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RESEARCH ARTICLE

Quality Control Evaluation and *In - vitro* Equivalence of Various Brands of Marketed Azithromycin Tablets

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ABSTRACT:

Azithromycin an antimicrobial medication, and belongs to a new class of azalide antimicrobials that belongs to the macrolide group of S50 protein inhibitors. Continuous monitoring of pharmaceutical products is vital because it is important for human health, Azithromycin recently more used effectively for treatment of lower and upper respiratory tract gram-negative and may gram-positive organisms in cases of resistance to another antibiotics used for these diseases. A set of physicochemical and microbiological tests and quality control tests using the modified constitutional chromatography method to assessment Azithromycin tablets quality of various national Syrian brands and compared to reference international band (Azicip[®]), the results of these tests showed that acceptable limit so can be used safely with suitable cost. The results of tests that used for evaluation; uniformity of weight, hardness, friability, and microbial assay. Their results ranged between 651 mg to 902.5 mg, 14.91 ± 0.42 to 19.58 ± 0.43 (Kg/cm²), 0.02 to 0.5%, 94.18 to 98.32%, (mean $\pm$ S.D) respectively. All tablets disintegrated within 3.8 to 8 minutes with distilled water. The dissolution (%) in 0.1 N HCL and phosphate buffer solution pH = 6.0 at 37.0 ± 0.5 °C after 45 minutes was between 87% to 92% by using HPLC device. The results of assay were (99.4 %, 97.8 %, 98.6 %, 97.4 %) of A, B, C of local companies and D of reference company respectively, these results were acceptable according to USP Pharmacopeia limit. The validation of the analytical method was verified in which, the value of limit of detection (LOD) was 0.0933 µg/ml, the value of limit of quantification (LOQ) was 0.311 µg/ml, correlation coefficient R value was 0.9998 that indicated the linearity of applied method within the range of concentration (27.25- 132.14 %).

KEYWORDS: Azithromycin, Brand name, Drug evaluation, Quality control, National Syrian drugs.

INTRODUCTION:

Azithromycin a semisynthetic derivative of erythromycin A dihydrate, and belongs to a new class of azalide antimicrobials, it has a common macrocyclic lactone ring to which one or more sugars is attached and are all weak bases that are only slightly soluble in water.

Azithromycin is one of the best-selling antibiotics in the world. Azithromycin belongs to a broad-spectrum antimicrobial macrolide in which the most used antibacterial drugs in the United States of America based on prescription. Azithromycin is characterized by greatly enhance the antibacterial activity against gram-negative bacteria involving Enterobacteriaceae and provides wide range of gram-positive organisms compared to prototype of macrolide group of Erythromycin A¹.

Azithromycin has also been approved for use in other upper respiratory infectious processes, including acute otitis media and acute exacerbation of chronic obstructive pulmonary disease².

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Azithromycin also has permission to use against of throatitis caused by Streptococcus pathogens as an preference of choice to a β -lactam drug involving skin contents infection due to some bacterial infections such as Streptococcus pyogenes, Streptococcus agalactiae, Staphylococcus aureus infection and protected agent for patients with progressed acquired immunodeficiency syndrome in aids infection for example, and sexually transmitted infections caused by chlamydia, gonococcal infections, chancroid, and Mycoplasma genitalium^{3,4,5}. It also used in treatment of typhoid fever and trachoma⁶. Azithromycin also has activity against some sensitive protozoal infection due to Babesia sp., Toxoplasma gondii and Plasmodium sp. Azithromycin sometimes used as curative in the treatment of that parasitic disease in combination with effective antiprotozoal agents to achieve synergism activity such as atovaquone^{7,8}.

There is a valuable up-to-date interest results in the estimation of the critical of a pan-demic accusation called COVID-19, which led to a fatal effect on the world's demo-graphics, resulting in more than 3.8 million deaths worldwide⁹. The treatment of choice for this new pandemic remains unclear, so effective and safe treatments must be found recently. The study illustrated that Azithromycin was greatly assessed for its activity against COVID-19 virus, and found to be highly fasted¹⁰.

Finally, Azithromycin is additionally unapproved used as long term prophylaxis for bronchitis producing obstruction due to inflammation and fibrosis. in patients who have suffered lung transplantation¹¹.

