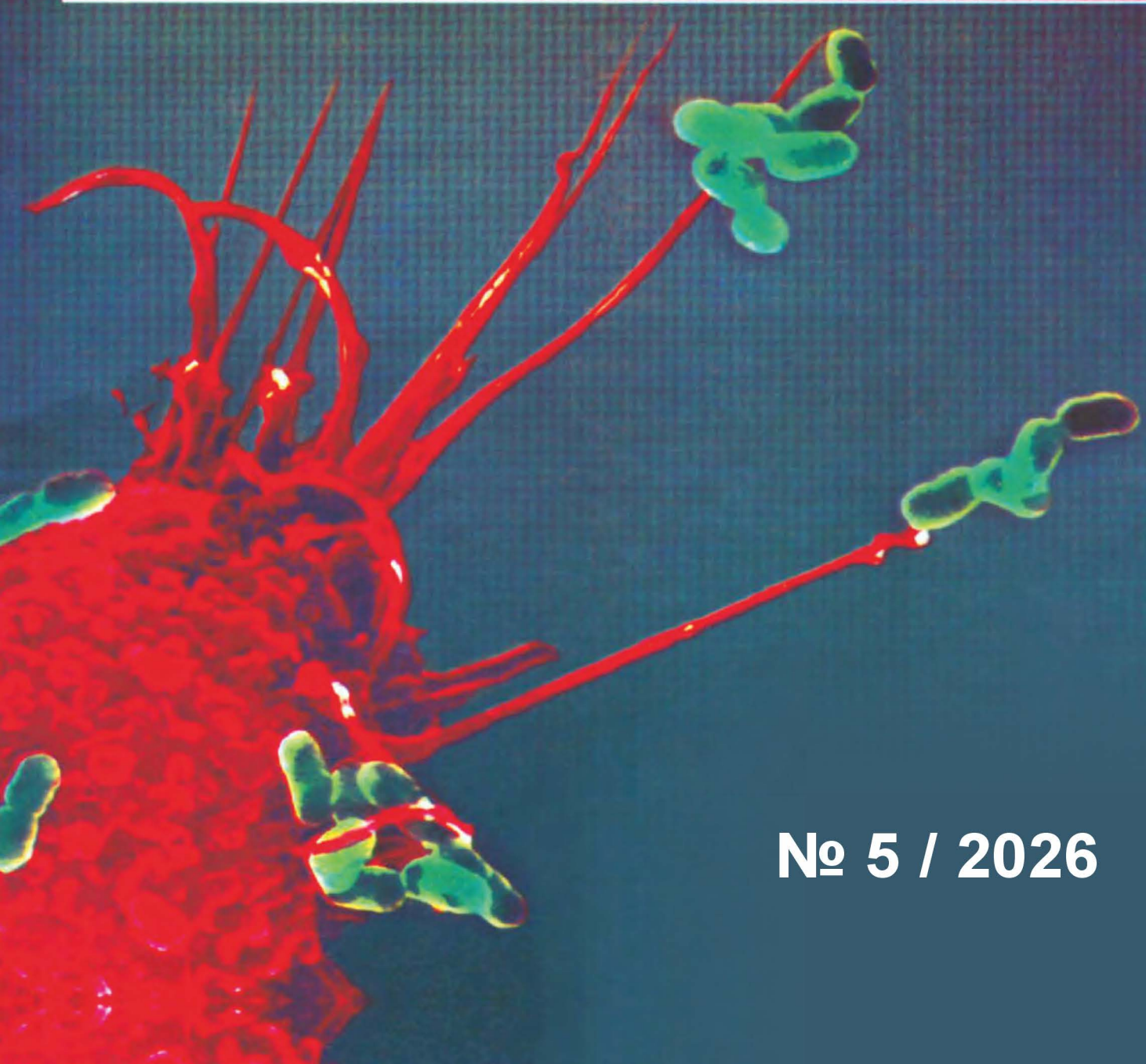
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MICROBIOLOGICAL QUALITY ASSESSMENT OF "CIPROMAX-AK" POWDER FOR ORAL SUSPENSION ACCORDING TO USP <61> AND USP <62>

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Keywords: *non-sterile pharmaceutical products; microbial enumeration; total aerobic microbial count; yeasts and moulds; Escherichia coli; USP <61>; USP <62>; powder for oral suspension; quality control; Uzbekistan*

