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A Comparative In-vitro Dissolution Profiles of Generic and Branded Amoxicillin

Profil Komparatif Disolusi In-vitro Amoksisilin Generik dan Bermerek

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ABSTRACT

There are two types of Amoxicillin in the form of tablets, generic and branded medicines. Generally, drug products undergo systemic absorption through a series of processes, including disintegration of drug products followed by drug release, dissolution of drugs in aqueous media, and absorption through cell membranes into the systemic circulation. Dissolution profiles of generic and branded Amoxicillin were used to reference the public to choose generic Amoxicillin or branded Amoxicillin. It was because branded Amoxicillin is more expensive than generic Amoxicillin. This study aims to determine the dissolution profile and physical properties of both generic and branded amoxicillin tablets produced by the same pharmaceutical manufacturer. The Measurement of physical properties was carried out with several parameters: uniformity in weight and size, fragility test (friability), and disintegration test. All the results can meet the acceptance requirements that refer Indonesian Pharmacopoeia 5th edition in 2013. The physical properties result obtained by each. The dissolution test was done using an ultraviolet spectrophotometric method; dissolution tools were typed two apparatuses at 75 rpm with aquadest for 30 minutes, 37 ± 0,5 ^{o}C. The dissolution profile of generic Amoxicillin was declared identical or similar to branded Amoxicillin. It can be seen from F1 value = 3.40 and F2 value = 67.77, each of which meets the identical category's standard. Dissolution profiles of generic and branded Amoxicillin were declared identical, which means the Amoxicillin's quality control was equally excellent.

Keywords: antibiotic, branded Amoxicillin, dissolution, generic Amoxicillin, physical properties

Introduction

Amoxicillin is a broad-spectrum group of β-lactam antibiotics used to treat infections of the airways, bile ducts and arteries, gonore, gastroenteritis, meningitis, and infections due to Salmonella sp., Such as typhoid fever. Amoxicillin is a penicillin derivative which resistant to acid but not to penicillinase. When compared to ampicillin, some benefits include better drug absorption in the gastrointestinal tract, so that blood level in plasma and arterial channels are higher, and food does not affect the absorption of drugs (Siswandono and Soekardjo, 1995).

This drug included antibiotics that were effective against both gram-positive and gram-negative bacteria in humans and animals (Kaur SP et al. 2011). Penicillin drug prevents bacterial growth by interfering with the transpeptidation reaction in the synthesis of bacterial cell walls. Each bacterial species has its own cell wall, which is a rigid outer layer. The inhibition of this reaction will stop the synthesis of peptidoglycan and kill bacteria (Katzung BG, 2007). Specifically, Amoxicillin has an excellent antimicrobial effect on microorganisms such as *Haemophilus influenzae*, *Escherichia coli*, and *Proteus mirabilis*. To prevent hydrolysis by broad-spectrum beta-lactamases present in gram-negative bacteria, this medication is usually provided with beta-lactamase inhibitors including clavulanate or sulbactam (Brunton LL et al. 2006).

The dissolution test is a crucial physical tool for determining the consistency of a drug preparation by calculating the rate at which the active substance is released and dissolved from the preparation (Banakar, 1992). Important dissolution test as a guide for developing drug formulation and product, quality control during the production process, ensuring the quality of bio-equivalent in vitro between batch and regulation of marketing of medicinal products (Allen et al. 2005). Comparative dissolution tests can be used to ascertain the medicinal product's quality and properties with minor changes in the formulation or manufacture after marketing permits.

The Indonesian National Agency of Drug and Food Control (BPOM) provided provision for comparable dissolution test, namely by looking at the value of f1 (difference) and f2 (similarity factor) between test product and comparable products (BPOM, Guideline of Bioequivalent Tes, 2004). The difference in additional materials (fillers, crushers, binders) and the production process can cause differences in the quality of amoxicillin tablet produced, namely dissolution profile. In this study, generic Amoxicillin compared to their profile was dissolved with branded Amoxicillin produced from the same company. The dissolution profile of the two drugs was measured using an ultraviolet spectrophotometry method. The expected result of Amoxicillin generic and branded have no difference

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in quality so that people can choose to consume generic or branded Amoxicillin produced at the same company. It can be seen from the parameter values f1 (difference) and f2 (similarity) between generic and branded. If it meets the requirement of f1 and f2, it can be said that the control of the quality of generic and branded Amoxicillin tablets is equally good and quality.

