Validation of vacuum consistency of the internal evacuated blood collection tube (BCT)
Muhammad Alif Inam Mohd Asri¹, Mohd Nasri Ishak², Amalina Amir¹,*

¹) School of Mechanical Engineering, College of Engineering, Universiti Teknologi MARA, 40450 Shah Alam, Selangor, Malaysia
²) Selia-Tek Medical, Selia-Tek Holdings Sdn. Bhd, Lot 18, Jalan Teknologi 3/5, Taman Sains Selangor, Kota Damansara, 47810, Selangor, Malaysia

*Corresponding e-mail: amalina.amir@uitm.edu.my

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ABSTRACT – Evacuated blood collection tube (BCT) or also known as Vacutainer® is a device that commonly being used in medical industry for pharmaceutical purposes. It is a device to evacuate blood for research and data analysis for curing and medication. BCT consist of two types, the one with hemogard closure and the other one is regular closure. Hemogard consist with plastic cover upon the rubber stopper. Meanwhile, BCT consist of three (3) components which is transparent tube, rubber stopper, and hemogard closure, also with content of negative pressure (vacuum mechanism) within it. Study of vacuum on BCT has become interest in many researchers about its consistency due to affected by its surrounding condition. In this research, impact of storage temperature will be studied to identify the effect of vacuum content within BCT, to investigate the problem and seek proper (surrounding) placement for these BCT. As a result, it should develop with a new benchmark vacuum volume (negative pressure) inside BCT aiming to obtain the standardise figure. This BCT should be placed under temperature condition between 4°C to 25°C as suggested by BD-Vacutainer® company and under certified humidity condition are ranged between 40% to 60%. It is to ensure the pharmaceutical device which is sterile and consist of shelf life does not deplete its properties drastically and sustain its life span as recommended in technical data sheet.

1. INTRODUCTION

In the industry of medication, treatment and curing have change their approach proportionally to illness and disease from ancient times to the present. By using blood of a patient, medical department can diagnose its symptom and illness that is fused with the patient. Blood consists with varies of information and data content of a particular person [1]. As such, blood needs to be evacuated from the body of an organism to a container and proceeded with a laboratory testing. This process is known as phlebotomy where the vein of a person is cut aiming to acquire blood or might be used for further treatment if requisite. Since the current legalisation being practice, the use of glass on such medical instrument and appliance starts to be abolish due it is freely ‘in-contact’ with human skin for evacuation purposes [2]. This is to overcome the case of accident or unwanted incident to be happened such as transmission of HIV/viruses due to container breakage/leak which may contact to the patient. As a result, polymer based being used since in 1990’s as to produce all the medical appliances that only in contact with patient for medication purposes [2]. The common product for blood evacuation is known to be syringe, vials and blood collection tube or regularly called as Vacutainer®.

However, plastic tubes have hydrophobic surfaces that interfere with the coagulation process. Clots formed on the surfaces of plastic BCTs are more gelatinous when compared to those formed in glass tubes. Furthermore, blood does not flow smoothly over hydrophobic plastic surfaces, which can result in the adherence of platelets, fibrin, or clotted[3]. Alternatively, the interior plastic tube wall surface can be coated via spraying, dipping, filling and aspirating, brushing, wiping with surfactants (SFs), water-soluble polymers (e.g., hydrogels), or hydrophilic–hydrophobic block copolymers[3]. SFs have the potential for desorption (leaching). Recently, Samuel Kim at all (2015) explained a chemical treatment process of the interior wall surface of plastic Polyethylene Terephthalate (PET) tubes via a transesterification reaction with polyols (e.g., ethylene glycol), catalysed by a guanidine base, to produce chemically modified PET (chmoPET) tubes and contain no problematic SFs [4].

Most common shelf life for a polymer base BCT are known to be minimal time of more than 12 month [5] compared to glass base BCT generally limited by the shelf life of the additive due to the minimal losses of vacuum and water vapor, over time [2]. Blood collection tube fill with blood automatically due there is a vacuum (negative pressure) within these tubes. The vacuum within evacuated tube is created artificially by pull out air from the tube. Amount of vacuum pull by manufacture from the Vacutainer® are based on the size and label on the BCT [6]. The existence of vacuum in a BCT is part and parcel requirement for medical purposes which mainly used for blood evacuation.

The amount of vacuum being produce are commonly refer to the size of the tube which can be categorise under its measurement with diameter of 13mm to 16 mm alongside with height of 100mm and 75 mm. Also, there are two types of BCT which is Hemogard and Regular [7]. There is usage for adult, paediatric and fingerstick which hold 3 to 10 ml of blood, 2 to 4 ml and one-half ml, respectively [6]. Thus, this research focuses on verify and validate the consistency of vacuum inside the Vacutainer® with hemogard (plastic/polymer material). At present, there is no such a benchmark validate the vacuum pressure or vacuum volume inside
BCT for purposes of standardisation. Besides, there is also a few variables which can influence the vacuum sustainability in order to provide best condition to store Vacutainer® so that the shelf life will be prolonged.

2. RESULTS AND DISCUSSION

2.1 Experiment 1: Effect of temperature on BCT (proper placement for BCT)
Before the experimentation being done, polymer BCT is used for the testing procedure, where water have been filled into the BCT. Thus, is to identify the zero error of volume collected in BCT, as a result the volume gained is 3.1ml differ from the labelled attached at the tube. However, for the (1st Objective) the results shown in Table 2.1 are as predicted, where the draw volume of tube from temperature condition of 38°C to 35°C start to deplete every week as present in table one below. Meanwhile, at 30°C, all the tube undergoes draw volume of 5% every week. But, for the BCT which placed under 20°C sustain its exact/origin volume 3.1ml.