Background. Microbiological purity is a mandatory and very essential quality attribute of non-sterile oral medicines, and it deserves particular attention in antibacterial powders that are made with water to make solution and administered mostly to children and minors. *Aim.* To create the microbiological quality of a locally manufactured powder for oral suspension, "Cipromax-AK" 125 mg/5 mL (60 mL) by Askam Pharma , against the harmonised requirements of USP <61> and USP <62>. *Methods.* A sample from a newly introduced production series of AS-KAM Pharma LLC (Uzbekistan) was examined at the Andijan branch testing laboratory of the Center for Safety of Pharmaceutical Products between 12 and 19 August 2026. Total aerobic microbial count (TAMC) and total combined yeasts and moulds count (TYMC) were determined according to USP <61>, and the absence of *Escherichia coli* in 1 g was verified according to USP <62>. Results were interpreted against the USP <1111> criteria for non-aqueous preparations for oral use. *Results.* Both TAMC and TYMC were below 10 CFU/g, the lowest count quantifiable at the dilution used, which places them at least 2.0 and 1.0 $\log_{10}$ units below the respective limits of 10^3 and 10^2 CFU/g. *E. coli* was not detected in 1 g of product which means very good. *Conclusion.* The checked series complied with requirements on Uzbek pharmacopoeia and USP for microbiological quality. Because the product contains an antibacterial substance, documented neutralisation and recovery data remain an essential condition for the reliability of such results; testing of other commercial series and of the water added suspension during in-use storage is recommended.

1. Introduction

Although most medicines do not need to be sterile in requirements, their microbiological quality is still an important

issue. Non-sterile medicines can become contaminated through different sources, including raw materials, water used during production, manufacturing equipment, packaging materials, or contact with personnel, human factor. Such microbial contamination may affect the stability and potency of a product and can sometimes result in a risk to patients [1, 2, 11]. According to medicine recalls in the United States have shown that microbiological contamination of non-sterile products occurs in different types of dosage forms statisticly. Gram-negative bacteria, particularly *Burkholderia cepacia* complex and *Pseudomonas* spp., are among the microorganisms that have frequently been associated with these problems [3, 4]. Studies examining non-sterile medicines available on the market have also reported differences in microbial contamination depending on the manufacturer or producer and the type of dosage form like suspensions or powders [5–8].

Oral powders intended for suspension are a little different from ready-to-use liquid preparations. They remain in powder form, their low water containing feature prevents microorganisms from growing. That is why, pharmacopoeial requirements for non-aqueous oral preparations differ from those applied to aqueous preparations [9, 10]. The situation changes after the powder is reconstituted or dissolved with water. The resulting suspension is an aqueous preparation, and it may contain sugars or other components that can provide more favorable conditions for microorganisms. In addition, dissolved powder is usually kept at home and used over several days. Therefore, microorganisms introduced during production or handling may remain viable and, under suitable conditions, may multiply. This is very important and relevant because oral suspensions are commonly used in infants and young children, who may be more vulnerable to exposure to potentially harmful microorganisms [2].

Testing requirements for microbes for non-sterile medicines have become largely harmonised across the United States, Europe, and Japan. In the United States Pharmacopeia (USP), chapter <61> describes methods for determining the total aerobic microbial count (TAMC) and the total yeast and mould count (TYMC), while chapter <62> focuses on detecting specified microorganisms. The acceptable microbial limits for different pharmaceutical preparations and routes of administration are provided in chapter <1111> [9, 10, 12]. Similar requirements are included in the European Pharmacopoeia in chapters 2.6.12, 2.6.13, and 5.1.4 [13]. For non-aqueous preparations intended for oral use, the limits are 10^3 CFU/g for TAMC and 10^2 CFU/g for TYMC. *Escherichia coli* must also be absent from 1 g of the product [10].

Microbiological testing becomes more complicated when the medicine contains an antibacterial substance. The active ingredient may inhibit microbial growth, making it difficult to recover the microorganisms that the test is intended to detect. If this antibacterial activity is not adequately neutralised through an appropriate procedure, such as dilution, chemical neutralisation, or membrane filtration, the results may underestimate the actual microbial content. For this reason, pharmacopoeial requirements state that the suitability of the test method must be demonstrated in the presence of the product before the results can be considered reliable [9, 12, 14, 15].