Amoxicillin is a water-insoluble antibiotic that can pass across cell membranes. It is graded as a Class II drug by the Biopharmaceutical Classification System (BCS) and can be evaluated for equivalence using only the dissolution test. Drugs in class II have a high absorption rate but a poor breakdown rate. In drug dissolution, in vivo, the absorption rate is limited except in very high doses. Generic dosage forms are created, regulated, and approved using in vitro dissolution testing. It can also be used to forecast how well those goods will do. Drug dissolution testing is used to determine how well drug profiles are released from pharmaceutical products (Qureshi, 2006). Comparing the reference drug and a standard drug release profile is one of the necessary pharmaceutical tests. Drug dissolution profiles, procedures, and processes must not jeopardize the product's bioequivalence.

This study aims to determine the dissolution profile and physical properties of both generic and branded amoxicillin tablets produced by the same pharmaceutical manufacturer. This research was conducted to prove that the quality of generic Amoxicillin has no different from branded Amoxicillin. The Measurement of physical properties was carried out with several parameters: uniformity in weight and size, fragility test (friability), and disintegration test. The test results for each parameter are then compared with the 5th edition of Indonesian Pharmacopoeia's acceptance requirements.

Materials and Method

Chemical, reagents, and sample

All reagents were of analytical grade. Samples were Amoxicillin generic and branded Amoxicillin tablets which were both from P.T. "X."

Instruments

The tools used were Ultraviolet-visible spectrophotometer Agilent Carry 60, Tablet Double Drum Friability Tester CS-2, BJ-3 Tablet Disintegration Test Apparatus Tester, type 2 dissolution tester DT 720 EWREKA, caliper, analytical balance, and other glassware.

Experiments

1. Test the physical properties of the tablet

Each test was performed referring to the 5th edition of the Indonesian Pharmacopoeia. Uniformity in the size test of tablets was conducted by taking 20 of each generic and branded amoxicillin tablets and measuring the tablets' diameter and thickness using the caliper, then averaged.

Weight uniformity of tablets was evaluated by weighing Amoxicillin tablets of 20 tablets were one by one,

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and at once, then the deviation of each tablet was determined. Terms of acceptability of irregularities are including (I) There should not be more than two tablets, each of which has a weight deviating from the average weight more significant than the price set in column A and (II) Not a single tablet whose weight deviates from its average weight is more than the price set in column B.

A fragility test was conducted by taking each tablet of Amoxicillin as many as 20 tablets and then cleaned, then weighed (W1 gram), then put into a tested tool. The tool was set for 4 minutes at a rotation speed of 25 rpm. The tablet was removed, then cleaned and weighed again (W2 gram)—calculated % fragility of tablets.

The disintegration test was conducted by putting aquadest into an Erlenmeyer glass, then heated to 37 ± 0,5 °C while measured using a thermometer. Taken six each generic and branded Amoxicillin tablet then put in each tube, after which each disc was inserted into each tube. The tube was inserted into an Erlenmeyer glass heated, and then the appliance was turned on. Record the time starting when the device was turned on and off when the medicine was no longer left in the basket.

2. Type 2 dissolution test

The standards solution was prepared as follows. A total of Twas weighed carefully, put in a 100 mL measuring flask, dissolved with aquadest to the mark limit (solution 1000 µg/mL). Piped 10 mL of a solution of 1000 µg/mL into a 100 mL measuring flask, diluted with aquadest to the mark limit (solution 100 µg/mL). Piped 10 mL of a 100 µg/mL solution into a 100 mL measuring flask, diluted with distilled water to the mark limit (concentration of 10 µg/mL), was obtained. The standard solution for the amoxicillin dissolution test used a single standard with three repetitions.

