



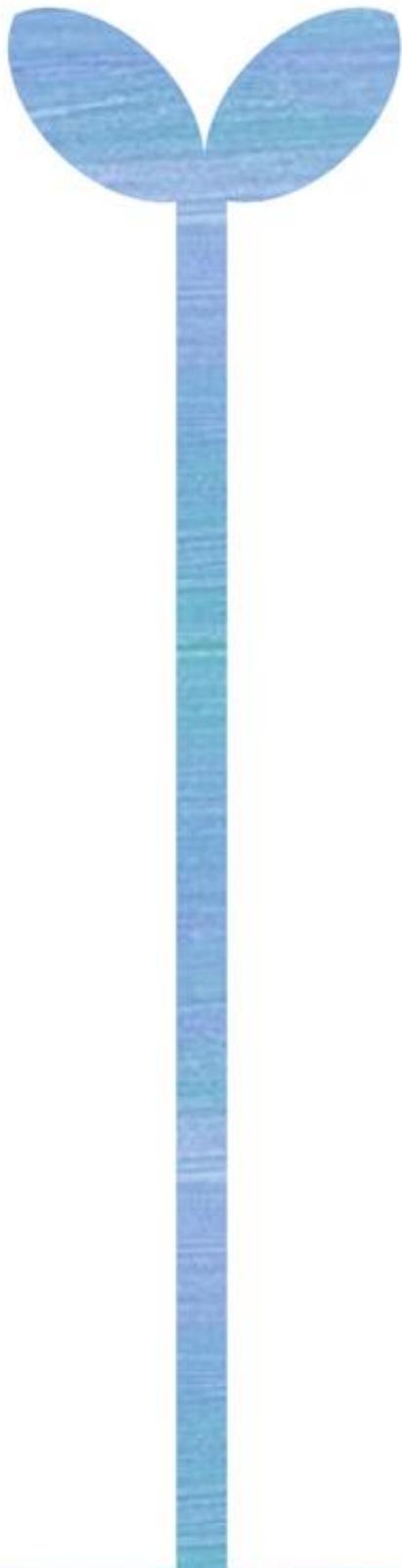
Gel Together GT

The Brand New Dosage Form for oral medication.

The next generation of oral administration
With better compliance for the elderly and children
Requiring easy intake of medicines



Morimoto Pharma Group



Why is GT?

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Why is GT?



Benefits of GT _ For patients

Delicious medicines for your kids!



◆ **GT supports people to take oral medicines conveniently** without crushing or breaking tablets or capsules by minimizing the size of the medicine with the new packaging method. The medicine is easily swallowed at one gulp without water.

◆ **GT allows you take your medication easier then before** especially if you have trouble with swallowing big pills because gel in the GT is the most appropriate liquid to support swallowing.

◆ **GT is the easy way of taking medicine orally especially for patients with less dexterity or hand tremor**, and also can help disabled older people who are struggling with their medication bottles or blister packs.

◆ **GT can cover the taste of medicine completely.** You don't need to fight with your children or hide their medicine in food or drink anymore. Children can only feel the taste of flavor jelly of GT delivered by the new technique of packaging medicine.

◆ **GT is the best product for your children with the accuracy of dosing** provided by its single dose delivered from each unit. You can read the appropriate administration guidance of the medicine based on the information on the label on GT.

◆ However, Syrup, which is the most commonly used medicine for children, can't perfectly mask the chemical smells and bitter taste of drugs. Even worse, **syrup has a serious risk of misuse especially for OTC drugs** because it is contained in a big bottle and has possibilities of overdosing.

Delicious medicines for your kids!



Take GT with you any time and any place!



◆ **GT can be easily carried in your pocket or bag, and help you take your medicine without water at any time and any place** when you need to take your medicine immediately or regularly.

◆ **You can take your medicine in a clean and sterile way with GT even with dirty hands** because the medicine is directly administered to your mouth without any contact to the medicine. You just need to push the Gel to your mouth.

◆ **GT is the most handy product for oral medication**, and is ideal for outdoor people, e.g. military, rescuer, sports person etc. GT also can be taken in patients with poor salivation, different from Oral Disintegrating Tablet(ODT).



Benefits of GT _ For Healthcare Professionals

Safe and easy way of administration with no more crushing!



- ◆ **GT can save your time and efforts for the preparation of medication administration** when compared with manually crushing and grinding tablets using mortar and pestle.
- ◆ **GT can protect you from the direct contact of medicines which is harmful** GT prevents possible exposure of the drugs during preparation and administration of medication.
- ◆ **GT can reduce the cost for labor and purchasing materials for crushing tablets** with the reduction of consumable materials such as wrapping paper, labeling paper, and the printer.

