Welcome to the lecture on capsules. It is impossible to separate the idea of preparing capsules from the purpose of using powders. Taking or swallowing a capsule is essentially administering a powder for internal use. Drugs that come as bulk powders are difficult to use and dose correctly. Putting that same powder in a capsule makes it easier to deal with. The official USP definition is that capsules are solid dosage forms in which the drug is enclosed in either hard or soft soluble container or shell. The shells are usually formed out of gelatin; however, they also may be made from starch or other suitable substances. Swallowing capsules is going to be easier than swallowing tablets because the gelatin shell hydrates in the mouth and passes easily into the esophagus. Another reason for the wide acceptance of capsules is that they are tasteless and odorless and once in the stomach the gelatin shell rapidly dissolves and releases its contents making it available for absorption. Thus, there is high patient acceptance for the use of capsules to administer drug powders. There are a variety of uses for capsules. First, hard shell capsules offer a customized dosage form that can be made easily and conveniently in any pharmacy. Besides being used orally, capsules can be administered by a variety of different administration routes including rectal or vaginal use. When given so, the capsule is actually more like a suppository and as such they should be moistened before insertion, and can be pierced with a pin or needle so that the aqueous body fluids can penetrate the capsule and dissolve its contents. But for our purposes in compounding lab, we will be discussing oral capsules exclusively. Oral capsules are especially ideal for very potent drugs and chemicals which need to be administered in relatively small amounts because the quantity of drug formulated into capsules can be measured very accurately. Also combining several active ingredients into a single dosage form can reduce the number products a person has to take and can also thereby improve medication adherence. Lastly, capsules can mask an unpleasant taste, aroma, or appearance of the drug and make it much more tolerable and help increase patient acceptance.
To start we will describe the three main capsule components. The first is the active ingredient, the second is an excipient, and the third a hard or soft soluble container or shell. The first component is the active ingredient or ingredients if there is more than one. Most often the source of active ingredient for capsules will be from a bulk powder. Because most commonly compounded drugs are very potent, the actual amount of active ingredient per capsule is relatively small and sometimes below the least weighable quantity of our digital or torsion balance. Therefore calculations and procedures involving solid aliquots might be necessary. Alternatively, active ingredient powder can be obtained using a manufactured solid dosage form such as commercially available tablets or capsules. Understand, if the source of active ingredient is a commercial tablet or capsule, you will have to take into account their use of diluents or excipients such as lactose, and perform crushed tablet powder calculations. You will set up a proportion of the amount of active drug per dosage unit, over the total weight of that dosage unit, and use that proportion to determine how much of the crushed tablet powder or contents of the commercial capsule to use in your formulation. Another consideration to keep in mind when working with powders, whether obtained from bulk or commercial tablets or capsules, are their properties which can affect compatibility. Examples include the potential of a powder to effloresce, or deliquesce, or become easily aerosolized. So you may have to deal with a powder with any of these properties. For example, efflorescence powders give off water of hydration and over time can allow water to leach into the capsule and make it soft and gummy instead of being a nice hard shell. On the other hand, a deliquescent powder can absorb water and will actually suck water out of the gelatin hard shell. Since gelatin shell capsules contain about 10 to 15% water, water pulled out by the powder results in a brittle capsule that can break very easily upon normal handling. Powders that can become easily aerosolized pose a potential exposure hazard to the compounder. Therefore, when compounding certain drugs or hormones such as thyroid or estrogen, preparation should be performed inside a powder containment or fume hood. The second component frequently used when compounding capsules is an excipient. Excipients are typically in the form of a bulk powder such as lactose or starch or calcium carbonate. While we will discuss their use in more detail later, they are essentially used to bring up the total weight of the capsule so that the capsule shell is tightly packed.
