*IOSR Journal Of Pharmacy*
*(e)-ISSN: 2250-3013, (p)-ISSN: 2319-4219*
*Volume 9, Issue 9 Series. I (September 2019), PP. 23-31* *www.iosrphr.org*

# Influence of Variation of Sodium Lauril Sulphate (SLS) Concentrate as Surfactant on Physical Character and Profile of Ibuprofen Tablet Dissolution

**Sholichah Rohmani[1], Siti Hanifah Fauziyyah[2]**
[1,2] *Pharmacy Department, Faculty of Mathematics and Natural Sciences, Sebelas Maret University, Indonesia*
*Corresponding Author: Sholichah Rohmani*
**Received 20 August 2019; Accepted 04 September 2019**

**Abstract:** Ibuprofen is an active substance whose solubility is practically insoluble in water so that absorption of the drug runs slowly. One way to increase the solubility of a medicinal ingredient is by the addition of surfactants, namely sodium lauryl sulfate. This research aims to improve the speed of the dissolution profile and its influence on the physical characteristics of ibuprofen tablets using SLS as a surfactant.
This research was conducted by laboratory experimental methods, using additives that function as surfactants, namely SLS with varying concentrations. Three formula designs were made, namely Formula Control 0% SLS, Formula I 1% SLS, and Formula II 2% SLS. Tablets are made by the wet granulation method. In each formula, the physical properties of granules and tablets are tested, and the dissolution tablets are tested. The results data obtained were compared with the standard literature, and the data were analyzed statistically with the one-way ANOVA variant analysis method, with a 95% confidence level, and continued with the t-LSD (Least Significant Different) test.
The results showed that increasing the SLS concentration had no influence on the uniformity test of tablet weights, hardness test of tablets, and the determination of levels. But SLS influences the tablet fragility test, the tablet disintegration time test, and the tablet dissolution test. The percentage of dissolution efficiency of ibuprofen dissolved in the 60$^{th}$ minute of Control Formula, I, and II, were 56.09%, 61.56%, and 64.48%, respectively.

**Keywords:** Tablet, Ibuprofen, Sodium Lauril Sulphate, Physical test, Dissolution test

## I. INTRODUCTION

Tablets are oral dosage forms that are widely produced and preferred by the public because the tablets have several advantages, namely the correct dosage, easy to use, relatively stable in storage, easy in transportation and distribution to consumers, and the price is relatively cheap (Banker & Anderson, 1986).

There are almost no active ingredients that can be directly compressed into tablets when making tablets. To be able to get a good tablet, then additional materials are needed in making tablets (Kumar, et al., 2014). Additional substances on tablets include fillers (diluents), binders, crushing material (desintegrants), lubricants (glidants, anti-adherents); in addition, they can be added to taste and coloring (Syamsuni, 2007).

Ibuprofen has a low melting point, poor flow properties, low bulk density, and undergoes elastic deformation during compression. The properties of ibuprofen are not suitable for direct printing because they do not have good flow and compactibility. Based on this, the research was carried out in the manufacture of tablets by the wet granulation method. The solubility of ibuprofen which is practically insoluble in water causes slow absorption of the drug. Water-insoluble materials cause wetting to become worse by particles due to interface stresses, water phases, vapor phases, and solid phases. Wetting becomes worse due to the existence of air sacs that are so small that are in solid substances that are difficult to be wetted by water media, so the drug will be difficult to dissolve (Lachman, et al., 1976).

There are several ways that can be used to increase the solubility of a drug ingredient, namely: complex formation, addition of cosolven, addition of surfactants, manipulation of solid conditions, and the formation of prodrugs (Yalkowsky, 1981). One of the surfactant materials used is sodium lauryl sulfate. Sodium lauryl sulfate is an anionic surfactant that is widely used for non-parenteral (oral and topical) pharmaceutical and cosmetic formulations. The addition of this surfactant is very useful in reducing interface tension, decreasing the contact angle, and helping move the air phase on the surface and replacing it with a liquid phase, and wetting will occur thereby increasing dissolution. Dissolution result data analysis was performed using the Dissolution Efficiency (DE) method. Sodium lauryl sulfate also has an effect on increasing the fragility of ibuprofen tablets and increasing the disintegration time of ibuprofen tablets.

Based on these descriptions, a research was conducted on the influence of variations in the concentration of sodium lauryl sulfate as a surfactant on the physical characteristics and dissolution profile of ibuprofen tablets. The purpose of this research is to increase the profile of drug dissolution and its effect on the physical characteristics of ibuprofen tablets using sodium lauryl sulfate as a surfactant.