Near past years Uzbekistan's pharma-

ceutical industry developed pretty well, including the local production of antibacterial medicines intended for children. The main legal framework governing medicine quality is established by the Law "On Medicines and Pharmaceutical Activity" [22]. The organisation of pharmaceutical regulation, including state quality control, was restructured in 2017 [23]. Testing laboratories of the Center for Pharmaceutical Product Safety operate under a quality management system based on O'z DSt ISO/IEC 17025:2019 [24]. Despite these developments, independent laboratory data on the microbiological quality of locally manufactured medicines remain relatively limited in international scientific publications.

Generally, the present study aimed to evaluate the microbiological quality of the first production batch of "Cipromax-AK" powder for oral suspension (125 mg/5 mL), manufactured by AS-KAM Pharma LLC in Uzbekistan. Testing was conducted according to USP <61> and USP <62>, and the results were assessed against the relevant pharmacopoeial acceptance criteria. Particular attention was given to the challenges of microbiological testing when the pharmaceutical product contains an antibacterial substance.

2. Materials and Methods

2.1. Test Article

The study tested "Cipromax-AK", a powder for the preparation of an oral suspension containing 125 mg/5 mL, supplied in a 60 mL presentation and made by AS-KAM Pharma LLC, Uzbekistan. The active ingredient is ciprofloxacin, which is a fluoroquinolone antibiotic.

The sample, identified as No. 17, was collected on 11 August 2026 from a batch entering production for the first time. As the batch had not yet been assigned its manufacturing and expiry dates or a batch number, these details were not available in the test protocol. The manufacturer delivered the sample to the laboratory on the same day under a our agreement (Table 1).

Table 1.

Characteristics of the test sample and testing conditions

Parameter	Details
Product	"Cipromax-AK", powder for oral suspension 125 mg/5 mL, 60 mL
Manufacturer / applicant	AS-KAM Pharma LLC, Uzbekistan
Series, date of manufacture, expiry	Newly introduced series (not yet assigned)
Sample number and sampling date	No. 17, 11.08.2026
Date of receipt by the laboratory	11.08.2026
Type of testing	Contractual
Normative documents	USP <61>, USP <62>
Testing period	12.08.2026 – 19.08.2026
Environmental conditions	Temperature +22.2 °C; relative humidity 50%
Testing laboratory	Andijan branch, State Institution "Center for Safety of Pharmaceutical Products", Ministry of Health of the Republic of Uzbekistan (test protocol No. 52 of 26.08.2026)

2.2. Laboratory, equipment and environmental conditions

Testing was carried out at the Andijan branch of the State Institution "Center for Safety of Pharmaceutical Products" under the Ministry of Health of the Republic of Uzbekistan. The laboratories of the Center operate a quality management system in accordance with O'z DSt ISO/IEC 17025:2019 [17, 24]. Sample handling and aseptic manipulations were performed in accordance with the laboratory's aseptic procedures. Room temperature during testing was +22.2 °C and relative humidity was 50%. Weighing and pH measurement were performed with instruments that had valid verification certificates (Table 2), in line with general recommendations for pharmaceutical microbiology laboratories [16, 17].

Table 2.

Measuring instruments used in the study

Instrument	Serial No.	Verification certificate
Electronic balance OHAUS	B933109709	No. 01.1285653 of 14.02.2026
pH meter BANTE 210	191030-008	No. 0901265 of 18.02.2026

2.3. Sample Preparation

The test solution was prepared according to USP <61> using a 1:10 dilution of the powder [9]. However, the available test protocol does not specify the diluent or the volume used. Since the product contains an antibacterial substance, its activity needed to be neutralised to avoid interfering with microbial recovery. The protocol available to the authors does not document whether this was achieved by further dilution, the addition of a neutralising agent, or membrane filtration. This lack of information is considered a limitation of the study and is discussed in Section 4.

2.4. Enumeration of TAMC and TYMC (USP <61>)

The total aerobic microbial count (TAMC) was tested using soybean–casein digest agar (SCDA), with incubation at 30–35 °C for 3–5 days. The total yeast and mould count (TYMC) was assessed using Sabouraud dextrose agar (SDA), incubated at 20–25 °C for 5–7 days [9].

