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Impact of organoleptic properties on pediatric antibiotic compliance: a comparative study of three commonly prescribed co-amoxycloclav suspensions in India

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ABSTRACT

Background: Palatability is a crucial factor influencing adherence of medication in pediatric populations, especially for oral antibiotic suspensions. This study aimed to evaluate and compare the organoleptic properties of three co-amoxycloclav 457 mg formulations: Product A (Advent), Product B (Comparator 1) and Product C (Comparator 2) in 55 healthy school-going children aged 6 to 9 years.

Methods: Each product was administered at 15–20-minute intervals and responses were recorded using a structured questionnaire that included behavioural analysis, taste discrimination, ranking and compliance perception.

Results: Product A showed the highest acceptability, with 94.5% of children displaying favourable facial expressions and 100% accepting the product. Based on taste, 91% rated product A as excellent or good, compared to 67% for product B and 82% for product C. Additionally, 85% of participants described product A's taste as sweet, with a fruity orange aftertaste. Smell ratings were also highest for Product A, with 89% rating it excellent or good, versus 71% for product B and 73% for product C. Regarding aftertaste, 78% found product A sweet, while about 55% found products B and C sweet. Overall, 57% of children preferred product A and more than 90% assured they would complete the course if prescribed this formulation.

Conclusions: These findings highlight the importance of organoleptic properties in pediatric antibiotic formulations. By considering organoleptic properties during prescribing, healthcare providers can significantly enhance adherence, leading to improved treatment outcomes and a reduced risk of antimicrobial resistance.

Keywords: Antibiotic compliance, Co-amoxycloclav, Organoleptic properties, Pediatric adherence, Taste evaluation

INTRODUCTION

Treatment of infections in children requires strict adherence to antibiotics when warranted. Nonadherence or inadequate adherence to antimicrobial therapy can lead to treatment failure and risk of antibiotic resistance. It may also contribute to slower recovery times and increased costs to the family as well as the health care system.¹ Various factors govern the choice of antibiotics

for doctors and patient's compliance which can in turn improve adherence. The doctor's choice of antibiotic depends on the site and severity of the illness, likely causative organism as well as known allergies. Several factors influence patient's compliance like the child's age, route of administration, formulation organoleptic properties and side effects.^{2,3} The rates of medication adherence exhibited significant variability in children, ranging from 11% to 93%, with an estimated average of

approximately 50%.⁴ More than 90% of pediatricians reported that the biggest barriers for completion of treatment are drug's taste and palatability. It is well known that children reject or detest bitter flavors and favour sweet ones. Basic research has shown that children of the same genotype being more bitter sensitive than adults and the changeover occurring during mid-adolescence. Thus, there should be no surprise that parents often have difficulties convincing their kids to accept bitter medications.⁵⁻⁸

Since the taste of antibiotics is frequently mentioned as a barrier to adherence, it should be taken into account while treating common infections in children. Children are frequently prescribed oral penicillin-based antibiotics such as amoxycillin or its combination with clavulanic acid as first-line antibiotics which have an unfavorable taste and aftertaste. Parents, caregivers and prescribers need to understand that different antibiotic formulations might vary greatly in terms of taste.^{4,9,10}

Evidence from the literature suggests that antibiotics for pediatric population should be given careful considerations for taste, texture and aftertaste of the medication.⁷ With this point of view, a single-centre, non-randomized, single blinded, active controlled study was undertaken to evaluate and compare the organoleptic properties (colour, thickness, smell, taste and after taste) of three commercially available suspensions of the most commonly recommended antibiotic (co-amoxycloxacillin) in healthy school-going Indian children.

METHODS

The present study is a prospective and open labelled clinical study and has been approved by the Independent Ethics Committee (CL/138/1222/STU). The study was conducted in C.L.A.I.M.S. Pvt Ltd, Mumbai, India from 11th May 2023 to 15th May 2023. The study details were explained to parents/legal guardian of participants and were asked to go through the provided informed consent form (ICF). Any queries that arose, as well as any clarifications that were requested, were addressed by the investigator. Thereafter, signatures were obtained on the ICF.

Inclusion criteria

A total of 55 healthy participants were enrolled in the study based on specific inclusion and exclusion criteria. Eligible participants were healthy school-going children between the ages of 6 and 9 years, whose parents or legal guardians were willing to provide written informed consent (ICF).