Azithromycin is therapeutically applicable macrolide antibiotic documented in fundamental drug listing of World Health Organization. Azithromycin is most efficacious, safe and cost effective medicine to engage a key need in the wellness program system¹².

This work aims to conduct quality control and verify that the four brands of Azithromycin tablets have similar physicochemical properties and microbiological activity. Moreover, knowing that if these brands can be used as alternative safely, and the patients maybe switch from one brand to another, which is the best economically. Various Azithromycin tablets brands in Syrian drug market today make a problem of alternative generic brands for physician and the pharmacist.

Azithromycin, a broadly used antimicrobial drug, is within reach in different marketed brands, raising concerns about their quality coherence and activity. lately study provide valuable knowledgeable into the quality and coherence of various marketed brands of Azithromycin tablets, aiding wellness program Skilled

and authoritative authorities in making informed decisions regarding their prescription and regulation. In addition, it will contribute to enhancing patient safety and optimizing therapeutic outcomes¹³. In Ethiopian quality control study verifying that Azithromycin in All of the evaluated brands agreed with WHO visual inspection criteria. so that, a continuous quality assessment of the drug should be Assignment to confirm that the right medication is available on the market¹⁴.

MATERIALS AND METHODS:

Materials:

Azithromycin Azer standard sample. (*Sigma Germany*) with a purity equivalent to 99.5%, provided by the Syrian drug control laboratories in Damascus. Three generic Syrian products of 500 mg Azithromycin tablets that given A, B, C codes were taken randomly from Syrian market, and reference product coded D (Azicip[®]) produced by Cipla Company (India). HPLC water gradient (*Scharlau Chemics S.A.*, (European Union). Distilled water. Methanol for HPLC, Potassium dihydrogen phosphate, Sodium hydration from (Merrick, United States of America).

Instruments:

HPLC chromatography device (Knauer, German) equipped with a dual pump, manual injector, analytical column oven, PDA detector, and UV/VIS diode array detector.

Dissolution device (Model PT-DT70, Hyderabad, India) Stirrer Speed Adjustable within 20-250 rpm Speed, accuracy $\pm 2\%$ of set speed, typically $<1\%$, Heater Range 25 - 45°C, heater Accuracy $\pm 0.3^\circ\text{C}$ inside the water bath. Disintegration tester (JKI, Shanghai, China) temperature-controlled tanks $37^\circ\text{C} \pm 1^\circ\text{C}$, accuracy 0.5%. Friability Tester (JKI, Shanghai, China) speed accuracy $0.1 \pm \text{rpm}$

Speed /Time: fixed type, working hours: 100 rpm 4 min 25r/min. Tablet Hardness device (YPD-300D, Zhejiang, China) resolution: 0.01N, accuracy $\pm 3\%$, plus, or, minus 1 digit. Carbon Steel Vernier Caliper Micrometre (China) range: 0-150mm, accuracy 0.05 mm. Balance (model JA303p . Pioway medical, China) capacity: 310g, accuracy 0.001g. Jval Ultrasonic Cleaner (Model LUC-420, Labtech, English) capacity 20.7 L, temperature 0-50°C (digital). PH Meter (Model PH211, Hanna Instruments, China) pH accuracy ± 0.01 Mv, pH resolution 0.01mV, pH Max +16, C Max +120°.

Methods:

A set of physical and chemical tests were carried out on the studied of four brand names of azithromycin tablets, where the results of these tests were compared among themselves (local three brands), and were compared with the reference foreign brand.

The content of these brand names azithromycin drug was examined using the constitutional chromatographic method HPLC device.

Quality control tests for Azithromycin tablets:

Appearance / Visual inspection:

This test was done to ensure the quality of the tablets by examining the general appearance of Azithromycin tablets, such as odor, color, taste, biconvex. This test was done by unpacking and scanning 20 tablets for each brand¹⁵.

Thickness and Diameter:

This test was used to measurement of shape and size of Azithromycin tablets brand names, as thickness of the individual tablet was measured with a micrometer and expressed in mm. The process is done by taking 5 or 10 tablets and measuring their total thickness with a sliding caliper. thickness should be within $\pm 5\%$ of the standard range¹⁶. There are many factors that affect the tablet thickness like: tablet weight, die filling and Granules size.