The dissolution test was carried out using a type 2 USP (paddle type) tool with an aquadest dissolution medium of 900 mL. Paddle rotational speed 75 rpm and medium temperature 37 ± 0,5 ˚C. Sampling was carried out at 5, 10, 20, and 30 minutes, as much as 5 mL. Each take of the solution was replaced with the same medium with the same temperature as 5 mL so that the volume remains the same. Then read the absorbance with an ultraviolet spectrophotometer at a maximum wavelength of 272 nm (Ministry of Health Indonesia, Indonesian Pharmacopeia 5th edition, 2013).

Results and Discussion

Physical properties test

The generic and branded Amoxicillin's physical appearance has no differences, including the shape, smell, taste, and color. However, there is a slight difference in the active substance content of the two. The generic

Amoxicillin contains 576 mg amoxicillin trihydrate, and the branded Amoxicillin containing 500 mg equivalent to Amoxicillin anhydrous. The description of both generic and branded Amoxicillin can be seen in Table 1. The tablet's thickness was calculated against the volume of material loaded into the mold, the mold's centerline, and the amount of pressure used by the punch to suppress the filling material. To get a uniformly thick tablet, it is necessary to monitor so that the material filled and the pressure applied remains the same (Ansel et al. l 1999). Generic and branded Amoxicillin did not fulfill the requirements of Pharmacopoeia Indonesia edition III, i.e., all products yielding tablet diameters were less than 1 1/3 times the thickness of tablet none of them exceed three times of thickness tablet, as seen in Table 2 and Table 3. However, from the data, it can be seen that the tablet diameter had a Coefficient of Variation uniformity requirement of less than 5 % so that, it can be said that every generic and branded Amoxicillin had a uniform diameter. According to statistical requirements (Ministry of Health Indonesia, Indonesian Pharmacopeia 5th edition, 2013).

Table 1. Description of generic and branded Amoxicillin

Description	Generic Amoxicillin	Branded Amoxicillin
Color	White	White
Shape	Tablet	Tablet
Smell	No smell	No smell
Contain	Amoxicillin trihydrate 576 mg is equivalent to Amoxicillin anhydrous 500 mg.	Amoxicillin trihydrate is equivalent to 500 mg of Amoxicillin anhydrous.
Expired Date	June 2018	May 2020
Price	Rp. 180.000, - (10 strips)	Rp. 49.950, - (10 strips)

Table 2. Diameter and thickness of generic Amoxicillin

No.	Diameter (mm)		Thickness (mm)	
1	6.70	6.70	5.80	5.70
2	6.75	6.75	5.70	5.65
3	6.70	6.70	5.60	5.75
4	6.70	6.70	5.60	5.80
5	6.70	6.70	5.65	5.70
6	6.70	6.75	5.80	5.55
7	6.70	6.75	5.70	5.55
8	6.70	6.75	5.75	5.55
9	6.70	6.70	5.80	5.45
10	6.70	6.75	5.65	5.65
Mean	6.72		5.68	
SD	0.02		0.09	
CV	0.003		0.016	

Table 3. Diameter and thickness of branded Amoxicillin

No.	Diameter (mm)		Thickness (mm)	
1	6.80	6.75	5.50	5.45
2	6.75	6.80	5.55	5.50
3	6.80	6.75	5.55	5.50
4	6.80	6.75	5.50	5.60
5	6.80	6.80	5.55	5.45
6	6.80	6.75	5.50	5.55
7	6.80	6.75	5.55	5.55
8	6.75	6.70	5.50	5.50
9	6.80	6.80	5.60	5.45
10	6.80	6.70	5.50	5.45
Mean	6.77		5.51	
SD	0.03		0.04	
CV	0.004		0.007	

The variation of tablet weight was influenced by the size and distribution of different granules. The poor granular flow properties will cause the amount of powder entering the compression chamber was not uniform, resulting in different tablet weights (Fonner, 1990). The uniformity of tablet weight was determined based on the amount of weight deviation on each tablet to all tablets' average weight according to the conditions specified by the Indonesian Pharmacopoeia.

