

THE CUTTING AMPOULE DESIGN INOVATION TO DEVELOP SAFETY AND HELATH PATIENT

Yuwono B Pratiknyo¹, Anita Purnamayanti²

¹ Lecture of Manufacturing Engineering, ² Lecture of pharmacy.
Universitas Surabaya

Jln Raya Kalirungkut, Surabaya, Telp/Fax: +62-31-2981258/+62-31-2981151
E-mail : yuwonobudi@ubaya.ac.id

ABSTRACT

The Sterilization process of pharmaceutical drugs in the world is important. That is absolutely necessary to prevent contamination of the drug to the effects from the outside. One of technique to keep the drug packaging sterilization is to use glass vials (glass ampoule). In the last decade Glass vials with click-open system widely used by the pharmaceutical industry to conduct drug packaging, especially in the form of Liquid. In terms of sterilization, glass ampoule was able to prevent the contamination of drugs against external influences, but from the use by health workers there are still some problems to the use of glass ampoules. Some of the problems include the possibility scratch paramedics hands when breaking ampoules head, the chances of transmitting diseases (hepatitis, HIV) and the possible presence of small pieces of glass ampoules are included in the drug when cutbacks are not perfect. This study will resolve the problem above design method that begins with identifying needs (Costumer Needs Identification), the development of concept (concept generation), the selection of concepts (concept selection), design analysis (ergonomics, engineering), prototype, prototype and improved prototype.

The result of this research is an innovative design with cutting ampoules press and broken system, where the design is attention to ergonomic aspects of the user's hands. The tool can also be used to adjust the size of the vial making it easier for health workers to conduct inject able drug delivery.

Key words: ampoule, opener, sterilization, design

1. INTRODUCTION

1.1. Background

The Comprehensive health services in Law No. 44 Year 2009 on the Hospital include efforts to improve the quality of life (promotion), prevention (preventive), healing (curative), and recovery (rehabilitative). In every health service generally involves the administration of drugs.

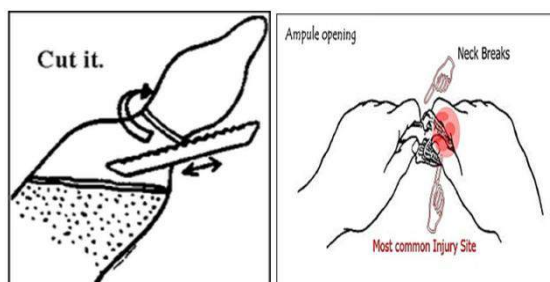


Figure 1 : (a) Process of Cutting ampoule,
(b) ampoule fracture.

One of the processes of drug delivery is through injecting drug ampoules in packs. On drug delivery with packing vials, ampoules must be cut using special saws (Figure 1 (a)) or a broken finger (Figure 1 (b)) in order to take liquid medicine in it with a syringe.

Cutting process with special saws or a broken finger is potentially hazardous and infectious HIV or hepatitis due to splashes of blood from a finger scratched. (Stoker, R, 2009). The Research in the United States of America, say that the costs related to accidents caused by sharp objects in the hospital for \$ 3000 - 9000/year. The biggest cost incurred for the initial test probability of disease, further tests and measures to address them. (Stoker R, 2008). One of the diseases is susceptible to infection of health workers, both as agents of disease transmission as well as victims who contracted the disease.

One of the most common diseases transmitted through a syringe or biological fluids such as blood is HIV / AIDS. As we know, there "iceberg phenomenon" related to HIV / AIDS, i.e. the number of cases that have been identified much less compared to the case of HIV / AIDS has not been revealed. In contrast, patients primarily in Emergency, Intensive Care Unit and the operating room was an individual susceptible to diseases due to decreased immune system for a particular disease, and the consequent reliance on aid health workers in private health maintenance efforts such as inject able drug delivery.

Ampoule cutter products currently grown using methods and materials that can be selected by the manager of the hospital, but there are still some shortcomings in terms of both technical (how to work, the pieces, the mechanism) and in terms of non-technical (availability, price). The specific objective of this study was to obtain design cutlery ampoule that suits your needs, is effective, efficient, and economical and can guarantee the safety of health care workers and patients. Based on these results, it is expected to formulate a future improvement of service standards operating procedures and control drug delivery utilizing cutting tools ampoules, as well as improving the quality of health services in general.