## II. MATERIALS AND METHOD

### 1. Tools

Analytical scales (OHAUS PA224), petri dishes, 16 and 18 mesh granule sieve, single-punch tablet molding machine (TDP 1 series), oven (IL-80EN), hardness tester (Guoming YD-1), disintegration tester (Guoming BJ -2), friabilator (Guoming CS-2), dissolution tester (RC-6), UV-VIS spectrophotometer (Genesys 10S), pH meter (Lutron PH-208), stopwatch.

### 2. Materials

Ibuprofen (SHISAM MAS Chemical Pharmacy), gelatin, avicel PH 101, lactose, Mg stearate, sodium lauryl sulfate, potassium phosphate monobase, NaOH and aquades.

### 3. Ibuprofen Tablet Formulation

Three ibuprofen 200 mg tablet formulations were made with a concentration of sodium lauryl sulfate control formula (0%), Formula II (1%), and Formula III (2%). Sodium lauryl sulfate is used at concentrations of 1% and 2% because sodium lauryl sulfate acts as a surfactant in the concentration range of 0.5% - 2.5%. Tablets are made by wet granulation method with 10% gelatin binder. Ibuprofen tablet formulations can be seen in Table I below:

**Table I. Ibuprofen Tablet Formulation**

| Ingredients | Function | Formula Control | Formula I | Formula II |
|---|---|---|---|---|
| Ibuprofen | Active ingredients | 200 mg | 200 mg | 200 mg |
| Gelatin | Binder | 25 mg | 25 mg | 25 mg |
| Avicel PH 101 | Disintegrate (Intragranular) | 25 mg | 25 mg | 25 mg |
| Avicel PH 101 | Disintegrate (Extragranular) | 25 mg | 25 mg | 25 mg |
| Lactosa | Filler | 220 mg | 215 mg | 210 mg |
| Mg Stearat | Lubricant | 5 mg | 5 mg | 5 mg |
| Sodium Lauril Sulfat | Surfactant | 0 mg | 5 mg | 10 mg |
| Total | | 500 mg | 500 mg | 500 mg |

### 4. Making of gelatin solution

Gelatin was developed with aquades. For a concentration of 10% in each formula, then weighed gelatin powder in each formula of 10 grams. Then suspended with cold water. Then added with hot water to 100 mL, and stirred until homogeneous, and formed into a clear gelatin solution.

### 5. Making of ibuprofen granule

Sodium lauryl sulfate powder is dissolved in 25% alcohol as much as 1 mL. Then ibuprofen powder is mixed with a solution of sodium lauryl sulfate until it is homogeneous. Then fillers (lactose) and disintegrator (avicel PH 101) are added for intragranular addition. Then mixed until homogeneous. Next 10% gelatin solution is added little by little. Then the making of a mass of granules, until a good granule is obtained, is marked by when the mass of the granule is mixed, then broken, there is no loss of mass. Then sifted with a sieve number 16 mesh, and continued drying the granules in an oven at 40°C for 17 hours. The dried granules are sifted again with a number 18 mesh sieve in order to obtain the optimum size. After the dry granules are obtained, a disintegrator (avicel PH 101) is added for extra granular addition. Then lubricant is added (Mg stearate). Then mixed until homogeneous.

### 6. Test of physical characteristics of ibuprofen granule

6.1. Flow Time Test

A 100-gram powder mixture is put into a funnel tool, then the time of the powder or granule flow is calculated to pass through the funnel. The flow properties are said to be good if the 100 grams of powder tested has a flow time of ≤ 10 seconds (Sulaiman, 2007).

6.2. Still Angle Test

100 grams of granules are put into a still angle measuring device until full, and flattened; the lid is opened, and the granules are allowed to flow until they run out. The height of the cone and the diameter formed are measured, the still angle is calculated. The still angle test is carried out before and after the addition of the lubricant.

**7. Making of ibuprofen tablet**

Granule mixtures that have been tested for their physical characteristics are printed using a single-punch tablet press, weighing 500 mg per tablet. Compression pressure is controlled in making tablets so that the weight of each formula is the same.

**8. Physical Characteristic Test**

8.1. Weight Uniformity Test

20 tablets are weighed one by one, then the weight of each tablet is recorded. The average weight is then calculated, and the weight deviation of each tablet to the average weight. Weight uniformity requirements are met for tablets with a weight of more than 300 mg, if not more than two tablets, each weighting deviating from the average weight greater than 5% (Column A). None of the tablets deviated from the average weight of more than 10% (Column B). A good CV percentage requirement is ≤ 5% (Ministry of Health, 1979)

8.2. Hardness Test

The tablet is placed at the end of the Hardness Tester tool in a vertical position. Turn the screw at the other end so that the tablet is depressed. The playback is stopped until the tablet breaks, and the tablet pressure is read on the scale. This test is carried out using as many as five tablets in each formula.