After incubation, the colonies were counted, and the results were expressed as colony-forming units per gram (CFU/g). When no colonies were recovered from the 1:10 dilution plated at 1 mL per plate, the result was reported as less than 10 CFU/g, representing a count below the lowest quantity that can be calculated level under the conditions used [9]. The culture media and incubation conditions are presented in Table 3.

Table 3.

Culture media and incubation conditions used for microbiological testing according to USP <61> and USP <62>

Test	Medium	Incubation	Purpose
TAMC	Soybean–casein digest agar	30–35 °C, 3–5 days	Enumeration of aerobic bacteria and fungi
TYMC	Sabouraud dextrose agar	20–25 °C, 5–7 days	Enumeration of yeasts and moulds

Test	Medium	Incubation	Purpose
E. coli – enrichment	Soybean–casein digest broth	30–35 °C, 18–24 h	Resuscitation and enrichment
E. coli – selection	MacConkey broth	42–44 °C, 24–48 h	Selective enrichment
E. coli – isolation	MacConkey agar	30–35 °C, 18–72 h	Isolation of lactose-positive colonies

2.5. Test for the Absence of Escherichia coli (USP <62>)

A quantity of the sample solution equivalent to 1 g of the product was added to soybean–casein digest solution, as required by USP <62>. The sample was then incubated at 30–35 °C for 18–24 hours. After mixing, 1 mL of the sample was transferred to 100 mL of MacConkey broth and incubated at 42–44 °C for 24–48 hours. The sample was subsequently streaked onto MacConkey agar and incubated at 30–35 °C for 18–72 hours [12].

The appearance of pink or red colonies on MacConkey agar was considered an indication of possible *E. coli* presence and required further identification deeper check. The product was considered to meet the pharmacopoeial requirement if no such colonies were observed or if further testing confirmed that the colonies were not *E. coli* [12].

2.6. Method Suitability and Growth Promotion

According to USP <61> and USP <62>, culture media must undergo growth-promotion testing to confirm that they support the growth of the required microorganisms. In addition, the suitability of the microbiological methods must be demonstrated in the presence of the product to ensure that its composition does not interfere with microbial recovery or detection. Reference microorganisms are used for these tests, with an inoculum of not more than 100 CFU, as specified in the relevant procedures [9, 12, 14].

For microbial enumeration, the number of microorganisms recovered in the presence of the product should not differ from the control recovery by more than a factor of two

2.7. Acceptance criteria and data treatment

Results were checked against the acceptance criteria for non-aqueous preparations for oral use given in USP <1111> and Uzbek pharmacopoeia which is same with USP: TAMC 10^3 CFU/g, TYMC 10^2 CFU/g and absence of *E. coli* in 1 g [10]. According to USP <1111>, a criterion expressed as 10^3 CFU is interpreted as a maximum acceptable count of 2000, and 10^2 CFU as a maximum of 200. Counts are presented as reported and, for graphical comparison, on a $\log_{10}$ scale. Results below the lowest quantifiable value (<10 CFU/g) were treated as censored and are shown as an upper bound ($\log_{10} = 1.0$) rather than as a measured value. The margin to the specification was calculated as $\log_{10}$(criterion) − $\log_{10}$(upper bound of the result).

The overall testing work is shown in Figure 1.