Commercial capsules are available and classified as either soft or hard depending upon the nature of the gelatin shell itself. Soft gelatin capsules are made from a more flexible plasticized gelatin film that forms a one piece shell. The soft shell is made by adding plasticizer such as glycerin sorbitol or propylene glycol to the gelatin. Soft gelatin capsules are most commonly used to contain liquids or suspensions, and are thus not commonly used for the extemporaneous formulations which utilize dry powders as the source of active ingredients. As such we do not really practice or use those in pharmacy skills lab. We focus more on the hard gelatin capsules. The hard gelatin capsules we use have very little elasticity and are composed of two parts, a longer body and a shorter cap. These parts are illustrated in the picture on this slide. On the left we see the cap and on the right is the body. The cap is designed to fit snugly over the body and be able to be pressed and locked into place. This ability to lock the cap into place is important because while the cap must be removable while compounding, once dispensed if the cap is not locked it could slip off and spill its contents. Gelatin capsule shells may contain other ingredients such as disbursing agents, hardening agents and preservatives. They also contain a certain percentage of water usually being about 10 to 15%. Hard shell capsules are available as either clear or opaque. Clear capsules can be either colorless or colored despite being clear enough to see the powder contained in the capsule. Some capsules are actually made opaque by the addition of titanium oxide for the purpose of hiding unattractive agents and thereby increase the aesthetic appearance of your final product.
For the rest of this lecture, we will be focusing on the use of hard shell gelatin capsules. We have talked about their composition so now we will discuss their different sizes. Capsule sizes are indicated by a size number. What is difficult to remember about a capsule size number is that the larger the number, the smaller the capsule. This is illustrated in the picture where you can see on the left, size number five capsules are the smallest available and are about half the diameter of a dime. Then as the size number gets smaller, going left to right, from 5 to 4 to 3 and so forth, the capsule sizes actually get larger. The largest capsule size available is a triple zero, and is larger than the diameter of a quarter. This large capsule is only used for veterinarian compounding and is not intended for use in humans. The largest size capsule used in humans is the double zero, although many patients would find this size difficult to swallow. Therefore the smaller the capsule size the easier it will be for the patient to swallow and will result in better patient acceptance. Clearly using smaller capsules is appropriate for younger children. However, using too small of a capsule size can have disadvantages, especially for compounding. Small capsules can be more difficult to fill with powder and since smaller capsules have less total weight, they are more difficult to fill to within an allowable 5% margin of their target weight. So as we talk about capsule size selection realize it is a trade-off between the size of a capsule the patient can swallow and a size that works best for the pharmacist to be able to carefully and accurately compound.
This is a very important reference table that we will refer back to several times in later discussions. This table shows a total of 8 different size capsules, ranging from 5, the smallest, to triple zero, the largest. Each of these capsule sizes have an approximate volume. The smallest size 5 capsule contains total of 0.13 milliliters, and the volume increases as you get up to the triple zero, which will hold 1.36 milliliters. Thus, different capsule sizes will contain different volumes of powder. The problem is, when we go to compound a capsule, we do not fill it by measuring volume, we fill it by weight. Therefore, different properties of powders such as density, and particle size, will influence how much weight we can put into a fixed volume capsule. The maximum weight for various powders, that can fill the fixed volume of any given capsule size, is given in the lower part of this table. For example, we can look at size 5 or the smallest capsule, and see that it ranges from quinine, which can contain the least amount at 0.07 grams, compared to aluminum hydroxide with more than double that amount at 0.18 grams. Please note that I bolded and separated out the values for lactose. This is because in the pharmacy skills lab, we will be primarily using lactose as our excipient. Thus, you will often come back to this table to look for the maximum weight of lactose that can be used in various size capsules.
Understand that when a doctor writes a prescription for a capsule to be compounded, they usually will not indicate a particular capsule size. It will be up to the pharmacist, to determine the most appropriate capsule size to use. How do you go about making that decision? The question highlights the idea that compounding is both an art and a science. While science and calculations ensure correct dosing each time, it also takes experience, and sometimes trial and error, before you know exactly how to proceed. This is the art of compounding. You start with what you think is the best selection and if it does not work, you have to try it again with a different size. There is no absolute hard and fast rule to capsule size selection. However, there are general guidelines to help guide your selection. The first is to use the smallest practical capsule size in order to minimize the difficulty in swallowing. On the other hand, the capsule must be large enough to hold the powder with no void space in the body of the capsule. When appropriately sized, the cap of the capsule is only needed to prevent powder from spilling, and should not be needed to contain any amount of the powder. Therefore, capsule size selection is based on balancing the patient need for ease of handling and swallowing, against the pharmacist need for accurate preparation and the best bioavailability of the powder. To that end, a loosely packed capsule is preferable because the powder disperses easily as the capsule shell dissolves. However, when filling capsules individually by hand, it is usually easier to fill capsules that are slightly packed. This is because when hand filling a capsule, your fingers can feel the degree of packing pressure within the body that corresponds to the desired weight of powder. This makes it easier to achieve the appropriate capsule weight with a minimum number of balance checks. You do not have the same sense of pressure if you only loosely pack the capsules. From our practical experience, size 2 and size 3 capsules represent a good compromise. They are generally small enough for adult patients to swallow easily, and yet are large enough to physically hold enough powder to allow quick and accurate preparation.