◆ **GT can promote the compliance of medication administration** with the simple and easy way of administration. You don't have to mix patient's drugs with food or beverage, even with syrup for better swallowing.

◆ **GT can assure you that patients take the whole volume of medicine.** When a drug is mixed with food or beverage, the drug might remain on its container, and the volume of the medicine can be reduced by 10% from its prescribed amount.

◆ **GT can assist you for effective administration of medication especially if you are working at nursing homes.** There is a report that shows 23% of patients in the nursing homes were given at least one drug mixed into their food or beverages from a total of 2,108 patients in 151 wards at 65 nursing homes in Norway. (Int. J. Nurs Pract. 2010)

Better compliance than before. No more mixing drugs in food or drink !



Prevent your medication error and



- ◆ **GT can help you to prevent accidental administration of medicine** by using labeling of each unit on the front and rear of GT. Compared to tablets and capsules which only have identity markings, GT provides enough space for more information of a drug such as warning, contraindication, dosage, etc.
- ◆ **GT can support you to administer medication correctly** with an easily distinguished shape which is very different from conventional drugs, and the bar code on GT which can identify the drug.
- ◆ **There was an incident that the crushing of verapamil tablets on the advice of a nurse resulted in the death of a resident**, as the patient received a large proportion of the dose relatively quickly, which produced toxic blood levels of the drug. (Freeman H, 2003 Crushing Blow. Daily Mirror. 17 April).

Benefits of GT For Pharmaceutical Companies

Speed up your research for oral medication!



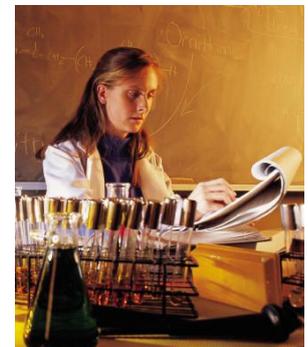
- ◆ GT will support you to develop your product easily and quickly by reducing the time for formulation study, and also optimize the stability of your medicine due to the separation of drug and liquid.
- ◆ GT provides a differentiated, patented dosage form, and also supports to develop controlled release products easily and quickly by using its medicine wrapping technology.
- ◆ GT can help you to speed up market launch of your product because it needs to have only bioequivalence test for its regulatory approval if the product is already approved. Also, GT can support you for the life cycle management of your product.

◆ GT can support you to develop or produce any kinds of drugs especially for challenging drugs. For example, the medicine containing high active ingredients can be perfectly produced in a closed manufacturing system of GT.

◆ GT makes you to develop the large volume of a medicine easier than before by excluding adding process for excipients. You can make the wide range of dose levels from less than 1mg using granulation up to 1g omitting excipients.

◆ You can make combination drugs in a safe way with GT based on the unique design for the premixed type of medicine for oral use, which is separated active ingredients into different rooms until it is administered by puncturing of the walls.

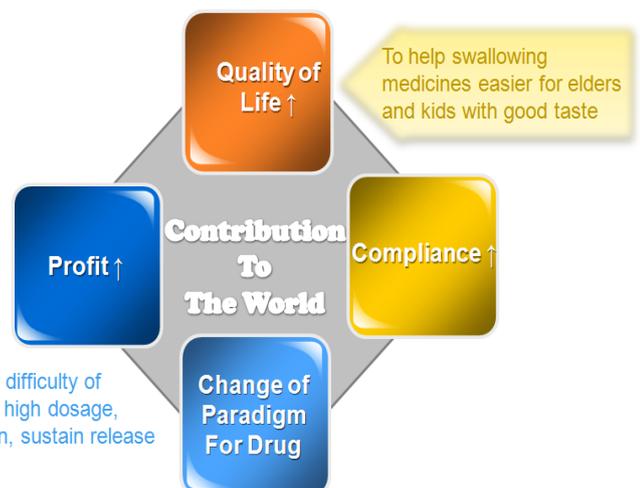
You can make any kinds of drugs that you want!



Reduce your manufacturing cost and process greatly!

◆ GT can guarantee low production costs and high capacity based on the simple production process which can eliminated excipients addition or granulating step for active ingredients.

◆ GT is produced by an automation system which requires minimum labor cost for its management.



Applicable Products

GT has many merits in the aspect of supporting patients, helping healthcare professionals, and promoting development of drugs for pharmaceutical companies.