8.3. Friability Test

A total of 20 tablets are dust-freed. All tablets are weighed on an analytical balance. Tablets are inserted into the test equipment (friabilator). The rotation speed is set at 25 rpm for four minutes. After testing, the tablets are dust-freed again, and weighed again.

8.4. Disintegration Time Test

Prepared as much as five ibuprofen tablets. Each tube in the disintegration tester is filled with one tablet. Put the basket in a beaker filled with water, artificial gastric fluid, or artificial intestinal fluid, at 37°C ± 2°C. Turn on the device to move the up-and-down basket that moves 5 to 6 cm at a frequency of 28 to 32 times per minute in liquid. Disintegration occurs perfectly if there are no particles of particles (except coatings) that remain on the sieve.

8.5. Level Uniformity Test

8.5.1. Determination of the Maximum Wavelength of Ibuprofen with 0.1N NaOH. The ibuprofen mother solution was prepared by dissolving 50-mg ibuprofen in 1000-mL 0.1N NaOH to obtain a concentration of 50 ppm. From the mother liquor, ibuprofen uptake was measured at wavelengths between 200 - 400 nm, using a UV-VIS spectrophotometer. The blank solution used is NaOH 0.1 N. Then the absorption curve for the wavelength is made.

8.5.2. Making of Ibuprofen Calibration Curve inside NaOH 0.1 N

The standard solution of ibuprofen in 0.1 N NaOH was prepared at concentrations of 4, 8, 12, 16, 20, 24 ppm. Then the absorption is determined at the maximum wavelength. The blank solution used was NaOH 0.1 N.

8.5.3. Determination of Ibuprofen Level inside Tablet

10 tablets are taken randomly, weighed, and then the average weight is determined. The ten tablets were crushed to powder. The powder is weighed as heavy as one tablet, which is equivalent to 100 mg. The powder was dissolved in 0.1 N NaOH in a 100-mL measuring flask, then filtered twice for filtering. Then piped as much as 5 mL, and put in a 25-mL volumetric flask, then added 0.1 N NaOH to the boundary mark. Next 1 mL is taken, and put in a 25-mL volumetric flask, then added 0.1 N NaOH to the boundary mark. The absorbance is observed at the maximum wavelength (222 nm) using a UV-VIS spectrophotometer. The blank solution used was NaOH 0.1 N. This test is carried out three times for replication in each formula.

**9. Dissolution Profile Test**

9.1. Making of Phosphate Buffer Solution pH 7.2

250-mL of potassium phosphate is added to 0.2 ML into a 1000-mL volumetric flask. Added a certain volume of 0.2 N NaOH of 173.5 mL. Then add aquades to the limit mark.

9.2. Determination of Maximum Wavelength of Ibuprofen with Phosphate Buffer pH 7.2

Ibuprofen mother solution is prepared by dissolving 50-mg ibuprofen in 1000-mL phosphate buffer pH 7.2 so that a concentration of 50 ppm is obtained. 5 mL of the main solution is taken, then phosphate buffer is added to pH 7.2 in 25 mL. Uptake of ibuprofen solution is measured at wavelengths between 200 - 400 nm using a UV-

VIS spectrophotometer. The blank solution used is phosphate buffer pH 7.2. Then the absorption curve for the wavelength is made.

9.3. Making of Ibuprofen Calibration Curve in Phosphate Buffer pH 7.2

The standard solution of ibuprofen in phosphate buffer pH 7.2 is made with a concentration of 4, 8, 12, 16, 20, 24 ppm. Then the absorption is determined at the maximum wavelength. The blank solution used is phosphate buffer pH 7.2.

9.4. Drug Dissolution Test

The dissolution test is carried out using the USP apparatus II model. The tablets are put into a flask containing phosphate buffer solution pH 7.2 as a medium with a temperature of 37°C. The stirring distance of the paddle from the bottom of the flask is 2.5 cm, and the paddle stirrer is rotated at a speed of 100 rpm. The volume of the medium used is 900 mL, and the volume that has been taken is replaced with new medium as much as the sample volume taken, so that the volume of the medium is always constant. Sampling is carried out at the 5th, 10th, 15th, 30th, 45th, and 60th minutes, totaling 10 mL. The sample solution is measured for absorption with a UV spectrophotometer at a wavelength of 222 nm. The blank solution used is phosphate buffer pH 7.2. Then the amount of solute is calculated at each time of collection.