While our first decision is to choose an appropriate capsule size, the second important decision is to determine the target weight of that capsule. This target weight will be a choice, meaning you will have to decide and make that determination. That determination begins by consulting the previous table, that gave the maximal weight capacities of the different size gelatin capsules for a variety of drugs and chemicals. Look through the table and choose a substance that has a density and particle size that is similar to that of the ingredient present in the greatest quantity in your formulation. In the pharmacy skills lab we often use lactose as our excipient, so that would be the chemical to find on the table. Looking across the lactose row, we determine the maximum capacity, in grams, that could be contained in our selected capsule size. Remember the value given in the table represents the maximum capacity that could be used. However, we are not going to want to use that number, since it would be very difficult to pack our capsule so tightly that it would hold the maximum amount. Instead, we want a target weight which would slightly pack the capsule. To find this weight, we must first calculate an acceptable range. To find the low end of the range, multiply the maximal amount found in the table by 75%. This would be the minimum weight to consider. We would not want a capsule filled with less than 75% of its maximum capacity and we can not fill it more than the maximum amount given in the table. Now, you are free to choose any convenient number that is within that range. Convenient, in this context, means a round number that is easy to remember, such as 200 mg rather than an inconvenient number, like 194 mg. Let us look at some examples. Size 3 capsules work well for adults, in terms of being small enough to swallow easily. Look in the table, for the lactose row, and then the column for size 3 capsules, and it gives 0.28 grams, which is the same as 280 mg. So, the maximum amount of lactose that can fit in a size 3 capsule is 280 mg. Multiplying that value by 75%, gives 210 mg. Therefore, an acceptable range between the minimum the maximum would be between 210 and 280 mg. Any value within that range would be acceptable, but it makes sense to choose an easy and convenient value such as 250 mg. This nice, round value makes your later calculations easier and is pretty much in the middle of the range so it should be an easy amount to fill into the capsule. It is worth memorizing, if you are using lactose as a diluent for a size 3 capsule, use 250 mg as your target weight. A second example, would be to use a size 2 capsule. These capsules are also easy for most adults to swallow, but are larger than size 3 capsules and many pharmacists find them easier to handle and fill. If we do the same calculations for the size 2 capsules, and go to the table under lactose, for size 2 capsules, we note that the maximum is 0.35 g or 350 mg. Now multiply that value by 75%, and get the minimum value of 263 mg. So, the range is 263 to 350 mg, and thus a convenient number to choose, would be 300 mg. Memorize that 300 mg is a good target weight for a size 2 capsule. When deciding between size 2 or 3 capsules, it is also worth remembering that the larger the target weight, the more weighing error you are allowed. You are only allowed a 5% weighing error when compounding. If you are compounding a 250 mg capsule, then you can only be off by a weight of no more than 12.5 mg. On the other hand, if you are weighing a 300 mg capsule, you’re allowed up to 15 mg. And while that may not seem like a lot of difference, a larger acceptable range allows you to more quickly fill and complete your capsules. Once you determine your actual target weight, it is important to understand that not all of that weight will be comprised of active drug. The difference between the selected target weight and the amount of active drug per capsule will need to be made up through the addition of an inert powder such as lactose. For example, 300 mg (target weight) - 50 mg (active drug) = 250 mg lactose per capsule.