Uniformity of Weight:

This test was used for film coated and uncoated tablets. To perform this test, 20 tablets are weighted randomly and the average mass is then determined. According to BP, a tablet corresponds with the test if no more than two individual weights aberration from the average weights by more than the percentage aberration as illustrate in table 1 and neither of them aberration by more than twice this percentage¹⁷. The weight uniformity test was carried out on all Azithromycin variants, and the deviation in the weight of each sample from the mean weight was calculated and compared with the allowed constitutional proportions.

Table 1.: limits of uniformity of wright

Average weight (mg)	Percentage Deviation (%)
80 or less	± 10
More than 80 and less than 250	± 7.5
250 or more	± 5

Mechanical strength test:

Hardness Test:

Ketan Disc Hardness Tester, a type of Monsanto hardness tester for evaluating hardness was used. The test device consists of a cylinder containing a compressible spring held between two pistons. The lower piston is placed in contact with the device and a zero reading is taken. The upper piston is then pushed against the spring by rotating a pin until the disc breaks. When the spring is compressed, the pointer moves along the scale in the cylinder to indicate the force. The breaking force is recorded in kilograms. The test is applied to 6 tablets¹⁶.

Friability Test:

For tablet with a unit weight of 650mg or less, a specimen of whole tablets weighing approximately 6.5g is taken. For tables with a unit weight greater than 650 mg, a specimen of 10 whole tables is taken and weighted of Azithromycin, the drum rotated 100 times at a speed of 25 ± 1 rpm for 4 minutes.

The test repeated 2x and the average of the 3 tests determined. The maximum average weight loss from the 3 samples of no more than 1.0% is acceptable for most products¹⁸.

The friability was determined by the following formula:

$$\text{Friability} = (Iw - Fw)/Iw * 100\%$$

where, Iw = Total Initial weight of tablets, Fw = Total final weight of tablets.

Disintegration Test:

According to USP, disintegration apparatus consists of 6 glass tubes that are 3 inches long, and held against a 10-mesh screen at the bottom end of the basket rack assembly. One tablet is placed in each tube of the disintegration apparatus in specified medium at 37°C. At the end of 15 minutes time limit, the tablet should disintegrate completely. If one or two tables fail to disintegrate completely, the test should be repeated to 12 additional tables. The acceptance is when not less than 16 of the totals of 18 tablets tested were disintegrated.

The disintegration test was carried out on six dose units of each studied drug formulation, where the A test was applied to the tables (diameter less than 18mm).

If 1 or 2 tables fail to disintegrate completely, repeat the test on 12 additional tablets.

The requirement was met if not less than 16 of the total of 18 tablets tested are disintegrated^{19,20}.

Dissolution Test by using HPLC:

Dissolution release profile of Azithromycin tablet was studied using in-vitro profile by using the dissolution device (pharma Test TD7, paddle type) at 100rpm in 900 ml of 0.1N HCL (pH = 6.0) and maintained at $37.0 \pm 0.5^\circ\text{C}$. The drug release acceptable if the percent of release more than 85% after 45 min.

Mobile phase: potassium Dihydrogen Phosphate buffer PH 7.3 + methanol (80:20) v/v.

A solubility study was conducted using a 500mg pharmaceutical tablet of pure drug of four brand, three local and one foreign as reference, with six duplicates. Every tablet Pharmaceutical 2ml of the solution is

withdrawn at specific time intervals of 15, 30, 45 minutes and 60 minutes, and each withdrawal is replaced with 2ml of the buffer solution. The sample is then filtered and analyzed in HPLC at a wavelength of 210nm with flow rate 1ml/min, column temperature 50°C. The water bath allows holding the temperature inside the vessel at $37 \pm 0.5^\circ\text{C}$ during the test and keeping the bath fluid in constant, smooth motion.

Dissolution releasing profiles: In this study, as model independent systems, two fit factors that compare the dissolution profiles of a pair of drug brands were performed to the dissolution data. These fit parameters directly compare the difference between percent drug dissolved per unit time for a tested and foreign product¹⁸.

Determination the concentration of Azithromycin tablet by using HPLC^{21,22}:

Mobile phase: potassium Dihydrogen Phosphate buffer PH 7.3 +methanol (80:20) v/v.

Flow rate 1ml/min, injection volume: 20 microliters (20 μl), Column RP-C18, column (4.6mm x 25cm x 5 μm), **Detector:** UV 210nm.