1.2. Ampoule

Ampoule has advantages as injecting drug packaging, which ensures sterility of the drug from germs or contaminants, and more suitable for a liquid drug that can undergo chemical change with rubber or glycerin that is often found on the packaging vial. In addition, the liquid medicine in the vial has been formulated in the correct dosage and requires no dilution or dilution. Ampoule consists of 4 main parts of the body ampoule, ampoule neck, scored points and conical top, as shown in figure 2.

The process of cutting ampoule has grown by several methods and material cutter. Ampoule cutting methods are generally divided into two methods, namely scratching (scratch) and fracture (break).

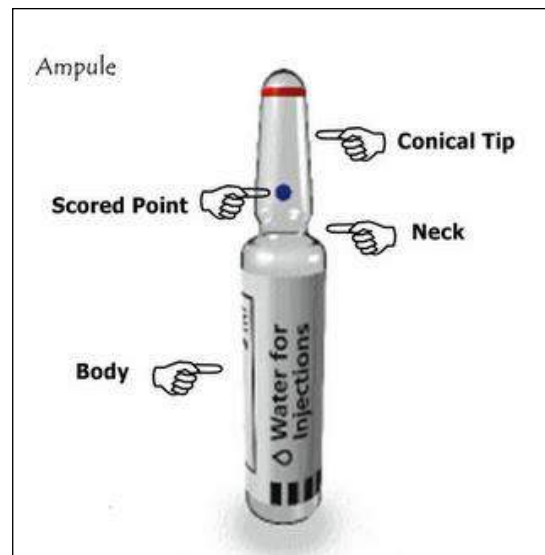


Figure 2: Part of the ampoule
Sources: <http://nursingskills-guide.blogspot.com/2010/03/ampoule.html>
Downloaded on August 30, 2012

Etching process done on glass ampoules (glass ampoule) on the neck ampoule glass ampoules for easy cut. Etching process done in general by using a special saw or a sharp knife. Etching by using a special cutter roller ampoules developed by Pro-Tech Inc., By introducing the ampoule opener multifunction products (multi functional ampoule opener) (Fig. 3).



Figure 2: Ampoule opener Pro-Tech Inc.
Sources: <http://www.protechinc.cn>
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The working principle of these products begins by etching proces part nect ampoule using a roller cutter, after scratching the glass ampoule is completed then the conical tip will be incorporated into the product (adjusts size) and do the breaking. In these products, health workers

must be careful not too deep etching process, because if the etching done too in the fine glass powder will go into ampoules and very dangerous for the patient.

In the method of breaking, breaking is done by tapping on the side of the conical tip

resulting in fracture at the neck ampoule. Some of the products developed with this system include the Break-safe ampoule opener (Figure 4 (a)), ampoule breaker (Figure 4 (b)), snap its opening glass ampoule (Figure 4 (c)), Click Open ampoule (Figure 4 (d)).

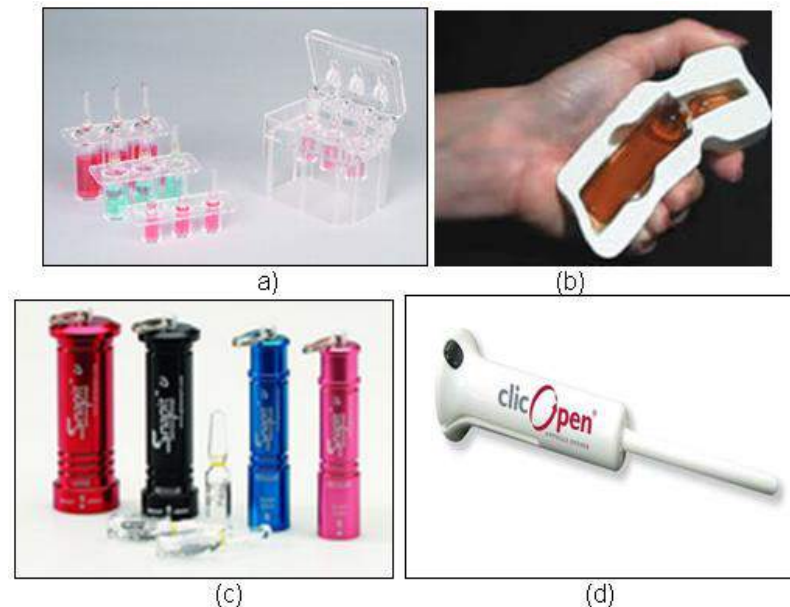


Figure 4: Example products using Fracture

Sources: <http://www.snapit.com.au/snapit/index.html>,
<http://www.emsdiasum.com/microscopy/products/preparation/general.aspx>, retrieved August 30, 2012

2. METHODOLOGY

Design methodology is necessary in designing a product in order to design a product can be arranged in a systematic way. With a design flow that has been determined, it will facilitate the process of designing a product.