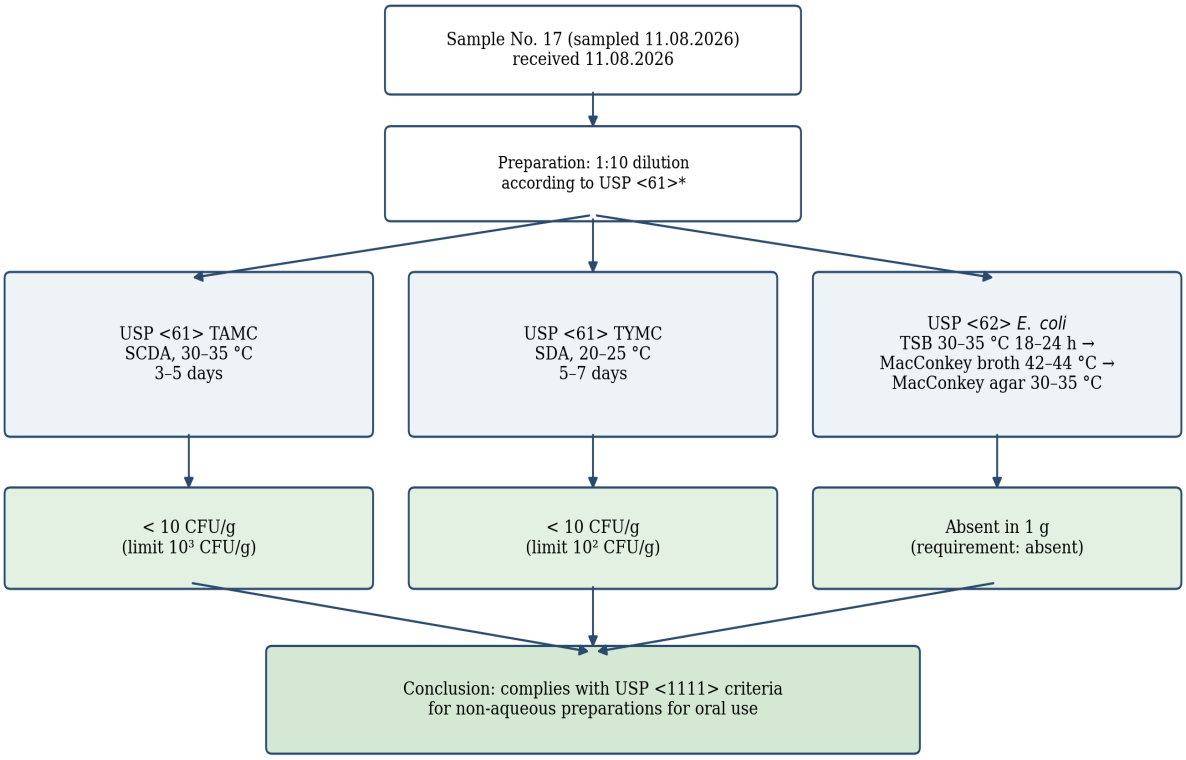


Figure 1. **Workflow of the microbiological examination of "Cipromax-AK" powder for oral suspension according to USP <61> and USP <62>, with the results obtained.**

3. Results

The results of the examination are presented in Table 5. No growth of aerobic micro-organisms that could be quantified was obtained on soybean–casein digest agar, and the TAMC was reported as less than 10 CFU/g. The TYMC on Sabouraud dextrose agar was likewise below 10 CFU/g. In the test for specified micro-organisms, *E. coli* was not found in 1 g of the product (reported as "absent" in the test protocol).

Table 5.

Microbiological quality of "Cipromax-AK" powder for oral suspension 125 mg/5 mL (sample No. 17)

Parameter	Method	Acceptance criterion (USP <1111>)	Result	Margin, $\log_{10}$	Compliance
TAMC	USP <61>	10^3 CFU/g (max. acceptable 2000)	< 10 CFU/g	≥ 2.0	Complies
TYMC	USP <61>	10^2 CFU/g (max. acceptable 200)	< 10 CFU/g	≥ 1.0	Complies
Escherichia coli	USP <62>	Absent in 1 g	Absent in 1 g	–	Complies

Figure 2 compares the results with the acceptance criteria on a logarithmic scale. Because both counts were below the lowest quantifiable value, the true contamination level is somewhere below the plotted bars; the margins given in Table 5 are therefore minimum estimates. Even under the most conservative assumption, the TAMC was at least one-hundredth of the permitted value and the TYMC at least one-tenth of it. The testing period (12–19 August 2026) covered the full incubation time required for the slowest medium (SDA, up to 7 days).