Analysis period/Run time 15-minute, Column temperature 50°C

System suitability parameters considered:

RSD (NMT 2%), Tailing factor (NMT 2.0), and Theoretical plate (NLT 2000).

Reverse-phase high-performance liquid chromatography (RP-HPLC) technology was used, using

A UV detector with a wavelength of 210nm. The stationary phase was column: ODS-3 reversed phase column (250mm x 4.6mm x 5 μm). A new modified method was applied and validated according to USP requirements.

Azithromycin was separated and determined using a C18 column over a 15-minute, analysis period by symmetric passage of the mobile phase consisting of a mixture of filtered and degassed phosphate buffer (4.5 grams of potassium dihydrogen orthophosphate in 1 liter of water and pH adjusted to 7.5 with sodium water) + methanol (80:20) v/v.

Prepare a standard solution of Azithromycin:

500 mg of Azithromycin determined solution was carefully weighed and completely dissolved with 80 mL of 0.1 M HCl in a clean, dry 100 mL volumetric flask and adjusted to 100 mL. standard solution with a

concentration of (5 mg/ml) was prepared, then a series of concentrations within the range of 1-5 mg/mL were prepared. And running for four brands.

Prepare the sample solution from the tablets:

Twenty tablets carrying 500mg of Azithromycin were carefully weighed and ground well with the help of a blender. The sample was homogenized, then 500mg was weighed, dissolved in 60mL of 0.1 M HCl, and placed in an ultrasonic bath for approximately 10 minutes. The sample was then filtered (No. 1 Whatman filter paper). It was transferred to a 100mL calibration balloon and the volume was adjusted with 0.1M hydrochloric acid.

Preparation of monobasic potassium phosphate buffer solution, 0.01M:

4.5grams of potassium dihydrogen orthophosphate was weighted and dissolved in 900ml of water. Adjust with 1 N sodium Hydroxide to a pH of 7.5, and dilute with water to 1liter.

Procedure of working:

A 20 μL was injected of the standard Azithromycin. The procedure repeated 5 times in a row then the peak area was recorded, the number of layers, and the resulting peaks. After that 20 μL (twice) of each solution sample was injected.

Validation Method:

The validation achievement of the tests was in accordance the recommendations of the Center for Drug Evaluation and Research (CDER).

The solution that gives the lowest response is repeated 6 times and the relative standard deviation (RSD) was calculated. The value of the relative standard deviation must not exceed 20%, which is the measurement limit = $(10 \times \text{SD})^{23}$.

Determination of Azithromycin antibacterial activity.

MEDIA PREPARATION:

30.5g of media, complete the volume to 1000ml with distil water, and dissolve by Sonicate Instrumental, then put the media solution. In autoclave to sterilization and mix the organism: Bacillus subtilis ALPHACO with media, finally distribution 25ml of mixed media with organism in each plate, then leave it to solidify.

Buffer preparation:

13.384g of dibasic potassium, 0.4184g of monobasic potassium, complete the volume to 500ml and adjust PH to 8 by phosphoric acid or KOH.

Standard solution Preparation:

High standard solution:

10.48mg of Azithromycin was dissolved in 10ml of

methanol and complete the volume to 100ml with buffer solution.

Low standard solution:

5ml of high standard solution was taken and complete the volume to 10ml with buffer solution.

Preparation of Sample solution:

High sample solution:

18.06mg, 16.6mg, 14.25mg, 13.015mg of sample A, B, C and D respectively then dissolve in 10ml of methanol and complete the volume to 100ml with buffer solution.

Low sample solution:

5ml of high sample solution was taken and complete the volume to 10ml with buffer solution.

Then under laminar flow inject 50 micrograms of; high sample solution (HT), Low sample solution (LT), High standard solution (HS), and Low standard solution (LS) on the plate and put it in Incubation 40C° to one day. Finally measure the zone by slide rule and complete the calculation to reach the percentage and compared with range of assay in ALPHA Co²⁴.