## III. RESULT AND DISCUSSION

### 1. Examination Results of Granule Physical Characteristic

The examination test of the physical characteristic of granule aims to determine whether the granules produced meet the requirements of good granules, and are expected to produce good quality tablets. This examination of the physical characteristic of the granules includes tests on the flow time and still angle, where the test is carried out on the mass of the granules that have been dried. The results of the physical characteristic of ibuprofen granules can be seen in Table II.

**Table II. Test results of ibuprofen granule physical properties**

| Granule Physical Characteristic | Control Formula | Formula I | Formula II |
|---|---|---|---|
| Flow time (s) | 6,22 ± 0,04 | 5,55 ± 0,03 | 4,20 ± 0,03 |
| Still angle (º) | 29,50 ± 0,94 | 27,27 ± 0,76 | 25,39 ± 0,95 |

Information :

Control Formula : Ibuprofen granule mixture without the addition of SLS

Formula I : Ibuprofen granule mixture with the addition of SLS 1%

Formula II : Ibuprofen granule mixture with the addition of SLS 2%

1.1. Granule flow time

This test is carried out to determine the flow rate of the granules in the device during the tablet printing process. These results will influence the printing process of tablets, which will later influence the uniformity of the resulting tablet weights. That is because the flow time will influence the process of filling the compression chamber, so that the granules that have a good flow time will produce a uniform tablet weight, because the filling volume is constant. From the uniform weight of the tablet, it is also expected that the tablet also has a uniform content as well. The results of the granule flow time test from each formula have a flow time of less than 10 seconds so that it can be said to meet the requirements, i.e., a good granule flow time is if the 100-gram granules tested have a flow time of ≤ 10 seconds (Sulaiman, 2007). From the experiments, the results obtained flow time F Control > FI > FII. The difference in the flow time of the three formulas is caused by variations in SLS concentrations added to the formula. In this case, SLS functions as a lubricant. SLS at a concentration of 1% - 2% serves as a lubricant, where SLS with low concentrate can reduce surface tension, reduce adhesion force and cohesion between granule particles (Rowe, et al., 2009), thereby causing granules to flow more easily. Statistical test results show that there are significant differences in the variation of SLS concentrations in the three formulas.

1.2. Granule still angle

The still angle is the fixed angle that occurs between a cone-shaped pile of particles with a horizontal plane. This test is carried out to determine the flow properties of granules. If the still angle is ≤ 300, it indicates that the granule has good flow properties; if the still angle is ≥ 400, it has poor flow properties (Lachman, et al., 1976). This still angle is influenced by the existence of friction and attraction between particles. If the friction and tensile forces are small, the still angle is small, and the granules will flow faster (Banker & Anderson,

1986). From the still angle test, it is found that the still angle of the three formulas in a row is F Control 29.500, FI 27.270, FII 25.390, has met the requirements for the good still angle ≤ 300, so the granules have good flow characteristic, with Formula II granules being granules with the best flow characteristic. From these results it can be seen that the addition of SLS has influence on the granular still angle. The sodium lauryl sulfate functions as lubricant, so the higher the SLS concentration, the smaller the attraction between particles, so that the granules are easily spread, and the smaller the still angle formed. The statistical test results show that there are significant differences in the variation of SLS concentrations in the three formulas.

## 2. Physical Characteristic Examination Result and Tablet Dissolution Profile

2.1. Tablet physical characteristic test

The test of the physical characteristic of these tablets aims to determine whether the tablets produced meet the requirements and have good quality. The test of the physical characteristic of the tablets includes weight uniformity test, hardness test, friability test, and disintegration time test. The results of the physical characteristic of ibuprofen tablets can be seen in Table III.

**Table III. Test results on the physical characteristic of ibuprofen tablets**

| Physical characteristic of tablets | Control Formula | Formula I | Formula II |
|---|---|---|---|
| Weight Uniformity (mg) | 503,10 ± 3,35 | 501,70 ± 2,25 | 501,40 ± 1,88 |
| CV (%) | 0,67 | 0,45 | 0,37 |
| Colom A 5% | 477,96 – 528,26 | 476,62 – 526,79 | 476,33 – 526,47 |
| Colom B 10% | 452,79 – 553,41 | 451,53 – 551,87 | 451,26 – 551,54 |
| Hardness (kg) | 5,82 ± 0,20 | 5,76 ± 0,25 | 5,64 ± 0,25 |
| Friability (%) | 0,38 ± 0,06 | 0,65 ± 0,06 | 0,89 ± 0,06 |
| Disintegration (s) | 12,20 ± 0,10 | 10,42 ± 0,09 | 8,54 ± 0,06 |