Problem Identification, Problem identification can be carried out with field survey (directly observed) and interviews with health professionals and patients

Data collection, data required include: data on the ampoule, behavior study, and the study of ergonomics use vials. These data are used as the initial product specification.

Design Concept Development. Preparation of design concepts in the form of the initial sketch, the design of the shape, dimensions and mechanism. From

design concepts that have been made, the chosen one of the best design concept. The concept design was chosen to be developed further and made the design process more seriously.

Technical analysis, technical analysis performed on components that are considered critical.

Making Drafting, Drawing techniques required in the manufacturing process.

Manufacturing and Assembly Processes,

At this stage of the manufacturing process and the process selected in accordance with the design assembly.

Prototype Fabrication and Testing, testing was conducted to determine whether the results of the design is functioning properly or not. Moreover, to

know that there are deficiencies in the design if the product is used.

The design process begins by mapping and resume to problems that occur in the use of ampoules. Several issues related to customer needs identification in this case is the need for health workers, among others, are:

- The process of opening glass ampoules can be performed safely and easily.
- Able to be used for some measure of ampoules (1 ml, 2 ml, 5 ml and 10 ml).
- Tool that is used to recycle / recycle.
- Components of cutting tools ampoules secure against the effects of chemical drugs and vice versa, the component does not affect the existing liquid medications.

- From the price, the hospital management wanted the price of the tool is not expensive with a price range between Rp 5.000,00 - Rp 10.000,00

From some identification on customer needs, the next step is to develop a design concept (concept generations).

2.1. Concept Generation.

In this ampoule cutter designs, there are several development concepts used to develop product specifications that will be designed. Preparation of concept to be used is made in the morphology chart as shown in table 1. As the references selected Click Open ampoule (Figure 4 (d)).

Table 1. Morphology Chart

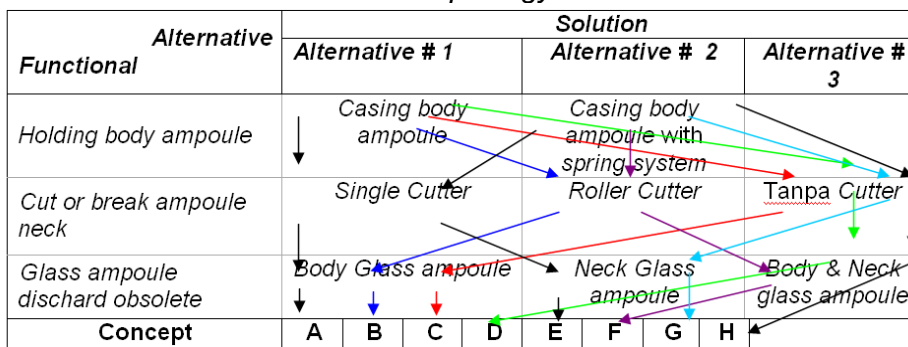


Table 2. Concept Screening

Selection criteria	Ref.	concept							
		A	B	C	D	E	F	G	H
Security for health workers	0	0	0	0	1	1	1	1	1
Ergonomic	0	-1	-1	-1	-1	-1	0	0	1
Results of ampoule neck pieces	0	1	1	1	1	1	1	1	1
Competitive price	0	-1	-1	-1	-1	-1	-1	-1	-1
Manufacturing & assembly process	0	-1	-1	-1	0	-1	0	0	0
Reliability		0	0	0	0	0	1	1	1
Contamination of drug equipment	0	-1	-1	-1	-1	-1	-1	0	0
TOTAL	0	-3	-3	-3	-1	-2	1	2	3
RANGKING	4	7	7	7	5	6	3	2	1
CONTINUED	N	N	N	N	N	N	Y	Y	Y

Table 3. Concept Screening

Selection Criteria	1	2	3	4	5	6	7	Total	Percentage
1	-	1	1	1	1	1	1	6	27,27
2	0	-	1	1	1	0	1	4	18,18
3	0	0	-	0	0	0	1	1	4,54
4	0	0	0	-	0	0	1	1	4,54
5	0	0	0	1	-	0	0	1	4,54
6	1	0	1	1	0	-	1	4	18,18
7	1	0	1	1	1	1	-	5	22,72
Total								22	100

From the morphology chart in Table 1, there are 8 concepts that can be developed in the design of cutting ampoules.