Participants were excluded if they had any health issues requiring medication, known hypersensitivity or allergy to antibiotics (specifically the test product co-amoxycloxacillin). Participants undergoing treatment with any other antibiotics or had a clinical suspicion of infection

were also excluded from the study. Children with medical conditions contraindicating the administration of the test antibiotic product, those with known allergies to the test products, impaired taste stimulation or perception or lack of adequate communication skills were excluded from the study.

Method of administrating antibiotic (co-amoxycloxacillin) formulations

Three reconstituted antibiotic (co-amoxycloxacillin) oral suspensions commercially available in India were coded as Product A, Product B, Product C and the manufacturers label on the bottles were masked to ensure blinding. Product A (Advent 457 mg; Cipla Ltd) was the test product whereas B and C (Comparator 1 and 2, respectively) were comparator products. These preparations were given to the participants to taste at the study center. Prior to the administration of these products, they were asked to rinse their mouth by gargling plain water at normal temperature. All the three products were offered at random one after the other.

As per the instructions of a study coordinator, parents/guardians of the participants were instructed to administer 0.5-1 ml of the product; their perception regarding organoleptic properties (colour, thickness, smell, taste and aftertaste) of the formulations were recorded in the questionnaire provided. In addition to the facial expressions on tasting, behavioral analysis, discrimination and scaling test, ranking test and compliance perception test were also analyzed.

Post administering the products, participants were requested to spit out the product, gargle and rinse their mouth with water. The interval between tasting of two products was 15-20 minutes. The same procedure was repeated for the remaining products. Total dosage of products did not exceed 3 ml.

Evaluation parameters

The investigator's feedback was recorded through a Yes/No questionnaire assessing children's behavioral responses such as acceptance, refusal, resistance, disgust, vomiting, spitting or crying during and after product administration. The investigators and participants feedback were taken regarding the acceptance and organoleptic properties of the formulations (Annexure A).

The participant's feedback was taken using the questionnaire for evaluating the organoleptic of the products. The organoleptic evaluation included assessments of colour, taste, thickness/consistency, flavour, smell, after-taste and overall. The compliance perception included assessments willingness to complete the prescribed course. Discrimination and scaling tests were done considering the parameters and scoring was done as shown in Figure 1.

RESULTS

All 55 participants who enrolled in the study successfully completed it (Table 1).

For product A

The investigator-observed behavior of the participants was documented as illustrated in Table 2. According to the facial expressions observed for product A, it received acceptance from 94.5% of participants. Investigator observed that, only 1.8% of children refused product A prior to administration. However, during the administration, it was accepted by 100% children and none of the participants exhibited crying, required physical restraint or expressed resistance either prior to or during the administration of product A (Table 2). With respect to the observed expression of the participants as seen in table 3, investigator noted that immediately after administration of product A, only 9.1% of the participants voiced disgust, while none of the participants vomited, spat out or cried immediately after administration of product A (Table 3).

The participant's feedback on organoleptic properties was recorded as shown in Table 4. Based on this feedback for product A, it was favored by 100% participants. The majority of participants (85.4%) perceived it to have a sweet taste, while only 10.9% of participants claimed that the product had a bitter taste. A significant number of participants (85.4%) liked the taste of product A and 90.9% of them rated it as good to excellent. Nearly 98.2% of participants claimed that it had a flavour, with 36.3% describing the flavour as sweet (fruity orange). The flavour of product A was appreciated by 87.3% of participants and 89.1% rated the flavour as good to excellent. The smell of the product was liked by 96.3% participants, with 89.1% rating the smell as good to excellent. A majority (78.1%) of participants reported that the product had an aftertaste, describing it as sweet and fruity (orange) and only 16.3% mentioning it as bitter. All children experienced after-taste of the product within first 5 minutes of intake and 21.8% of children experienced after-taste immediately (Table 4).