The experimental results revealed that the weight of generic and branded Amoxicillin was greater than 300 mg, with a variance of no more than two tablets of average weight greater than 5 % and no single tablet whose weight deviates by more than 10 %. Each deviation of the weight of generic and branded Amoxicillin can be seen in Table 4 and Table 5. It can be concluded that generic and branded Amoxicillin had weight uniformity, which fulfills the Indonesian Pharmacopoeia 5th edition requirements.

Table 4. Weight deviation of generic Amoxicillin

No.	Tablet weight (g)	Deviation (%)	No.	Tablet weight (g)	Deviation (%)
1	0.6434	0.0130	**11**	0.6254	0.1510
2	0.6327	0.0036	**12**	0.6370	0.0031
3	0.6301	0.0077	**13**	0.6280	0.0110
4	0.6432	0.0130	**14**	0.6495	0.0228
5	0.6457	0.0169	**15**	0.6364	0.0022
6	0.6331	0.0030	**16**	0.6342	0.0012
7	0.6306	0.0070	**17**	0.6337	0.0020
8	0.6238	0.0176	**18**	0.6373	0.0036
9	0.6337	0.0020	**19**	0.6228	0.0192
10	0.6326	0.0038	**20**	0.6392	0.0066
	Average	0.6346		**CV**	0.011

Table 5. Weight deviation of Branded Amoxicillin

No.	Tablet weight (g)	Deviation (%)	No.	Tablet weight (g)	Deviation (%)
1	0.6460	0.0205	**11**	0.6373	0.0068
2	0.6277	0.0083	**12**	0.6399	0.0109
3	0.6287	0.0067	**13**	0.6335	0,0008
4	0.6307	0.0036	**14**	0.6425	0,0150
5	0.6256	0.0117	**15**	0.6312	0.0028
6	0.6347	0.0027	**16**	0.6284	0.0072
7	0.6330	0.0000	**17**	0.6417	0.0137
8	0.6313	0.0026	**18**	0.6273	0.0090
9	0.6297	0.0052	**19**	0.6279	0.0080
10	0.6300	0.0047	**20**	0.6295	0.0055
	Average	0.6328		**CV**	0.0090

The calculation results of all data obtained for generic and branded Amoxicillin branded had a coefficient of variation (CV) of less than 5 %, so it can be said that generic and branded on each product had a good weight. Branded Amoxicillin had a smaller variation value coefficient than generic Amoxicillin, which means that the product had better weight uniformity. So it can be concluded that the two types of Amoxicillin drugs fulfill the uniformity requirements of good tablet weight. The difference in tablet weight between branded and generic Amoxicillin was because each drug had different formulas, such as fillers, binders, crushers, and lubricating materials.

Fragility was expressed as the resistance of a tablet to shock during the transport and storage process. The tablet that was easily fragile and broken would lose its elegance in shape, resulting in weight differences and medication dosage uniformity. The fragility values of generic and branded Amoxicillin were 0.135 percent and 0.131 percent, respectively, and were reported to meet the fragility criterion, according to the results of the experiment in Table 6. The acceptable fragility value as the highest limit was 1 % (Banker and Anderson, 1986).

The tablet disintegration time was when the tablet needed to break into suitable media so that no part of the tablet was left on top of the gauze. Disintegration time was influenced by granules' physical-chemical properties and tablet hardness (Banker and Anderson, 1986). The disintegration of generic Amoxicillin was 5.31 minutes and the disintegration time of branded Amoxicillin was 6.08 minutes. Both drugs have fulfilled the requirements following Pharmacopoeia. Unless otherwise stated, the time taken to disintegrate the coated tablet was no more than 15 minutes and no more than 60 minutes for the sugar-coated or membrane-coated tablet (Ministry of Health Indonesia, Indonesian Pharmacopoeia 5th Edition, 2013). The smaller the time of destruction, the faster the release of the nutritious ingredient will give effect faster.