<table>
<thead>
<tr>
<th>Week</th>
<th>Label</th>
<th>Temperature</th>
<th>Average Volume Collected (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A1 / A2 / A3</td>
<td>20°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>B1 / B2 / B3</td>
<td>30°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>C1 / C2 / C3</td>
<td>35°C to 38°C</td>
<td>2.95</td>
</tr>
<tr>
<td>2</td>
<td>D1 / D2 / D3</td>
<td>20°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>E1 / E2 / E3</td>
<td>30°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>F1 / F2 / F3</td>
<td>35°C to 38°C</td>
<td>2.90</td>
</tr>
<tr>
<td>3</td>
<td>G1 / G2 / G3</td>
<td>20°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>H1 / H2 / H3</td>
<td>30°C</td>
<td>3.05</td>
</tr>
<tr>
<td></td>
<td>I1 / I2 / I3</td>
<td>35°C to 38°C</td>
<td>2.85</td>
</tr>
<tr>
<td>4</td>
<td>J1 / J2 / J3</td>
<td>20°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>K1 / K2 / K3</td>
<td>30°C</td>
<td>3.05</td>
</tr>
<tr>
<td></td>
<td>L1 / L2 / L3</td>
<td>35°C to 38°C</td>
<td>2.80</td>
</tr>
<tr>
<td>5</td>
<td>M1 / M2 / M3</td>
<td>20°C</td>
<td>3.10</td>
</tr>
<tr>
<td></td>
<td>N1 / N2 / N3</td>
<td>30°C</td>
<td>3.00</td>
</tr>
<tr>
<td></td>
<td>O1 / O2 / O3</td>
<td>35°C to 38°C</td>
<td>2.70</td>
</tr>
</tbody>
</table>

From Figure 1, the data recorded and collected, polymer BCT that been left under temperature condition of 25°C and above has been affected of its vacuum content inside the BCT. Also, can be seen from the data collected at temperature 35°C to 38°C the vacuum starts to draw at 3rd week, saying that it is not a proper condition to place the BCT under high temperature condition. As stated in ideal gas law, deduce from the general equation as PV=nRT, as temperature increase and the pressure inside the product is lower from surrounding condition cause the product to contract and damage due the particle inside the product is at far apart [2]. Thus, simultaneously draw the volume of vacuum inside the BCT as to stabilize with outside condition. Humidity of the circumstances which 45 pieces of BCT been placed are not in certified condition as 4°C-25°C in well-ventilated environment with relative humidity of less than 80% RH [8]. However, the precise and best condition of humidity is at 40% to 60% RH as mentioned in Carel Industries [9]. Moreover, as we can look to the PET structure after moulding process, present of the appearance of crystalline as shown in Figure 2 [10]. Thus, may cause defect if place under the high humidity condition due to the content of hydrogen molecule that may affect the structure and mechanical properties of the PET. Thus, with high humidity which also can be explained high hydrogen (H2) solubility in polymers, may lead to mechanical degradation or failure upon decompression [11]. The phenomenon known to be blistering which induce by hydrogen molecule as depicted in Figure 3.

2.2 Experiment 2: Development of a new benchmark (specification) vacuum volume of BCT
Validation of Vacuum Consistency done with six (6) trays, altogether in total are 600 units of BCT tube. Three (3) trays been tested using fluid volume test with plain water using burette setup and the result presented in Figure 4, while another three (3) trays tested using pressure leak test machine/vacuum check machine to evaluate the (vacuum) volume of negative pressure inside the BCT presented the results in Figure 5.

Figure 5 present the reading fluctuates inconsistently ranged between 304mmHg to 324mmHg for three (3) trays. The data fluctuate exceed from the limit that has been set at ±5(unit) as shown in Figure 5, known to be a random error. This happened due to the failure of the machine to run properly as known to be a random error. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly. On the other hand, using the vacuum check machine, as ordinary Process Inspection (PI)/Quality Control (QC) cannot be seen with naked eyes and clearly.
check machine (technician feasible to calibrate). Improvement, upon the machine must be done by servicing and re-calibrate the machine to its proper condition as to gain better outcome for the industry to use as a Quality Control (QC) tool to ease the process of inspection.

Figure 1 Temperature effect on vacuum content of BCT.

Figure 2 Polymer structure of PET [10].

Figure 3 Hydrogen induce polymer blistering [9].

Figure 4 Graph of fluid volume test for tray 1, 2 and 3.
3. CONCLUSION

This, BCT should be placed under temperature condition between 4°C to 25°C as suggested by BD-Vacutainer® company, also under certified humidity condition are ranged between 40% to 60%. Thus, can be placed in clean room as the comply with the pharmaceutical approach. This is to ensure the pharmaceutical device which is sterile and consist of shelf life does not deplete its properties drastically and sustain its life span as recommended in technical data sheet. However, during transportation process, the installation of dehumidifier and cooling system on truck is such an important step to reduce or prevent from draw volume of vacuum by the BCT, since the product being delivered only by using truck. As to reduce the cost of delivery and no installation made for as such device on the truck, we may deliver the product during night-time since the temperature and humidity are at desired state.

REFERENCES


Figure 5 Graph of negative pressure vs number of BCT for vacuum check machine.