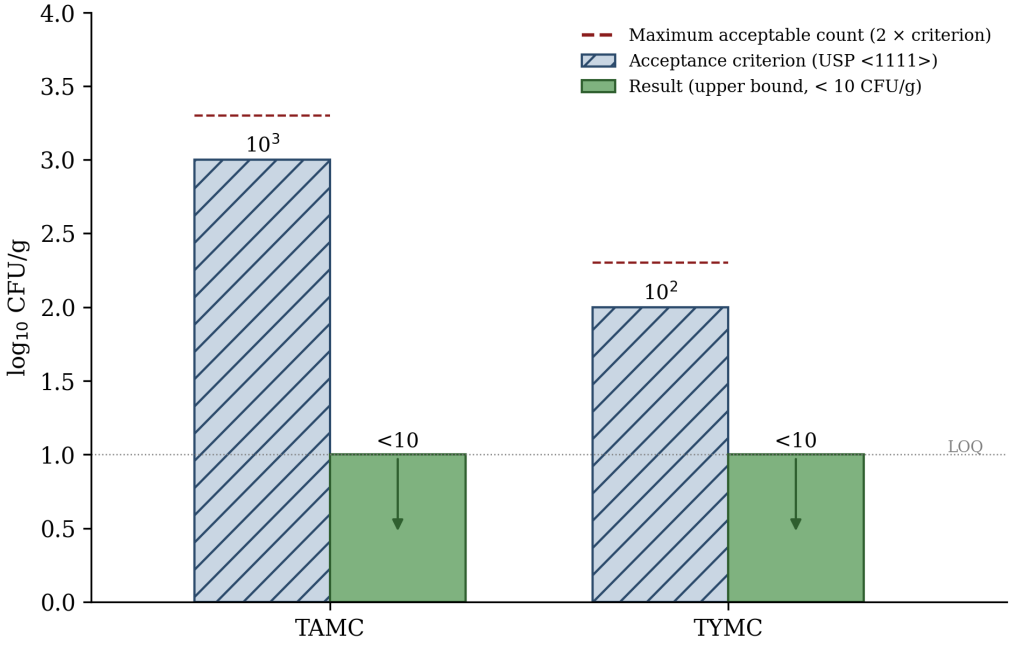


Figure 2. TAMC and TYMC results for "Cipromax-AK" compared with the USP <1111> acceptance criteria ($\log_{10}$ CFU/g). Green bars represent the upper bound of the reported results (<10 CFU/g), while arrows indicate that the actual counts fall below this level. Dashed lines show the maximum acceptable counts (twice the stated criteria). LOQ, lowest quantifiable count at the 1:10 dilution.

4. Discussion

The tested series of "Cipromax-AK" met the three microbiological acceptance criteria for non-aqueous preparations intended for oral use. Both the total aerobic microbial count and the total yeast and mould count were below 10 CFU/g. Such low counts may be expected in well-controlled dry powder formulations and are consistent with previous studies reporting generally lower microbial levels in dry and solid medicines than in liquid preparations [5–8]. One possible explanation is the low water activity of dry products. Most bacteria require a water activity above approximately 0.9 for growth, whereas some moulds can tolerate drier conditions but generally require a water activity of around 0.6 or higher. Pharmaceutical powders may have water activity levels below these values [18, 19]. However, water activity was not tested in our study, so this explanation is based on published articles rather than direct experimental evidence.

The result reported as "less than 10 CFU/g" also requires careful explanation. It does not establish that the product contained no microorganisms. Rather, it indicates that no colonies were recovered

under the test conditions and at the dilution and plating volume used. At low microbial concentrations, plate counts may be affected by sampling variability. And colony-forming units (CFU) represent organisms or groups of organisms capable of forming colonies under the specified conditions, rather than an exact count of individual microbial cells [20]. For this reason, the result was reported as below the quantifiable level instead of calculating a mean or confidence interval from a value below that level.

We should carefully consider when testing "Cipromax-AK" is the antibacterial activity of its active ingredient because this is antibiotic. Antibiotic-containing formulas can interfere with microbiological testing because the active substance definitely inhibit microbial growth even after dilution because ciprofloxacin is one of the wide ranged antibiotics. Beacause of that, microorganisms exist in the sample could not grow under the test conditions [14, 15]. Ciprofloxacin has activity against many Gram-negative bacteria, including Enterobacterales such as *Escherichia coli*. Inadequate neutralisation of its antibacterial activity could therefore affect the recovery of microorganisms and the reliability of the *E. coli* test. Unlike some β-lactam antibiotics, fluoroquinolones are not generally inactivated through the same enzyme-based neutralisation approaches. Depending on the formulation and the validated procedure, antibacterial activity may be reduced through dilution, membrane filtration followed by washing, or other suitable approaches. The use of divalent cations, including Mg^{2+}, has also been investigated in relation to quinolone activity, but any such approach would require appropriate validation for the specific test system [14, 15].