Comparative dissolution test

Two medicinal products with the same doses are called bioequivalent if the number and speed of active drugs that can reach the systemic circulation of both did not have a significant difference (Shargel and Kanfer, 2005).

Table 6. Fragility test results generic and branded Amoxicillin

Data	Generic Amoxicillin	Branded Amoxicillin
Initial Weight (g)	12,7009	12,6588
Final Weight (g)	12,6838	12,6422
Fragility (%)	0.135	0.131

The comparative dissolution test was carried out as a preliminary test to determine the formulation and fabrication process's effect on dissolution profiles in estimating bioavailability and bioequivalence between test and comparison product. The comparative dissolution test can also be used to ensure the similarity of the medicinal product's quality and properties with minor changes in the formulation or manufacture after the drug marketing permit (BPOM, Guideline of Bioequivalent Test, 2004).

In the dissolution test, a single standard solution was used with three replications. The test data for the standard solution can be seen in Table 7. The sampling of both generic and branded Amoxicillin carried out in the dissolution test is at 5, 10, 20, and 30 minutes with six replications, respectively. Drug levels for each sampling and their respective absorbances can be seen in Tables 8 and 9.

The comparative studies of generic and branded amoxicillin bioequivalence were carried out using calculation formulas (1) and (2) in the BPOM Guideline of Bioequivalent Test, with the following information: F1 is The different tolerance factor 0 - 15; F2 is The equality tolerance factor 50 - 100; R (t) is the cumulative percentage of drug dissolved at each sampling time of the comparative product (R = reference) (Amoxicillin Generic). Tt is the cumulative percentage of drug dissolved at each test product's sampling time (T = test) (Branded Amoxicillin).

$$F1 = \left\{ \frac{\sum_{i=1}^{n} |R_i - T_i|}{\sum_{i=1}^{n} R_i} \right\} \times 100 \qquad (1)$$

$$F2 = 50 \log \left[\frac{100}{\sqrt{1 + \frac{\sum_{i=1}^{n} \left[\bar{R}(t) - \bar{T}(t) \right]^2}{n}}} \right] \qquad (2)$$

The result of the comparative dissolution test on generic and branded Amoxicillin can be seen in Table 10. The Table showing the average percentage of drug solubility, in summary, are 429,62 % for generic Amoxicillin and 426,79 % for branded Amoxicillin. The value of (R - T) and $(R - T)^2$ for both generic and branded Amoxicillin are 14,63 and 92,18. Furthermore, the dissolution test's comparative results will be incorporated into the calculation formulas (1) and (2) to determine whether there are any differences in dissolution profiles of both. After being calculated, the result of F1 = 3.40 and F2 = 67.77 equation with term of acceptance F1 = 0 - 15 and acceptance requirement F2 = 50 – 100. It can be concluded that generic and branded Amoxicillin fulfill the requirement of F1 and F2 and declared similar. If F1 is getting closer to the value of 0, there is less difference in the dissolution profile of the two tablets, and if F2 is closer to the value of 100, the more similar the dissolution profile of the two tablets.

Table 7. The absorbance of Amoxicillin standard solution

Amoxicillin standard	Concentration (mg/L)	Absorbance	Rate (%)
Repeat to 1	10	0.2155	
Repeat to 2	10	0.2159	10
Repeat to 3	10	0,2157	
Average of absorbance		0,2157	