Now we will go through a practice calculation in more detail. We need to compound ten capsules, which contain 10 mg of drug zee per capsule, for an adult patient. Drug zee is available as a bulk powder, and we will use lactose as our excipient. The first consideration is to determine how many capsules to base our calculations on. Because there is always some loss of powder while compounding, we always base calculations on the preparation of at least two additional capsules. We will only dispense the number prescribed, but by calculating for two extra capsules, we should have enough powder, despite some loss, to prepare the quantity prescribed. So, for this example we will base our calculations on the preparation of 12 capsules. Next, determine how much drug zee is needed to compound 12 capsules. Multiply 12 capsules times 10 mg per capsule and find that we need to weigh 120 mg of drug zee. Now we must decide which capsule size, and what target weight would be appropriate. Any capsule size that would be appropriate for an adult is acceptable. In this example, we will select size 3, to have a small capsule that facilitates swallowing. Now that we have made a capsule size choice, we have to consult our table of the approximate weight capacities and look under lactose for a size 3 capsule. The table gives the maximum capacity as 0.28 g or 280 mg. Multiply that maximum amount by the 75% to determine our minimum amount which is 210 mg. Therefore our target weight selection ranges from 210 to 280 mg. Choose 250 mg as the target weight. Next, determine the total weight of powder needed to fill 12 capsules, that each contain 250 mg of powder. Multiply 12 capsules times 250 mg per capsule to determine that we need a total of 3000 mg of powder. This total weight of powder contains both active ingredient and excipient. Next, to determine the amount of lactose required, subtract the total amount of drug zee. Take 3000 mg of total powder and subtract 120 mg of drug zee to find that we require 2880 mg of lactose. On a practical note, while I want every capsule to weigh 250 mg, I am allowed a 5% weighing error which is 12.5 mg. Thus while compounding, I will accept any capsule that weighs anywhere from a low of 238 mg to no more than 263 mg.
We have spent a lot of time reviewing the calculations and the decisions that have to be made in order to formulate capsules. Now it is time to discuss the compounding goals necessary to physically prepare capsules of high quality. The first and the most important goal is weighing accuracy. It is essential that the correct amount of drug is in each capsule, because most of these drugs are very potent and the amounts needed in most capsules are very small. Accuracy begins with correct calculations, and ends with careful weighing procedures. The most frequent error that occurs while compounding capsules, is a weighing error. You have to weigh the correct amount of drug, then weigh the correct amount of excipient, and then weigh each individual capsule as you make them. Thus, there are a lot of opportunities to make a weighing error. The second compounding goal is to ensure that the powders used are in as fine a particle size as possible. To do that, we have to triturate our powders to a fine particle size using a mortar and pestle. This is especially important for granular powders which are very difficult to hand fill and punch into capsules, because they are not cohesive. Reducing particle size to a fine powder increases cohesiveness and makes each capsule easier to fill. The third compounding goal is to ensure thorough blending of all ingredients. To accomplish that, we need to use the technique of geometric dilution, which combines only equal amounts of powders. Begin with the ingredient present in the smallest amount, and combine and mix with an equal part of the larger ingredient. Once thoroughly mixed, the next addition can be twice as much as the first, and so on until all of the products have been combined. To help visualize this process, some pharmacists add a single drop of food color to the first amount of powder mixed. Then, as you add your excipients and other ingredients, the uniformity of the color change helps visualize the dilution process and ensure that the final product is well blended. The fourth compounding goal is proper capsule size selection. Make sure the size is appropriate for the patient age, using the smallest practical size with a minimum amount of void space. The fifth and last compounding goal is that our final product should have a pleasant, aesthetic appearance. Capsules should not be dulled or smeared with fingerprints, which can be avoided by using gloves while compounding. Nor should there be excess powder on the outside of the capsule. Use paper towels to gently roll and polish off your final product. It is important to keep all of these compounding goals in mind as we begin to discuss the actual compounding procedure.