Stander equation was used to calculate percentage of activity of Azithromycin.

$$a = (HT + LT) - (HS + LS), b = (HT + HS) - (LT + LS)$$

where:

HT= high sample solution, LT= Low sample solution

HS = high standard solution, LS= Low standard solution

$$AR = a/b \times \log 2, \text{Percent}\% = \text{anti log } AR \times 100\%$$

STATISTICAL METHOD:

Statistical processing of the result by using T-test to show the difference among national Trades Azithromycin drug and among reference and national Trades Azithromycin drug if it is present, the highly significance is considerable, in which ($p \leq 0.05$)²⁵.

RESULTS AND DISCUSSION:

Appearance Tests:

Table 2. Results of the appearance test

Product	Physical description (shape and color)	Break line	Logo
A	A white tablet with a round shape	Yes	No
B	A white tablet with a round shape	Yes	No
C	A white tablet with a round shape	No	No
D	A white tablet with a round shape	yes	No

All azithromycin tablets showed acceptable appearance, in which the surface of the tablets was smooth, no cracking or chipping, staining or color change, all tablets are film coated, they had a break line in the tablets of brands A, B and D, except brand C. There were no logos or symbols on the surface of all of the manufacture's tablets.

Thickness and diameter:

The standard deviation of the thickness and diameter of tested products A , B, C, and ,D ranged from 5 ± 0.01 mm to 7 ± 0.27 mm, and 17.0 ± 0.09 mm to 19 ± 0.02 mm respectively. As a result, all of the tested brands had thickness and diameter values that were deemed to be satisfactory as they were within the acceptable range. T-test results for two independent tested products A and B, when compared with reference product D with in terms of average diameter, they showed a significance difference, product A&B were better.

While product C, showed no statistical differences compared with reference D product.

Uniformity of Weight:

Table 3. Results of the weight uniformity test.

Product	Average mass (mg)	Permissible deviation	Acceptance range(mg)
A	902.5 mg	$\pm 5\%$	(947.6-857.4)
B	828 mg	$\pm 5\%$	(869.4-786.6)
C	716 mg	$\pm 5\%$	(751.8-680.2)
D	651 mg	$\pm 5\%$	(683.5-618.4)

The deviation of the weight of each product from the average weight was calculated and compared to the constitutional permissible percentages. The constitutionally permissible deviation for the tablets was ($\pm 5\%$), as their average weight was within the range.

The results of the statistical analysis when comparing the reference product with the local product in terms of average weights, showed that a significant difference in which brand A, followed by B, and C better than reference product D.

Hardness and Friability test:

Table 4. Results of the hardness test.

Product	Hardness test (Kg/cm2) (mean $\pm$ S.D)	Friability test
A	14.91 $\pm$ 0.42	0.5%
B	19.58 $\pm$ 0.43	0.09%
C	18.69 $\pm$ 0.39	0.02%
D	15.81 $\pm$ 0.68	0.03%

Hardness and Friability study explained good mechanical resistance, brand A showed the highest percentage of loss in the friability test 0.5%, brand B, C and D showed low percentage of loss 0.09,0.02, 0.03% respectively. As a result of the statistical analysis comparing the reference product with local products in terms of hardness, showed no significance differences in the average hardness values in respect to brand A, while brands B and C showed a significant difference.

Disintegration Test:

The disintegration test was carried out on six dose units of each studied brand, the disintegration time was

calculated, no tablet exceeded the USP limit this mean not more than 30 min. The result of disintegration time for all tested products A, B, C, and D was 3.8, 8, 4, 5.5 min respectively. The results of the statistical analysis using the T-test there were a significant difference in respect to product A compared with products B, C and D. Product A was the best one in this test study followed by product C.

Dissolution results:

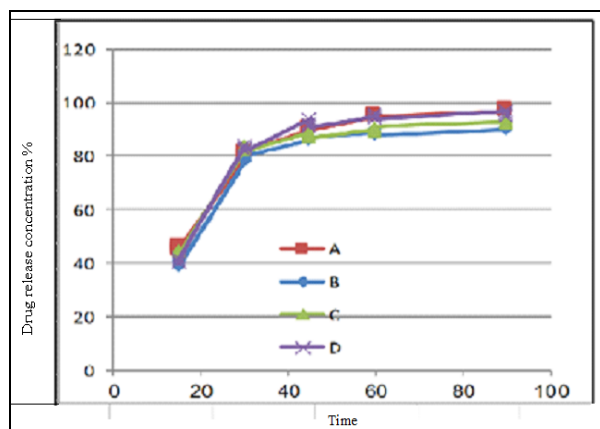


Figure 1. Dissolution profiles comparison of Azithromycin national brands names and reference brand D

The results of the statistical analysis using the T-test showed that there was no statistically significant difference between the average dissolution values at 45 minutes for products A and the reference product, but there was a statistically significant difference between the reference product when compared with products B and C. The results showed acceptable release rate of all the tablets after 45 min, greater than 85%. f1 values vary between 0-5% and f2 values it changes between 72-97%.