For product B

Based on the facial expressions, product B received acceptance from 76.4% of participants. The investigator noted that the children exhibited no resistance towards product B before its administration. However, during the administration, 7.3% of the children refused it. None of the participants cried, required physical restraint or voiced resistance prior to or during administration of product B (Table 2). The investigator observed that, immediately following the administration of product B, 20% of the participants expressed disgust, 5.5 % of the participants vomited immediately and 7.3% spat it out immediately. Nevertheless, none of the participants cried immediately after the administration of product B (Table

3). Based on the feedback from participants regarding product B, it was liked by 100% participants, with 60% indicating that it had a sweet taste, while 34.5% claimed it had a bitter taste. Additionally, 67.3% of participants enjoyed the taste of the product, whereas 23.6% did not find the taste appealing. Furthermore, 67.2% of participants rated the taste of product B as good to excellent. A total of 94.5% of participants claimed that product B had a flavour and only 43.6% described the flavour as fruity. The flavour of the product was appreciated by 70.9% of participants and 63.6% rated the flavour as good to excellent. Moreover, 85.4% of participants liked the smell of the product, with 70.9% rating the smell as good to excellent. Additionally, 92.7% of participants reported that product B had an aftertaste, with 54.5% describing the aftertaste as sweet while many (36.3%) of the participants also experienced bitter aftertaste. All children experienced the aftertaste of the product within the first 5 minutes of consumption and 14.5% of children noted the aftertaste immediately (Table 4).



Figure 1: Five-face Likert scales presented to subjects aged 6-9 years. Left to right: Bad (1 star), Not Good (2 stars), Neither Good; Nor Bad (3 stars), Good (4 stars), Excellent (5 stars).

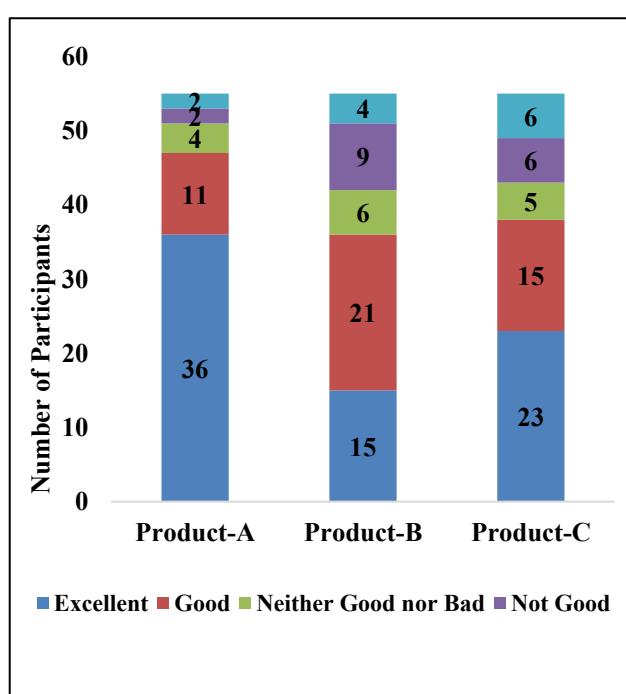
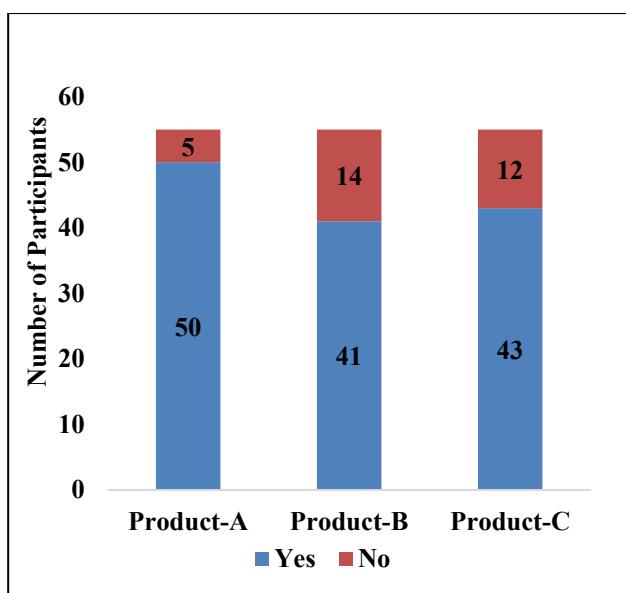


Figure 2: Participants feedback- overall ranking of products.