Table 8. Generic Amoxicillin levels at each sampling time

Repetition	Sampling time	Concentration (mg/L)	Absorbance	W Amoxicillin (mg)	Rate (%)
1		6.0385	0.1302	543.4650	108.69
2		5.7612	0.1243	518.5080	103.70
3	5^{th} Minute	6.5931	0.1422	593.3790	118.68
4		6.5931	0.1422	593.3790	118.68
5		6.1234	0.1321	551.1060	110.22
6		5.9989	0.1294	539.9010	107.98
1		5.6989	0.1229	512.9010	102.58
2		6.0611	0.1307	545.4990	109.10
3	10^{th} Minute	5.5857	0.1205	502.7130	100.54
4		6.1743	0.1332	555.6870	111.14
5		6.0272	0.1300	542.4480	108.49
6		6.1630	0.1329	554.6700	110.93
1		5.8291	0.1257	524.6190	104.92
2		6.1404	0.1324	552.6360	110.53
3	20^{th} Minute	5.6197	0.1212	505.7730	101.15
4		5.7668	0.1244	519.0120	103.80
5		6.0724	0.1310	546.5160	109.30
6		5.7555	0.1241	517.9950	103.60
1		5.8857	0.1270	529.7130	105.94
2		6.2818	0.1355	565.3620	113.07
3	30^{th} Minute	5.5914	0.1206	503.2260	100.65
4		5.7668	0.1244	519.0120	103.80
5		5.7895	0.1249	521.0550	104.21
6		5.8913	0.1271	530.2170	106.04

These results can be seen exactly because both Amoxicillin tablets were produced by one company. Generic and branded Amoxicillin were also expressed as having the same or equivalent of both dissolution profiles and having a good dissolution profile. It proved that the control of Amoxicillin tablets' quality was carried out well by the same factory because it produced generic drug products with similar trademark medicinal products.

The similarity or equivalence of the two curves was shown by F2 = 50 or greater (50 - 100), which means the similarities of the 2 product dissolution profiles. Suppose the product "copy" and the comparison product has a swift dissolution (> 85 % dissolves in time = 15 minutes in the media with the recommended test method). In that case, a comparison of dissolution profiles is not needed (BPOM, Guideline of Bioequivalent Test, 2004).

Table 9. Branded Amoxicillin drug levels at each sampling time

Repetition	Sampling time	Concentration (mg/L)	Absorbance	W Amoxicillin (mg)	Rate (%)
1		6.0215	0.1299	541.9350	108.39
2		5.6004	0.1208	504.0334	100.81
3	5^{th} Minute	5.3990	0.1165	485.9100	97.18
4		5.8630	0.1265	527.6700	105.53
5		4.3577	0.0940	392.1930	78.44
6		5.3594	0.1156	482.3460	96.47
1		5.9253	0.1278	533.2770	106.66
2		6.4290	0.1387	578.6100	115.72
3	10^{th} Minute	5.8065	0.1252	522.5850	104.52
4		6.4177	0.1384	577.5930	115.52
5		5.8065	0.1252	522.5850	104.52
6		5.1952	0.1121	467.5680	93.51
1		5.8183	0.1255	523.6439	104.73
2		5.6593	0.1221	509.3370	101.87
3	20^{th} Minute	5.4895	0.1184	494.0550	98.81
4		5.6480	0.1218	508.3200	101.66
5		5.4273	0.1171	488.4570	97.69
6		6.5591	0.1415	590.3190	118.06
1		6.7912	0.1465	611.2080	122.24
2		6.2309	0.1344	560.7810	112.16
3	30^{th} Minute	6.0951	0.1315	548.5590	109.71
4		6.6384	0.1432	597.4560	119.49
5		7.5985	0.1639	683.8665	136.77
6		7.4594	0.1609	671.3491	134.27

Table 10. The result of comparative dissolution test on generic and branded Amoxicillin

Sampling Time	The average percentage of drug solubility (%)		(R - T)	$(R - T)^2$
	Generic Amoxicillin	Branded Amoxicillin		
0	0	0	0	0
5	111,32	103,80	7,52	56,55
10	107,13	106, 74	0,39	0,15
20	105,55	104,73	0,82	0,67
30	105,62	111,52	5,9	34,81
Summary	429,62	426,79	14,63	92,18