The procedure used for hand filling capsules is also called punching capsules. It is commonly done in pharmacies and does not require any additional or special equipment. After completing all necessary calculations, begin by weighing the required amounts of active ingredients and excipients. Remember to make enough powder for at least two extra capsules, because there will be some powder loss in the blending process. If the prescription contains a controlled substance, this loss during compounding must be minimal, and should be documented on the prescription order or compounding record, and any excess powder saved for destruction. After blending the powders using geometric dilution as previously described, the final powder mixture is placed onto a pill tile or ointment slab. Using a spatula, arrange the powder into a compact, flat powder bed of uniform thickness. This is sometimes referred to as blocking the powder bed. A blocked powder bed is shown on this slide, in the top, left picture. The height of the powder bed should be just slightly shorter, than the long dimension of the body piece of the capsule shell, and allows for efficient punching of powder into the shell. If the powder bed is even and uniformly packed, it is possible, after a few tries, to get an idea of the number of times to punch powder into each shell body, to give the approximate desired weight of powder. At one time, it was considered permissible to handle capsules with clean hands, but now it is standard procedure to use disposable gloves. In addition to being more sanitary, the use of gloves protects the compounder from contact exposure to the drugs or chemicals being encapsulated. Furthermore, use of gloves eliminates the problem of fingerprints on capsule shells, as any dampness on bare fingers will cause a partial dissolution of the gelatin shell, and a smudging of its surface. Additionally, you may use an extra cap from a capsule as a holder, slipped over the body of the capsule being filled. To punch a capsule, separate the cap from the body, and rapidly and repeatedly press the open end of the body downward into the powder bed. This action is why the term punching us used. The top right picture shows the empty body punching the powder bed for the first time. This punching process is repeated quickly all along the powder bed until the capsule becomes filled, as shown in the lower picture. Replace the cap on the body loosely and check the weight of the capsule. Add to, or empty powder from, the capsule body until the desired weight is achieved. A tolerance in final capsule weight of plus or minus 5% usually can be achieved without too much difficulty. Some powders will not pack easily inside the capsule body even with repeated punching. In these cases, consider using the alternative scoop method, whereby you place the body on its side and use a spatula to guide the powder into the body. Take care not to scrape or scratch the capsule body. Either way, when the capsule contains the correct amount of powder, secure and lock the cap by firmly pressing it down on the body. You may hear or feel a slight click when it seats into place. Polish the capsule to remove loose powder by rolling it between the folds of a towel.
An important part of the procedure that we just discussed, and that was glossed over quickly, was the actual weighing of the capsule to ensure it has the correct target weight. Because weighing errors are common, it is important to go through the weighing procedure in more detail. The most common error made in compounding capsules is having the final weight of a capsule be off by the weight of an empty gelatin capsule. This can be as much as 45 to 60 mg for size 3 or 2 capsules, and which is much more than the allowable 5% weighing error. It is extremely important to understand that the selected target weight, is the weight of the powder within the capsule, only, and does not include the weight of the gelatin capsule. To ensure the weight displayed on the balance while compounding only represents powder weight, it must be first zeroed with an empty capsule of the same sized used for compounding. Thus, before placing a compounded capsule to be evaluated on the balance, the balance display would show a negative weight, which is the weight of an empty gelatin capsule. The full procedure for weighing is as follows. First, place balance on smooth, level surface and ensure weighing pan is clean. Next, zero or tare the balance. Place weighing boats or paper and an empty capsule on weighing pan (ensure same size capsule). Re-zero (re-tare) the balance. After this step do not touch the tare button again during the weighing operation. Remove empty capsule but leave weigh boat on balance. The digital display will read a negative value which represents the weight of the empty capsule shell. Weigh filled capsule (handle with tongs). Add or remove powder until target weight obtained. Suggestions: 1) don’t cap tightly and 2) weigh within margin of error.
Handing Filling Capsules - Procedure
Up to this point we have discussed the time-tested method of hand filling or punching capsules, which most pharmacies use because it can be done with no additional equipment and quickly and efficiently. However it is usually reserved for doing relatively small numbers of capsules at a time. Pharmacists who frequently compound capsules, or who do so in larger quantities, often invest in a capsule filling machine. There are hand-operated fillers available through pharmacy vendors in prices ranging from as little as 20 to over $3000. There are also motorized capsule-loading machines in the 5000 to $10,000 price range, that can fill 300 capsules per batch. These fillers work on a principle of calibrated volume fill, rather than weight, and their use requires good quality control procedures to insure precise and accurate dose per capsule. Also note that when using a capsule filling machine, an inert diluent may be needed to improve the flow of the powder, so that capsules of uniform weight are obtained. Also, the capsule filling machine may not have plates for all capsule sizes, and you may need to add diluent to accommodate larger capsules sizes. The exact methods for using these devices vary, but the general steps for using a hand-operated machine are as follows. Start by first loading empty hard capsules into the machine. Most machines come with a capsule loader, which is pictured on the right side of this image, and which correctly aligns all of the capsule bodies in the machine base. The machine has plates on its base that can be moved by turning adjustment screws as shown in the picture with two in the front, and two in the back. Tighten the screws so the plates bind the capsule bodies in place and remove the caps all at one time in a top plate. Then loosen the adjusting screws, allowing the capsule bodies to drop so their tops are flush with the working surface of the plate. Then pour the formulation powder onto the plate and use special spreaders and combs to fill the individual capsules. Be sure and spread the powder evenly over the plate, and use the comb to tap and pack the powder into the capsules. Repeat the two processes of spreading and tapping powder until the capsule bodies are filled with the powder. The capsule tops are then reattached to the bodies and the completed and closed capsules are removed from the machine. When using a capsule filling machine, a quality control procedure, such as a modified weight variation test, should be performed on each batch of capsules, to ensure consistent weight, since there is a tendency to pack the capsules in the middle of the machine more tightly, and thus, will weigh more than capsules along the edges. For example, if compounding 30 capsules select and weigh 10 of them individually. Then calculate a mean, a standard deviation, and a relative standard deviation. The capsules are satisfactory if all 10 units are within the range of 85 to 115% of the labeled amount of drug per capsule, and if the relative standard deviation is less than or equal to 6%. Pharmacists who routinely compound batches of capsules using these devices, should also develop written formula and batch record sheets and written standard operating procedures for their use.