**Figure 3: Compliance perception test.****For product C**

According to the facial expressions observed for product C, it was accepted by 90.9% of participants. The investigator noted that the children exhibited no resistance towards product C before its administration. However, during administration it was refused by 1.8% of children. None of the participants cried, required physical restraint or voiced resistance prior to or during administration of product C (Table 2). The investigator observed that immediately after the administration of product C, 7.3% of the participants voiced disgust, 1.8%

of the participants vomited immediately and 3.6% of the participants spat out immediately. While 1.8% of the participants cried immediately after administration of product C (Table 3). Based on participant's feedback for product C, it was liked by 98.1% participants, with 85.5% finding it to have a sweet taste, while 14.5% reported a bitter taste. Almost 80% of the participants liked the taste of product, 81.8% of participants rated the taste of product C as good to excellent. Nearly 89.1% of participants claimed it had a flavour, with 45.4% describing the flavour as sweet. The flavour of the product was appreciated by 78.2% participants and 76.4% rated the flavour as good to excellent.

Additionally, 76.4% liked the smell of the product, while 72.7% rated the smell as good to excellent. Around 83.6% of participants claimed that product C had an after taste, 56.3 % of them described the after taste of product as sweet while 23.6% described it as bitter. All children experienced after-taste of the product within first 5 minutes of taking the product and 21.8% of children experienced after-taste immediately (Table 4). A comprehensive comparison between all the three products with respect to the participants' feedback on overall ranking of the products is shown in figure 2. Out of 55 participants, 85.45% of them rated product A as good to excellent, followed by product C as 69.09% and product B rated as 65.45%. Similarly, when compared on the basis of compliance perception, 90.9% of the participants agreed that they would complete the course on prescription of product A, while only 74.54% and 78.18% agreed that they will complete the course on prescription of product B and product C, respectively (Figure 3).

Table 1: Demographics of the population.

	N	%
Gender		
Male	23	41.82
Females	32	58.18
Age (in years)		
6	7	12.73
7	14	25.45
8	21	38.18
9	13	23.64
Mean	7.348 (Females)	
	8.000 (Males)	
Std deviation	0.982 (Females)	
	0.880 (Males)	

Table 2: Investigator observed behaviour.

Question	Yes or No	Product A N (%)	Product B N (%)	Product C N (%)
Facial expression indicates child accept the product	Yes	52 (94.5)	42 (76.4)	50 (90.9)
	No	3 (5.54)	13 (23.6)	5 (9.1)
Facial expression indicates child does not accept the product	Yes	3 (5.54)	13 (23.6)	5 (9.1)
	No	52 (94.5)	42 (76.4)	50 (90.9)
Child refuses product prior to	Yes	1 (1.8)	0 (0)	0 (0)

Continued.

Question	Yes or No	Product A N (%)	Product B N (%)	Product C N (%)
administration	No	54 (98.2)	55 (100)	55 (100)
Child refuses product during administration	Yes	0 (0)	4 (7.3)	1 (1.8)
	No	55 (100)	51 (92.7)	54 (98.2)
Child cries/screams prior to product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)
Child cries/screams during product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)
Child requires physical restraint prior to product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)
Child requires physical restraint during product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)
Child voice resistance prior to product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)
Child voice resistance during product administration	Yes	0 (0)	0 (0)	0 (0)
	No	55 (100)	55 (100)	55 (100)

Table 3: Investigator observed expression.

Question	Yes/No	Product A N (%)	Product B N (%)	Product C n (%)
Child voiced disgust immediately after product administration	Yes	5 (9.1)	11 (20)	4 (7.3)
	No	50 (90.9)	44 (80)	51 (92.7)
Child vomits immediately after product administration	Yes	0 (0)	3 (5.5)	1 (1.8)
	No	55 (100)	52 (94.5)	54 (98.12)
Child spit out product immediately after administration	Yes	0 (0)	4 (7.3)	2 (3.6)
	No	55 (100)	51 (92.7)	53 (96.4)
Child cries immediately after product administration	Yes	0 (0)	0 (0)	1 (1.8)
	No	55 (100)	55 (100)	54 (98.2)

Table 4: Participant's feedback.