Pharmacopoeial articles addresses situations like this, in which the antimicrobial activity of a product interferes with the detection of specified microorganisms [9, 12]. But , we can not say microorganism is absent because of this interference. The suitability of the method must be assessed and the results documented according to the applicable pharmacopoeial procedure.

The interpretation of the acceptance limits also need some attention. In the laboratory protocol, the TAMC criterion was recorded as "less than 10^3 (not more than 1000) CFU/g", whereas the TYMC criterion was given as "not more than 100 CFU/g". Under the applicable USP <1111> framework, the maximum acceptable count may be expressed as twice the specified acceptance value, corresponding to 2000 CFU/g for TAMC and 200 CFU/g for TYMC [10].

Only *E. coli* was investigated as a specified microorganism in this study, in line with the stated requirement for non-aqueous preparations intended for oral use under USP <1111> [10]. However, the microbiological risks associated with a particular medicine may depend on its formula, way of administration, manufacturing process, and intended patients. Regulatory guidance recommends considering these factors when assessing the potential presence of objectionable microorganisms [2, 4]. Because "Cipromax-AK" is intended for children, other bacterias, such as *Burkholderia cepacia* complex, *Salmonella* spp., or bile-tolerant Gram-negative bacteria, are relevant to the product and it is very important to check them as well. Any additional testing should be based on a documented risk assessment and the applicable regulatory requirements.

First of all, the study examined only one sample from a newly introduced pro-

duction series. The results therefore describe the tested sample and cannot establish the microbiological quality of subsequent batches. Secondly, the microorganisms responsible for any background contamination were not identified, as the reported counts were below the quantifiable level.

5. Conclusion

The tested first production series of "Cipromax-AK" powder for oral suspension (125 mg/5 mL), manufactured by AS-KAM Pharma LLC in Uzbekistan, met the reported microbiological acceptance criteria for non-aqueous preparations intended for oral use. TAMC and TYMC were both below 10 CFU/g, corresponding to results at least 2 and 1 $\log_{10}$ units below their respective stated limits. *Escherichia coli* was not detected in 1 g of the sample-Further testing of consecutive commercial batches and the reconstituted suspension during its in-use period is recommended to provide a more comprehensive assessment of microbiological quality.

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РЕЗЮМЕ
“CIPROMAX-AK” SUSPENZIYA TAYYORLASH UCHUN KUKUNINING MIKROBIOLOGIK SIFATINI USP <61> VA USP <62> TALABLARI ASOSIDA BAHOLASH

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Kalit so‘zlar: nosteril dori vositalari; mikrobiologik tozalik; aerob mikroorganizmlarning umumiy soni; achitqi va mog‘or zamburug‘lari; *Escherichia coli*; USP <61>; USP <62>; suspenziya uchun kukun; sifat nazorati; O‘zbekiston.

Xulosa. Tekshirilgan seriya mikrobiologik sifat bo‘yicha farmakopeya talablariga mos keldi. Mahsulot antibakterial modda saqlaganligi sababli neytrallash va mikroorganizmlarni qayta ajratib olish samaradorligini tasdiqlovchi ma’lumotlar (usulning yaroqliligi) natijalar ishonchliligining zaruriy sharti hisoblanadi; keyingi tijorat seriyalarini hamda tayyorlangan suspenziyani foydalanish davomida tekshirish tavsiya etiladi.

РЕЗЮМЕ
ОЦЕНКА МИКРОБИОЛОГИЧЕСКОГО КАЧЕСТВА ПОРОШКА ДЛЯ ПРИГОТОВЛЕНИЯ СУСПЕНЗИИ ДЛЯ ПРИЁМА ВНУТРЬ «ЦИПРОМАКС-АК» В СООТВЕТСТВИИ С USP <61> И USP <62>

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Ключевые слова: нестерильные лекарственные средства; микробиологическая чистота; общее число аэробных микроорганизмов; дрожжевые и плесневые грибы; *Escherichia coli*; USP <61>; USP <62>; порошок для приготовления суспензии; контроль качества; Узбекистан

Заключение. Испытанная серия соответствует фармакопейным требованиям по микробиологической чистоте. Поскольку препарат содержит антибактериальное вещество, документально подтверждённые данные о нейтрализации и восстановлении микроорганизмов (пригодность методики) являются необходимым условием достоверности подобных результатов; рекомендуется испытание последующих промышленных серий и восстановленной суспензии в период применения.