How-to video on how to make capsules using a capsule filling machine.
By RC Compounding
Uploaded on Jan 14, 2010
http://www.youtube.com/watch?v=WNYjHITHjh8
The next topics to discuss are the preparation guidelines that influence how were going to compound our capsules. The first guideline describes how to ensure that the compounded product meets quality control standards. The most important quality control measure is to check the weight of each capsule. Allowable error is plus or minus 5% of the stated weight of the capsule. In small batches, each capsule weight should be measured and documented in the compounding record. When compounding in larger quantities, a combination of individual capsule weights as well as group weights of 10 capsules can be used.

The second preparation guideline describes the packaging and storage of capsules. Hard gelatin capsules should be stored at room temperature and maintained at a constant humidity. High humidity may cause the gelatin to soften whereas low humidity can may them dry enough to become brittle and crack.
The third preparation guideline describes the excess quantity to prepare, and comes from the USP chapter 795, which states that for solid dosage forms, prepare an amount of the total formulation sufficient to allow the prescribed amount or quantity to be accurately dispensed. When compounding capsules, powder loss is very common. It can occur during mixing and blending or become left on the ointment slab or weigh boats. Therefore you will always need to prepare excess, and in lab be sure and always base calculations on a minimum of two extra capsules. You may base calculations on more than two extra capsules, but never less than two. The fourth guideline is the USP 795 recommendation for beyond use dating. This chapter states, in the absence of stability information that is applicable to a specific drug and preparation, that for non aqueous formulations, the beyond use date is not later than, the time remaining until the earliest expiration date of any active ingredient, or 6 months, whichever is earlier.
The last topics to discuss are the required specialized prescription documentation, and patient prescription bottle labeling. Starting with prescription documentation, it is very important to remember that you must record the size, and color of the capsule, on the face of the prescription, or included on the compounding record, to ensure that refills are prepared with the same capsule size and type. Typically, the number of the capsule size is written inside of a triangle, and the capsule color is recorded directly below the triangle. As shown in the sample prescription on the right-hand side of this slide, you can see we have written a triangle on the far right, and within that triangle have written the number three, to indicate that we used size 3 capsules. Then, below the triangle we indicated the color of the capsule. Keep in mind, pharmacists often use clear or colorless capsules. These would be indicated by writing the word clear. On the other hand, if a colored capsule was used, it would be indicated by writing the color below the triangle. Additionally, this example prescription contains a controlled substance. Therefore the pharmacist would also notate the excess drug not dispensed and that was kept for proper disposal. Typing a prescription label for capsules is very straightforward. Simply indicate the weight of the active drug per capsule. So, you would have your drug name, and then the weight, typically in milligrams, and then the word capsule. If the capsules are intended for oral use, it is not necessary to specify the dosage form as an oral capsule. However, if you are compounding a capsule to be used by a route, other than by mouth, then it is extremely important to indicate the dosage form as either a rectal capsule, or vaginal capsule. You always explicitly indicate the correct route in the patient instructions. For example, take one capsule by mouth, or insert one capsule rectally, or insert one capsule vaginally. Also, if appropriate, you would attach auxiliary labels indicating rectal or vaginal use only.