2.1.1. Tablet Weight Uniformity

The weight uniformity test aims to determine the uniformity of the preparations produced after the tableting process. The weight variation of tablets is influenced by the nature of the granule flow, the density of the granules, and the condition of the equipment. The easier it is to flow a granule mixture, the better the uniformity of tablet weight (Ministry of Health, 1979). The condition for the uniformity of weight, for tablet weighing more than 300 mg is no more than two tablets, each weighting deviates from the average weight more than the price set by column A which is 5%, and no single tablet deviates from the average weight is more than the price determined by column B, which is 10% (Ministry of Health, 1979). A good tablet also has a requirement that the CV value (%) is less than 5% (Banker & Anderson, 1986). Based on the results in the table above, it can be seen that the uniformity of weights of the three formulas has met the requirements of column A and column B in accordance with the requirements stated in Pharmacopoeia Indonesia (Ministry of Health, 1979). The weight uniformity of tablets can also be seen through the value of the CV (Coefficient of Variance) from the weight uniformity data of each formula. A good tablet has a requirement that the CV value (%) is less than 5% (Banker & Anderson, 1986). So that ibuprofen tablets produced by the three formulas already meet the requirements of good uniformity of tablets with a CV value of less than 5%. According to the Ministry of Health of the Republic of Indonesia (1979), states that the uniformity of tablet weight is influenced by the nature of the granule flow in each formula. The better the flow characteristics of the granules, the better the uniformity of the weight of the tablet, thus the coefficient of variation will be smaller. The results obtained are in accordance with the theory that the formula which has the smallest coefficient of variation is formula II with a CV value of 0.37%. This is because Formula II granules have the best flow properties. Statistical test results showed that there was no effect of adding variations in SLS concentration to the uniformity of the weight of ibuprofen tablets.

2.1.2. Tablet Hardness

Tablet hardness test is carried out to determine the resistance of a tablet if it experiences mechanical stresses such as shaking, scraping, and cracking during packaging and distribution. Good tablets have a hardness of between 4 - 8 kg (Parrot, 1971). The hardness of this tablet will affect the fragility and dissolution of active tablets. The harder a tablet is, the less fragility it is, and the longer the dissolution of active tablets. While the hardness of these tablets is influenced by the concentrate of the binder used during the formulation. The greater the concentrate of the binder added, the stronger the bond between the particles, resulting in a harder tablet. In

this research, the tablet hardness was used as a controlled variable so that the of tablets hardness for the three formulas was considered the same. At the time of tableting, the compression of each formula was distinguished with the aim of equalizing the violence between the three formulas. The results of the ibuprofen tablet hardness test showed that the results were as intended, and met the tablet hardness requirements. Statistical test results showed that the addition of SLS concentration variations did not affect the hardness of ibuprofen tablets.

2.1.3. Tablet Fragility

The purpose of this ibuprofen tablet fragility test is to determine the resistance of tablets against mechanical stress, both shaking and erosion. This fragility test is related to loss of tablet weight due to abrasion that occurs on the surface of the tablet. The greater the percentage of fragility, the greater the lost tablet life. Tablet fragility also has to do with tablet violence, the greater tablet violence will usually have a small fragility. A good fragility value is < 1% (Agoes, 2006). From the results of the ibuprofen tablet fragility test, showed that the Control Formula had the smallest fragility, and Formula II had the greatest fragility, so that the successively fragility of the three formulas was F Control < FI < FII, whereas the three formulas had the fragility that met the requirements, i.e., fragility value < 1%. The results showed that the higher the SLS concentration, the greater the fragility value of the tablets. That is because the increasing concentrate of SLS, the binding capacity of the binding material, to the particles of tablet components, will be weaker, so that the tablet becomes more fragile, and more easily destroyed. Statistical test results showed that there were significant differences in the variation of SLS concentrations in the three formulas.