These are possible indications for applying GT to your drugs which in on development stage or on the market.

Firstly, GT can help the patients with these diseases by enhancing their compliance with easy swallowing :

- Schizophrenia
- Dementia
- Alzheimer disease
- Pediatric disease
- Dysphagia



GT also can support the patients with these diseases with less dexterity, and easy to take medicines.

- Parkinson disease
- Dystonia
- Peripheral neuropathy
- Multiple sclerosis
- Stroke

GT can give the advantages for these people to take their medicines easily and handy without water.

- Electile disorder
- Military, Sports people
- Water restricted patients

GT should be applied to the drugs which are contraindicated to crush tablet or open a capsule.

- Ampicillin due to be destroyed at stomach acid
- Furosemide due to altered diuresis

GT is applicable to produce the drugs hard to manufacture.

- Anticancer drugs
- Hormone drugs
- Large volume of API
- Combination drug

◆ **Tablets were crushed or capsules opened for 25.5% (266/1045) of solid oral doses.** For 44.0% (117/266) of these doses the tablet crushing had not been authorized by the prescriber. **For 4.5% (12/266) of doses crushing was specifically contraindicated by the manufacturer.** In 57.5% (153/266) of doses, tablet crushing was avoidable by the correct use of more suitable preparations. Crushing caused contamination, spillage and hygiene problems. (Stubbs J. *Int Psychogeriatr.* 2008)



What is GT?





● ● About GT

Characteristics

- A brand new dosage form using innovative flexible packaging containing medicine and gel into separate compartments of a single dose unit.
- The next generation of medicine taken without water, and suitable for patients who have difficulty swallowing.
- Provides the most appropriate viscosity that helps medicine to be easily swallowed in the patients in elderly and children.
- Reduces manufacturing process and cost by potentially eliminating excipients adding and granulating process for active ingredients.



Developing History

In 1988, There was a Japanese government research for *silver science research* for investigation of preferences regarding medicines for elderly patients.

The result was that around 20% of the patients complained about difficulty of swallowing tablets. And, the most preferred type of dosage form turned out to be Jelly and Pudding because of easy swallowing and taste masking.

Even though 2 decades have passed since this research, only 10 products have been launched onto the market, and numerous numbers of products have failed to be developed because of the stability problem caused by the moisture in puddings and jellies.

Who developed

After 10 years of research, the president Morimoto of Morimoto Iyaku CO., LTD. has developed GT based on his experience gained in research, development and manufacture of medicines with the top Japanese pharmaceutical company, Takeda.

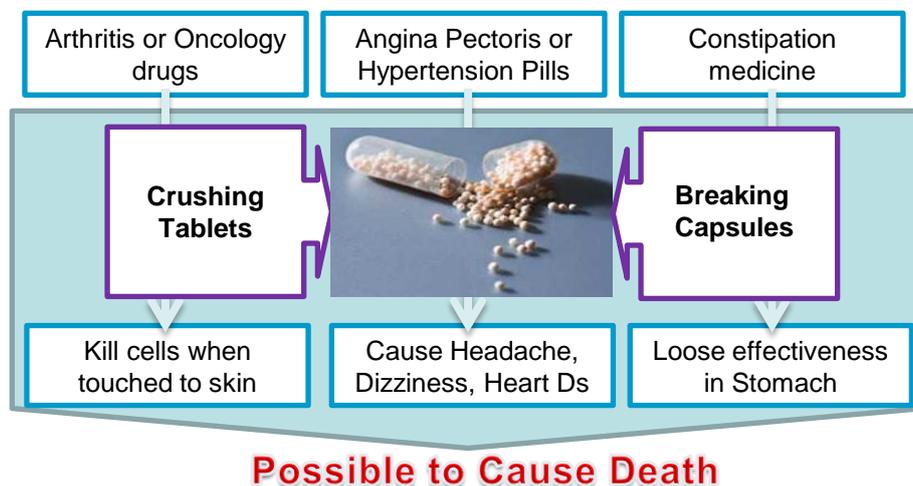
His research endeavor brings to fruition the best dosage form for oral medication.



Problems of Conventional Oral Dosage Forms

Compared to Tablet & Capsules

Tablets and Capsules are the most widely used dosage form for oral administration. However, due to the process of producing these, many additives besides API are used, and this can make the size of tablets and capsules big leading to swallowing difficulties.



In our neighborhood, some patients try to crush or divide their medicines in order to take it comfortably, and this is common to elder and pediatric patients. In spite of the prohibition for crushing or dividing Control Released medicine, there is no choice to administer CR in the patients who have dysphagia. To make matters worse, this causes into death when this crushing method is used in long term period.