Question	Choose one of the below-mentioned options	Product A N (%)	Product B N (%)	Product C N (%)
Rate how did you like the colour of the product	Excellent	51 (92.7)	48 (87.3)	48 (87.2)
	Good	4 (7.3)	7 (12.7)	6 (10.9)
	Neither good nor bad	0 (0)	0 (0)	1 (1.8)
	Not good	0 (0)	0 (0)	0 (0)
	Bad	0 (0)	0 (0)	0 (0)
Identify the taste of the product	Sweet	47 (85.5)	33 (60.0)	47 (85.5)
	Bitter	6 (10.9)	19 (34.5)	8 (14.5)
	Sour	1 (1.8)	3 (5.5)	0 (0)
	No taste	1 (1.8)	0 (0)	0 (0)
Did you like the taste of the product?	Yes	47 (85.5)	37 (67.3)	44 (80.0)
	Not sure	4 (7.3)	5 (9.1)	5 (9.1)
	No	4 (7.3)	13 (23.6)	6 (10.9)
Rate how did you like the taste of the product?	Excellent	40 (72.7)	24 (43.6)	34 (61.8)
	Good	10 (18.2)	13 (23.6)	11 (20.0)
	Neither good nor bad	3 (5.5)	7 (12.7)	4 (7.3)
	Not good	0 (0)	4 (7.3)	3 (5.5)
	Bad	2 (3.6)	7 (12.7)	3 (5.5)
How did you feel about the consistency of the product?	Sticks to the measuring cup	55 (100)	54 (98.2)	2 (3.6)
	Does not stick to the measuring cup	0 (0)	1 (1.8)	53 (96.4)
Do you think the product has any flavour?	Yes	54 (98.2)	52 (94.5)	49 (89.1)
	No	1 (1.8)	3 (5.5)	5 (9.1)
	Confused	0 (0)	0 (0)	1 (1.8)

Continued.

Question	Choose one of the below-mentioned options	Product A N (%)	Product B N (%)	Product C N (%)
Mention the flavour of the product	Sweet	20 (36.3)	18 (32.7)	25 (45.4)
	Fruity	14 (25.4)	24 (43.6)	17 (30.9)
	Bitter	2 (3.6)	7 (12.7)	7 (12.7)
	Other	19 (34.5)	6 (10.9)	6 (10.9)
Did you like the flavor of the product?	Yes	48 (87.3)	39 (70.9)	43 (78.2)
	Not sure	4 (7.3)	8 (14.5)	2 (3.6)
	No	3 (5.4)	8 (14.5)	10 (18.2)
Rate how did you like the flavour of the product?	Excellent	38 (69.1)	25 (45.5)	31 (56.4)
	Good	11 (20.0)	10 (18.1)	11 (20.0)
	Neither good nor bad	4 (7.3)	9 (16.4)	2 (3.6)
	Not good	0 (0)	6 (10.9)	5 (9.1)
Did you like the smell of the product?	Bad	2 (3.6)	5 (9.1)	6 (10.9)
	Yes	53 (96.34)	47 (85.4)	42 (76.4)
	Not sure	1 (1.8)	4 (7.3)	7 (12.7)
	No	1 (1.8)	4 (7.3)	6 (10.9)
Rate how did you like the smell of the product	Excellent	28 (50.9)	19 (34.5)	22 (40.0)
	Good	21 (38.2)	20 (36.4)	18 (32.7)
	Neither good nor bad	4 (7.3)	8 (14.5)	8 (14.5)
	Not good	0 (0)	6 (10.9)	4 (7.3)
Is there an after taste in the mouth after taking the product?	Bad	2 (3.6)	2 (3.6)	3 (5.5)
	Yes	54 (98.2)	51 (92.7)	46 (83.6)
	Not sure	1 (1.8)	4 (7.3)	0 (0)
Mention the after taste of the product	No	0 (0)	0 (0)	9 (16.4)
	Sweet	43 (78.1)	30 (54.5)	31 (56.3)
	Fruity	2 (3.6)	1 (1.8)	0 (0)
	Bitter	9 (16.3)	20 (36.3)	13 (23.6)
After how long you experience the after taste?	other	1 (1.8)	4 (7.2)	10 (18.1)
	Immediately	12 (21.8)	8 (14.5)	12 (21.8)
	After 5 minutes	43 (78.2)	47 (85.5)	43 (78.2)
	After 10 minutes	0 (0)	0 (0)	0 (0)
	After 15 minutes or more	0 (0)	0 (0)	0 (0)