2.1.4. Tablet Disintegration Time

The purpose of the disintegration time test is to find out the time taken by the tablet to disintegrate into its constituent particles or granules. Disintegration time of the tablet is intended so that the components of the drug that is in the tablet can dissolve, and easily absorbed in the digestive tract. This test does not guarantee that the granule particles will release drug ingredients in solution at the proper speed (Lachman, et al., 1976). Unless stated otherwise, the disintegration time to destroy a non-coated tablet is no more than 15 minutes (Ministry of Health, 1979). Disintegration time of this tablet can be influenced by tablet hardness. The smaller the value of violence, the faster the time of disintegration. In addition, the disintegration time is also influenced by porosity, in which a small porosity can inhibit water penetration into the tablet, thereby slowing down the disintegration time. From this test, it can be seen that the Control Formula had the longest disintegration time, Formula I had the disintegration time between F Control and FII, and Formula II had the fastest disintegration time. Consequently, from Control Formula to Formula II, the results were 12.20 minutes, 10.42 minutes, and 8.54 minutes, so it can be said that the three formulas met the requirements stated in the literature. The difference in the time of disintegration of this tablet showed that there was influence of variations in the concentration of SLS given to each formula. The greater the concentrate of SLS given, the faster the time to disintegrate the tablet. In this case, SLS functioned as a wetting agent at a concentrate of 1-2%. The addition of SLS caused a decrease in the contact angle between the drug and water, so that the tablet became easily wetted, and water quickly entered the tablet, which then the tablet would become more quickly disintegrated. Statistical test results showed that there were significant differences in the variation of SLS concentrations in the three formulas.

**2.2. Test of level uniformity and tablet dissolution profile**

2.2.1. Tablet Level Uniformity

The test of level uniformity and tablet dissolution profile aims to determine whether the tablets meet the requirements for the ibuprofen level for each tablet and the dissolution of the active substance ibuprofen on the tablets.

**Table IV. The results of the test of uniformity of levels and release profile of ibuprofen tablets**

| Test | Control Formula | Formula I | Formula II |
|---|---|---|---|
| Level Uniformity (%) | 94,72 ± 0,74 | 94,93 ± 0,96 | 94,66 ± 1,36 |
| DE (60) | 56,09 ± 0,01 | 61,56 ± 0,11 | 64,47 ± 0,45 |

Determination of active substance level in ibuprofen tablets aims to ensure homogeneity of the mixture of active substances with additives. Uniformity of active substances in these tablets influence the uniformity of dosages and the safety of the use of drug preparations. The requirement of ibuprofen tablet level is not less than 90.0%, and no more than 110.0% (Ministry of Health, 1979).

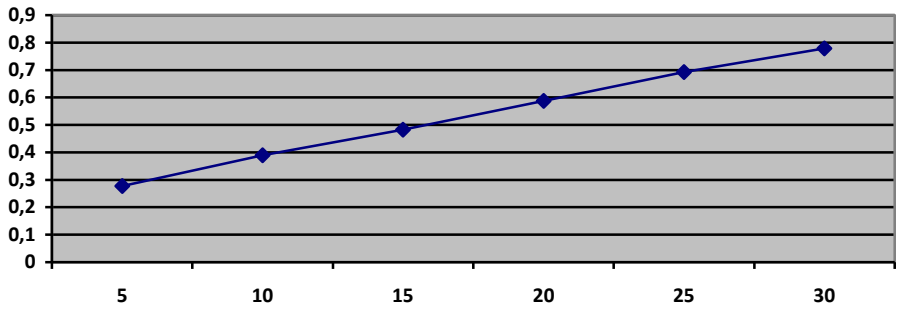
The blank solution used in the assay uniformity test is 0.1N NaOH solution. This blank solution is a solution which has the same treatment as the analyte, but does not contain the analyte component. The purpose of making a blank solution is to determine the amount of absorption by substances that are not analytes (Laksi, 2000).

2.2.1.1. Determination of Maximum Wavelength

Determination of the maximum wavelength is to get the maximum absorbance value of ibuprofen. This maximum wavelength is used to analyze the entire sample studied. The result of the maximum wavelength is 222 nm.

2.2.1.2. Determination of Ibuprofen Standard Curve

The standard curve of ibuprofen is made with concentrations of 4, 8, 12, 16, 20, 24 ppm, in NaOH 0.1 N. Each solution is measured for its absorbance at the maximum wavelength of ibuprofen which is 222 nm, and the results obtained by the value $r = 0.9996$ with the equation $y = 0.0251x + 0.1829$




**Picture 1. Ibuprofen Standard Curve in NaOH 0,1N**

2.2.1.3. Determination of Ibuprofen Level Uniformity

The determination of drug level is intended to determine the level of efficacious drugs contained in a tablet. From the test results it can be seen that the level of ibuprofen in tablets is equal to F Control 94.72%, FI 94.93%, FII 94.66%. Based on these results, it can be concluded that the three formulas have met the requirements of ibuprofen levels in tablets according to Pharmacopoeia Indonesia (Ministry of Health, 1995), namely ibuprofen level is not less than 90%, and no more than 110%. Things that influence the uniformity of this level are homogeneous mixing of active substances with additional ingredients at the time of mixing powder or granulation, the occurrence of separation of the powder mixture or granulation during the manufacturing and storage process that influences the weight of the tablet (Chemate & Priyanka, 2017). Statistical test results showed that there was no influence of adding variations in SLS concentrations to the uniformity of ibuprofen tablet levels.