The dissolution test was intended to determine the suitability of each monograph's dissolution requirements for tablet preparation. The Amoxicillin tablet dissolution test result was expressed in percent (%). The amount of dissolved Amoxicillin made a plot of the relationship with time to form a curve between the amount of dissolved content (%) as a function of time. This study was intended to determine the suitability of each monograph's dissolution requirement for tablet preparation. The stirring effect occurred evenly at each point of the dissolution medium in the container by placing the stirrer in the container's middle. The tablet was always in contact

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with the dissolution medium. During the dissolution process, the tablet will undergo a dissolution process. When contacted with the dissolution medium and the medium's movement, dissolution occurred bioequivalence gradually until the solid form of the dissolved drug was complete.

Based on Figure 1, it can be seen that the dissolution profile between generic and branded Amoxicillin produced in water media had a different dissolution profile in the 5th minutes and 30th minutes. However, in the 10th and 20th minutes, the dissolution profile was almost the same. The difference in dissolution profile in the 5th and 30th minutes was thought to be related to the influence of the formulation and manufacturing methods on each of these drugs even though they were both produced by the same company. It was also suspected because branded Amoxicillin was also nearing expiration time, which caused their solubility to be lower than generic Amoxicillin and decreased from the 5th to the 30th minutes. Amoxicillin tablet's solubility requirement has fulfilled that in 30 minutes, it must not be less than 75 % (Q) of the amount stated in etiquette (14). Generic and branded Amoxicillin tablets in the 5th to 30th minutes were above the range of 80 % (Q + 5) for six tablets/tablets to fulfill the dissolution requirement.

The comparative dissolution test was carried out as a preliminary test to determine the formulation and fabrication process's effect on dissolution profiles in estimating bioavailability and bioequivalence between test and comparison product. The comparative dissolution test can also be used to ensure the similarity of the medicinal product's quality and properties with minor changes in the formulation or manufacture after the drug marketing permit (BPOM, Guideline of Bioequivalent Test, 2004).

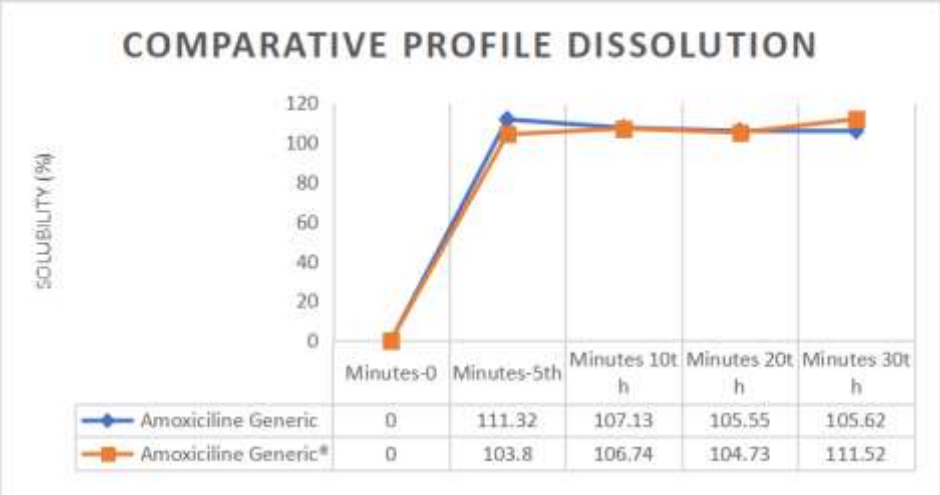

Figure 1. Profile of dissolution comparison of generic and branded Amoxicillin

Conclusion

The physical properties test result, both generic and branded Amoxicillin, can meet the acceptance requirements that refer to Indonesian Pharmacopoeia 5th edition in 2013. The dissolution profile of both generic and branded Amoxicillin was declared identical to branded generic seen from F1 value = 3.40 and F2 value = 67.77, each of which meets the standard for identical/similar categories. Dissolution of both Amoxicillin tablets had the appropriate solubility requirement.

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