Drug concentration(assay) results:

The concentration of Azithromycin for each product was determined by analyzing using HPLC and drug content was calculated. The retention time for Azithromycin was 4.3 minutes, the mobile phase(methanol with potassium phosphate buffer solution at a ratio of 20:80 v/v) showed good effectiveness in separating Azithromycin in the

form of a symmetrical peak.

The results of assay were 99.4 %,97.8 %,98.6 %,97.4 % of A, B, C, D brand names respectively.

Azithromycin content of all tablets was within acceptable USP limit (90-110) %.

The results of the statistical analysis using the T-test showed that there were statistically significant differences between A, B, and C when compared with D reference Azithromycin. In which national products achieved a higher percentage level than reference product.

Validation results:

The validation of the analytical method was confirmed in which the value of limit of detection (LOD) was 0.0933 μ g/ml, the value of limit of quantification (LOQ) was 0.311 μ g/ml, correlation coefficient R value was 0.9998 that indicated the linearity of applied method within the range of concentration (27.25- 132.14%), and the value of method precision relative standard deviation (%RSD) was 0.0577 that verified the accuracy of applied method.

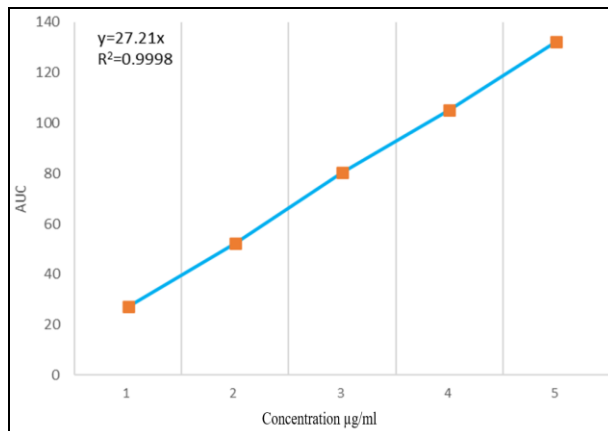


Figure 2. Plotting graph of area under the curve versus corresponding concentration

Antimicrobial activity of Azithromycin:

Table 5. The result of antimicrobial activity of four brand names.

Sample	A	B	C	D	STD
Low conc.	13.8 mm	13.9 mm	13.6 mm	14 mm	14 mm
High conc.	18 mm	17.8 mm	17.7 mm	17.5 mm	18 mm
A	-0.2	-0.3	-0.7	-0.5	
B	8.2	7.9	8.1	7.5	
AR	-0.0073422	-0.01143152	-0.02601494	-0.02006867	
anti-log AR	0.983236076	0.974021361	0.9418572	0.954841604	
Percent%	98.32	97.40	94.18	95.48	

The results showed that product A achieved highest antimicrobial activity (98.32%) followed by product B (97.40%), product C (95.48%), and product D (94.18%). All the products were accepted because of their antimicrobial activity was within the USP limit 90-110%.

CONCLUSION:

All pharmaceutical products of azithromycin tablet passed the physical and chemical quality control applied tests in this study, with some differences between the national brand products and international product. National product A tablet was the best among all the other national and reference product.

According to the statistical study of tests results that applied to each brand names separately showed similar consistency and compatibility of azithromycin products within the same pharmaceutical company, except the products B and C, their results in dissolution test by HPLC were not identical when compared with the reference product.

The statistical analysis showed a significant difference in the assay results studied analytical methods in which the national Syrian products achieved a higher percentage level than reference product.

In respect to antimicrobial testing, the results showed a difference in efficacy between the tested products at different concentrations, products A showed highest; efficacy and antimicrobial activity than the other products.

These results led to suggestion that products A and B may be superior options in certain circumstances, especially in acute infections, which required a better antimicrobial activity.

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