2.2.2. Tablet Dissolution Profile

Dissolution is defined as the process of dissolving chemicals or drug compounds from solid preparations into a certain medium. Dissolution test is used to determine the dissolution profile of drugs in vitro. This test aims to determine compliance with the dissolution requirements stated on each monograph for tablet and capsule preparations, unless etiquette states that tablets must be chewed. In this research, the medium used was phosphate buffer pH 7.2 with a temperature of 37°C. The test instrument used was the dissolution test apparatus II USP model or paddle type, with paddle rotation speed of 100 rpm, and the time required was 60 minutes.

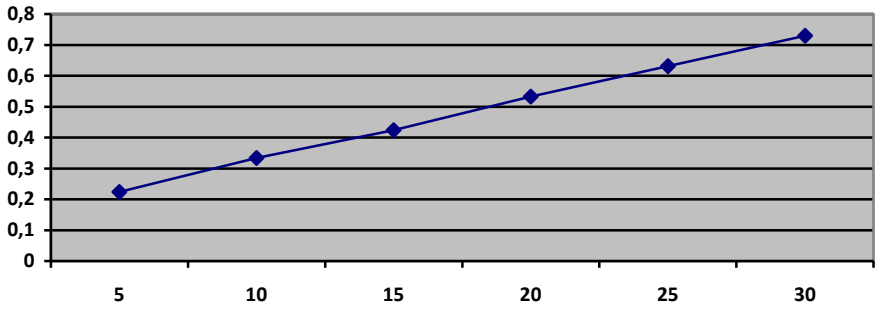
The blank solution used in the uniformity test is a phosphate buffer solution pH 7.2. This blank solution is a solution that has the same treatment as the analyte, but does not contain the analyte component. The purpose of making a blank solution is to determine the amount of absorption by substances that are not analytes (Laksi, 2000).

2.2.2.1. Determination of Maximum Wavelength

The determination of the maximum wavelength aims to get the maximum absorbance value of ibuprofen. This maximum wavelength will be used to analyze the entire sample studied. The result of the maximum wavelength is 222 nm.

2.2.2.2. Determination of Ibuprofen Standard Curve

This ibuprofen standard curve was made with a concentration of 4, 8, 12, 16, 20, and 24 ppm, in a phosphate buffer of pH 7.2. Each absorbance was measured at the maximum wavelength of ibuprofen which is 222 nm, and the results obtained $r = 0.9998$, with the equation $y = 0.0252x + 0.1263$.




**Picture 2. Ibuprofen Standard Curve in Phosphate Buffer pH 1,2**

2.2.2.3. Ibuprofen Tablet Dissolution Profile

This dissolution profile represents a drug compound from a tablet to dissolve in a certain medium. Dissolution requirements of ibuprofen tablets are: within 60 minutes, must dissolve not less than 80% C13H18O2 of the amount listed (U.S.P, 2007). Sampling is carried out at the $5^{th}$, $10^{th}$, $15^{th}$, $30^{th}$, $45^{th}$, and $60^{th}$ minutes, totaling 10 ml. The sample taken is then replaced by a new dissolution medium in the same amount, so that the volume of dissolution medium is fixed. Then the sample taken is diluted with appropriate dilution so that the absorbance can be read at a wavelength of 222 nm. Each sample is diluted 10 times. Disclosure of the results of the profile of ibuprofen release or dissolution profiles in preparations using the concept of Dissolution Efficiency ($DE_{60}$) (%). Dissolution efficiency is the area under the dissolution curve divided by the area of a rectangle that shows 100% of the solute at a given time. Control Formula is a formula without the addition of SLS in the formulation. This Control Formula is used to compare with other formulas that use SLS. The $DE_{60}$ price of this Control Formula is 56.09%. From these results it can be seen that SLS influences the speed of the dissolution profile of ibuprofen tablets where it is shown an increase in $DE_{60}$ prices. The increase in dissolution of ibuprofen can be caused by several mechanisms, among others, a decrease in the contact angle between the material and the solvent, so that the drug is relatively easy to dissolve, and a decrease in surface tension (Shargel, et al., 2005). Statistical test results showed that there were significant differences in the variation of SLS concentrations in the three formulas. The higher the concentration of SLS used, the higher the amount of $DE_{60}$ produced. The price of $DE_{60}$ in Formula I is higher compared to Control Formula. This means that the addition of SLS in 1% levels has been able to increase the speed of the dissolution profile of ibuprofen from ibuprofen tablets. Formula II, with the addition of SLS, with a concentration of 2%, has the greatest effect in increasing the speed of the profile of releasing the active substance ibuprofen in ibuprofen tablets. $DE_{60}$ price increase is due to SLS, in this case acting as a wetting agent, which causes a decrease in the contact angle between the drug and the medium, so that the drug is easily wetted, and an increase in the rate of dissolution of ibuprofen in ibuprofen tablets.