DISCUSSION

The current research evaluated three suspensions of the antibiotic co-amoxyclovin in healthy school-aged children following a single administration. This evaluation was based on the feedback from investigators on the behavioural analyses of the participants, as well as feedback from the participants regarding the organoleptic characteristics (including colour, thickness, smell, taste and aftertaste), in addition to the overall perception and adherence to the medication. It is a first of its kind Indian study comparing the widely used antibiotic formulations in pediatric patients. This study highlighted the importance of colour, texture, flavour and after taste of an antibiotic formulation for pediatric use. These sensory characteristics are particularly important in pediatric populations, as they significantly influence the acceptability and, ultimately, adherence to antibiotic therapy. Among the three products evaluated, product A scored better in most of the parameters as compared to product B and C. Its sweet orange flavour, coupled with minimal aftertaste, emerged as a key differentiator. This

data, when correlated with the previous studies suggested that the flavour acceptance is affected by age. In general, children like flavoured fruit syrup, adults prefer a more acid taste, while many older adults find mint or wine flavours more agreeable.¹⁰ The study also showed that the colour and consistency were not influencing factors amongst the three products for children to accept them.

The frequency of antibiotic prescriptions is considerably greater in children compared to adults. Young children are recognized as the primary consumers of antibiotics and studies have consistently demonstrated that antibiotic usage is significantly elevated among younger children relative to older children. Consequently, the likelihood of developing antibacterial resistance is high in the pediatric population.¹¹⁻¹⁵ As recently discussed by Peng et al the taste of pediatric pharmaceutical products for children can negatively affect their adherence to medication. The refusal of unappealing pharmaceutical products can adversely influence therapeutic compliance, which may subsequently result in treatment failure.¹⁶ This failure can have both immediate effects (for instance, in the case of

oral liquid antimicrobials, the continuation of the disease) and potentially delayed repercussions (such as the development of antibiotic resistance).¹⁷⁻¹⁹ Literature suggests that acceptability of medicinal products has emerged as a major factor in adherence.²⁰ Palatability appeared to be a key aspect of antibiotic acceptability.² In a study examining drug administration techniques and their correlation with compliance, it was reported that over 50% of children aged 6 years or younger experienced challenges in swallowing oral drug formulations.²¹ Factors that may contribute to this issue include the size and shape of specific solid oral drug formulations, as well as, for both solids and liquids, aspects related to palatability, including taste, flavour and aroma.²²⁻²⁴

The present study aligns with the existing literature in that the participants preferred product A due to its fruity (orange) sweet flavour, which resulted in an improved overall perception, ranking and willingness to adhere to the therapy. Consequently, this enhances medication adherence and reduces the likelihood of antibiotic resistance. In another study, brand and generic suspensions were compared in a pediatric group and demonstrated that brand name liquid antibiotics do not necessarily taste better than their generic counterparts.^{25,26} In our study, a generic version of amoxycyclav oral suspension viz. product A was ranked as better overall than the brand name version.

The significance of palatability in pediatric medicine has been recognized at regulatory levels as well. A request was made to examine palatability and taste of medicines prior to granting European marketing authorization, as palatability plays a crucial role in the successful administration of a course of therapy.² Given that the majority of pediatric infectious diseases occur in low-resource settings, the palatability of pediatric formulations should be taken into account in a larger context. But most studies on palatability are not carried out in low-resource environments, the taste preferences differ greatly from one another. In pursuit of regional research on palatable antibiotic formulations, the current study done in a low resource setting country like India will help pediatricians in making informed decisions while choosing the right antibiotic formulation to ensure medical adherence in children.⁷⁻⁹

The study should be conducted with a larger population size. Since it was conducted on a smaller sample size it may limit the generalizability of the findings.

CONCLUSION

Organoleptic properties particularly flavour, taste, smell and aftertaste play a crucial role in ensuring children complete their antibiotic regimens, as palatable medications significantly improve acceptance and compliance. When antibiotics are more agreeable to a child's senses, the likelihood of full adherence increases,

thereby enhancing therapeutic outcomes and reducing the risk of antimicrobial resistance. This study highlights the importance of sensory attributes in pediatric formulations, emphasizing that poor taste is a common barrier to medication adherence. By incorporating these findings, healthcare providers can make more informed decisions when prescribing antibiotics, prioritizing formulations that are both effective and child friendly. Ultimately, this approach supports better health outcomes and contributes to the global effort to combat antibiotic resistance.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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