2.2. Concept screening.

The concepts that have been obtained in the process of concept generation, the next step is to filter concept (concept screening). Table 2 shows the filtering concept untuk cutlery ampoule.

In the screening process concept, distilled three concepts that will be followed up to do the assessment process further concept is Concept H, G and F.

2.3. Concept Scoring

In concept scoring, selection criteria previously set remain in use. This selection criterion will be ranked from the highest to the lowest. From this ranking, will be determined weight of each selection criteria. Table 3 shows the process of assigning weights to each of the selection criteria.

Selection criteria:

1. Security for health
2. Ergonomic
3. Results ampoule neck pieces
4. Competitive Price
5. Manufacturing and assembly process
6. Reliability
7. Contamination of drug equipment

The explanation for Table 3 above are as follows:

- a. Values 1 and 0 indicate which functions are more primary and important to be applied in the design concept. Matrix seen by rules row to column.
- b. Range is calculated by weighting the percentage scale 1-100 to produce a more accurate percentage and valid.

From the results of the above assessment, it can be seen the percentage of the weight of each concept used for further assessment of the concept. Weight that was obtained will be multiplied with the rating of the performance of a concept. The rating of the performance can be seen in table 4.

Table 4. Rate from concept Performance

Performance concerned	Rating
Very poorly compared with concept of reference	1
poorly compared with concept of reference	2
Same with concept of reference	3
Better than concept of reference	4
Very goods from concept of reference	5

After having determined the weighting and rating to rank the performance of a concept, the next step into the concept assessment phase to determine the final concept to be used. Elections for the concept that has been obtained, the three concepts can be selected by the method of scoring concept.

Table 5. Rate from concept Performance

Selection Criteria	weighting	Concept					
		F		G		H	
		Rating	Value	Rating	value	Rating	value
Security for health	27,27	4	109.4	4	109.4	4	109.4
Ergonomic	18,18	2	36.36	3	54.54	4	72.72
Results ampoule neck pieces	4,54	4	18.16	4	18.16	4	18.16
Competitive price	4,54	2	9.08	2	9.08	2	9.08
Manufacturing & assembly process	4,54	2	9.08	3	13.62	3	13.62
Reliability	18,18	3	54.54	4	72.72	4	72.72
Contamination of drug equipment	22,72	2	45.44	2	45.44	3	68.16
Total Value		282.06		322.96		363.86	
Rating		3		2		1	
Develop?		no		no		yes	

From the assessment matrix concept, we can see that the concept of H has the highest total value. Thus, the concept of H are selected concepts and will do the manufacturing and assembly process. H concept sketches can be explained in Figure 5.

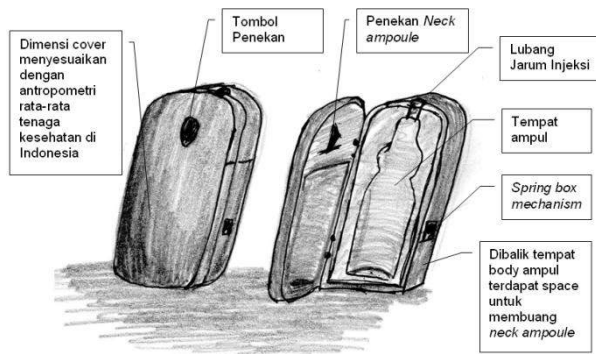


Figure 5: Selected Concept

5. CONCLUSION

Comprehensive health services in Law No. 44 year 2009 should be pursued and followed up significantly in order to improve the quality of services in Indonesia. Synergy engineering technology to the world of pharmacy and medicine need to be improved to create improved facilities and infrastructure pharmaceutical and medical world. Ampoule cutter design is expected to help much in charge of health care while maintaining the safety and security of health workers and patients. The end result of this research is the design of cutting ampoules safe and easy to use, can be cut ampoules with some variations in size, made of safe materials to the effects of chemical drugs and did not have any effect / risk for drug use. As well as in terms of the price, this product is more expensive than similar products

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AUTHOR BIOGRAPHIES

Yuwono B Pratiknyo is a lecturer in Department of Manufacturing Engineering, Faculty of Engineering, Universitas Surabaya. He received his Master of Engineering from Institut Technology Bandung in 2008. Her research interests are in the area of Engineering design and Design Product. She is a member of the manufacturing Engineering, as a Head of department.