Pharmaceutical Preparations*. Volume IV, Appendix XVID (pp. A426-A427). London: The Stationery Office.
- BP (2023). *British Pharmacopoeia 2023*. London: The Stationery Office.
- British Pharmacopoeia Commission- BPC (2024). *British Pharmacopoeia 2024 (Volume I-VI)*. London: The Stationery Office.
- Cheesbrough M (2010). *Laboratory Manual*. In: *District Laboratory Practice in Tropical Countries* (pp.146-157). United Kingdom: Cambridge University Press.
- Eke, G. I., Nwachukwu, N. C. & Nweke, M. U. (2023). Microbiological quality control of some non-sterile pharmaceutical products in Nigeria. *Journal of Pharmaceutical Microbiology*, 9 (1), 45-53.
- Gandhi, A., Patel, P. & Patel, J. (2020). Microbial contamination: An important issue in pharmaceutical industry. *World Journal of Pharmaceutical Research*, 9 (9), 1150–1162.
- Hussein, A. H., Al-Mayahie, S. M. & Al-Ani, F. S. (2020). Evaluation of microbiological contamination of cosmetic and topical products in Baghdad. *Systematic Reviews in Pharmacy*, 11 (3), 221–226.
- Ibrahim, A., Mohammed, H. & Adeyemi, O. (2022). Microbial contamination in non-sterile pharmaceutical products: A threat to patient safety.



- Nigerian Journal of Pharmaceutical Research, 18 (2), 100–108.
- Khanna, R., Jaiswal, S. & Kumar, R. (2019). Significance of retention samples in the pharmaceutical industry. *International Journal of Pharmaceutical Sciences and Research*, 10 (11), 5072–5076.
- Li, L., Zhang, J. & Ma, X. (2020). Assessment of microbial contamination in liquid pharmaceutical preparations. *Journal of Applied Microbiology*, 129 (3), 684–692.
- Mahajan, R., Sharma, S. & Gupta, R. (2021). Role of retention samples in product quality complaints. *International Journal of Pharmaceutical Quality Assurance*, 12 (3), 241–245.
- Mohite, R., Deshpande, K. & Jadhav, V. (2020). Microbiological quality control in pharmaceutical industry: Current trends. *International Journal of Research in Pharmaceutical Sciences*, 11 (1), 113–120.
- Mourya, V. K., Shrivastava, R. & Jain, P. (2021). Significance of GMP compliance in microbiological quality of pharmaceutical products. *International Journal of Pharmaceutical Sciences Review and Research*, 66 (2), 30–35.
- Oloninefa, S. D., Areo A. J., Titus, J., Aisoni, J. E. (2020). Microbial Purity and Ibuprofen Contents in Four Branded Ibuprofen Tablets Sold within Minna City, Nigeria. *Anchor University Journal of Science and Technology*, 1 (1), 76–81.
- Omoya, F. O. & Adewale, A. A. (2019). Assessment of microbial contamination in some non-sterile liquid pharmaceuticals. *Journal of Applied Sciences and Environmental Management*, 23 (4), 643–648.
- Patel, N., Shah, K. & Thakkar, V. (2020). Microbial testing strategies for non-sterile pharmaceutical products. *Journal of Pharmaceutical and Biological Sciences*, 8 (1), 12–19.
- Rathore, S., Singh, R. & Verma, P. (2022). Assessment and control of microbial contamination in pharmaceutical liquid dosage forms. *Journal of Microbiology and Biotechnology Research*, 12 (1), 13–19.
- Samad, A., Ahmad, M. & Hussain, S. (2023). Retrospective microbial analysis of retention samples as an effective quality tool. *Pharmaceutical Science and Research*, 15 (2), 107–114.
- Singh, R., Kaur, H. & Aggarwal, G. (2024). Ensuring microbiological quality in non-sterile pharmaceutical products: Current challenges and strategies. *Pharmaceutical Science and Technology Today*, 15 (1), 9–16.
- United States Pharmacopeia- USP (2022). USP <61> Microbiological examination of non-sterile products. United States Pharmacopeial Convention.
- World Health Organization- WHO (2020). WHO guidelines for sampling of pharmaceutical products and related materials. <https://apps.who.int/iris/handle/10665/334145> (Retrieved on 09/07/25).
- WHO (2021). WHO good manufacturing practices: Main principles for pharmaceutical products.
- WHO (2025). Good Manufacturing Practices (GMP) for pharmaceutical products: Main principles (updated 2025 ed.). World Health Organization. <https://www.who.int/publications/gmp-2025> (Retrieved on 11/07/25).