## IV. CONCLUSION

1. The addition of SLS concentrate variations on the formulation of ibuprofen tablets, namely 1% and 2% concentrates, did not influence the weight uniformity test, tablet hardness test, and content determination test. But SLS influenced the tablet fragility test, disintegration time test, and the dissolution of active substances ($DE_{60}$), whereby the higher the SLS concentrate, the more fragile the tablets, the faster the disintegration time, and the greater the dissolution profile of the active substance.
2. The best concentrate of the three formulas in this research was in the Formula II, with the addition of 2% SLS concentrate. Although it did not meet the requirements of the active substance dissolution profile, however the addition of SLS with 2% concentrate was able to increase the speed of dissolution profile of the active substance.

## REFERENCE


[1]. **Banker, F J and Anderson, R N.** *The Theory and Practice of Industrial Pharmacy.* 3. Philadelphia : Lea and Febiger, 1986.

[2]. **Kumar, S, Chowdary, K P.R and Suresh** *A COMPARATIVE EVALUATION OF DIRECT COMPRESSION AND WET GRANULATION METHODS FOR FORMULATION OF STAVUDINE TABLETS. (5)* : 3, 2014, Journal of Global Trends in Pharmaceutical Sciences, pp. 2000-2003.

[3]. **Syamsuni, H A.** *Recipe Science.* Jakarta : EGC, 2007.

[4]. **Lachman, L, Lieberman, H A and Kanig, J L.** *The theory and practice of industrial pharmacy.* Second. Philadhelpia : Washington, 1976.

[5]. **Yalkowsky, S H.** *Techniques of Solubilization of Drugs.* New York : Marcel Dekker Inc, 1981.

[6]. **Sulaiman, T N.S.** *Tablet Technology & Formulation.* Yogyakarta : Pharmacy Technology Laboratory Library, Faculty of Pharmacy, Gadjah Mada University, 2007.

[7]. **Indonesia, Ministry of Health of the Republic of.** *Indonesian Pharmacopoeia.* III. Jakarta : Ministry of Health of the Republic of Indonesia, 1979.

[8]. **Ministry of Health, Republik Indonesia.** *Indonesian Pharmacopoeia.* III. Jakarta : Ministry of Health of the Republic of Indonesia, 1979.

[9]. **Rowe, R C, Sheskey, P J and Queen, M E.** *Handbook of Pharmaceutical Exipients.* Sixth. London : The Pharmaceutical Press, 2009.

[10]. **Parrot, E L.** *Pharmaceutical Technology Fundamental Pharmaceutics.* 3. Minneapolis New York : Burgess Publishing Company, 1971.

[11]. **Agoes, G.** *Development of Pharmaceutical Products.* Bandung : ITB, 2006.

[12]. **Laksi, M.** *Basic Analytical Chemistry.* Bandung : Grafindo Media Utama, 2000.

[13]. **Ministry of Health, Republik Indonesia.** *Indonesian Pharmacopoeia.* IV. Jakarta : Ministry of Health of Republik Indonesia, 1995.

[14]. **U.S.P.** *The Natiional Formulary.* Rockville : U.S.Pharmacopeial Convention, 2007.

[15]. **Shargel, L, et al.** *Applied Biopharmaceutics and Pharmacokinetics.* 5. New York : The Mc Graw-Hill Medical Publishing Devision, 2005.

[16]. **Chemate, S Z and Priyanka, S Bothe** *.FORMULATION AND EVALUATION OF LOSARTAN POTASSIUM BI-LAYER BUCCAL TABLET USING MUCOADHESIVE POLYMER. (8):*6, 2017, International Journal Of Pharmaceutical Sciences And Research, pp. 2624-2630.


IOSR Journal of Pharmacy (IOSR-PHR) is UGC approved Journal with Sl. No. 3365, Journal No-62875

Sholichah Rohmani. "Influence of Variation of Sodium Lauril Sulphate (SLS) Concentrate as Surfactant on Physical Character and Profile of Ibuprofen Tablet Dissolution." IOSR Journal of Pharmacy (IOSRPHR), vol. 9, no. 9, 2019, pp. 23-31.