Compared to ODT



Orally Disintegrating Tablet(ODT) is one of the most recently developed dosage form. However, it still has the limitation to use in patients with poor salivation, and in some cases is not easy to handle because it is fragile and easily melts on your palm.

Compared to Film

Another newly developed dosage form is Orally thin film, but it also has the limitation regarding drug load which is up to approximately 100mg per single unit.





● ● Features & Specification

General Features



Easy to open seal

GT is divided into 3 parts by seals which are easily punctured by pinching of the fingertips.

Medicine Part

Medicine is packaged in a pharmaceutically-acceptable medical film, and it is separated from jelly in order to keep the stability of medicine until it is taken.

Gel Part

Jelly pushes the medicine when pressure is applied by fingertips. It helps medicine to be taken without water and can be flavored.

Cover Part

The cover part covers the medicine part when it is folded, and keeps the medicine part clean until it goes into the mouth.

Outer Packaging

GT is covered by an overwrap for to contain multiple single dose units.



Specification

1) Edible Thin Film

The edible thin film which overwraps medicine is specially developed for GT, and can regulate the releasing time of active ingredients based on the producing method of coating know-how of the film.

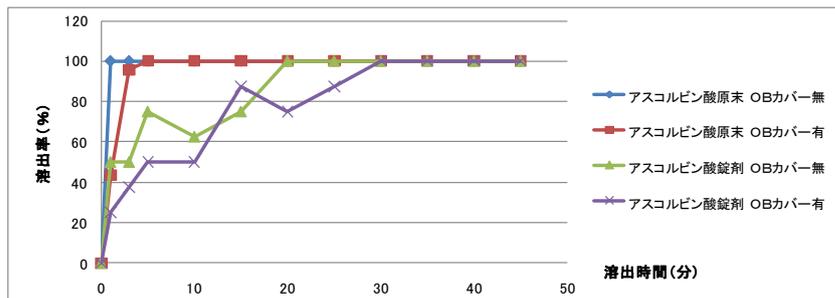


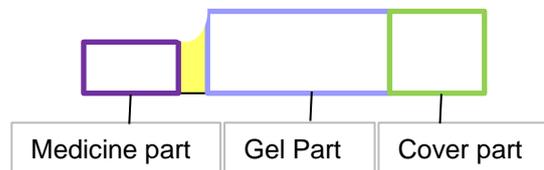
Figure1. Fast dissolved drug, Ascorbic acid

● ● Features & Specification

Specification

2) Sealing

Each parts is sealed by different pressure, heat and time levels. by different pressure and heats with different time application. As a result, GT is possible to hold the pressure in the maximum for 70kg vertically, but the medicine part is easily opened with 2 kg of pinch power.



3) Gel

The viscosity of gel of GT is 000 which widely exists in food. The taste of gel can be applied based on the preference of patients with the various of flavors such as orange, lemon, strawberry, coffee, green tea, etc..

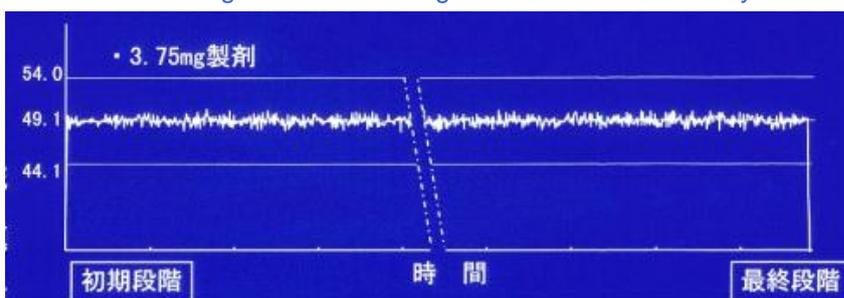
4) Filling

GT is produced by micro-sterile power filling machine which is developed, and patented by Morimoto-Iyaku Co. LTD, and it is automatically run without an operator for 24 hours with safe manufacturing, and assuring quality for foreign matters.

The filling precision is assured by Automatic Weight Control which is very different from conventional vacuum absorbing type of filler, and it guarantees the accuracy of the volume of the medicine less than 1.0 c.v and inside of typically $\pm 5\%$.

That's because powder filling is weighed on-line and rejects are removed if it is failed. This machine can the accuracy of volume of fill within the range of active ingredient from 10mg to 1,500mg.

1) Data of Filled weight/ automatic weigh and feedback control system

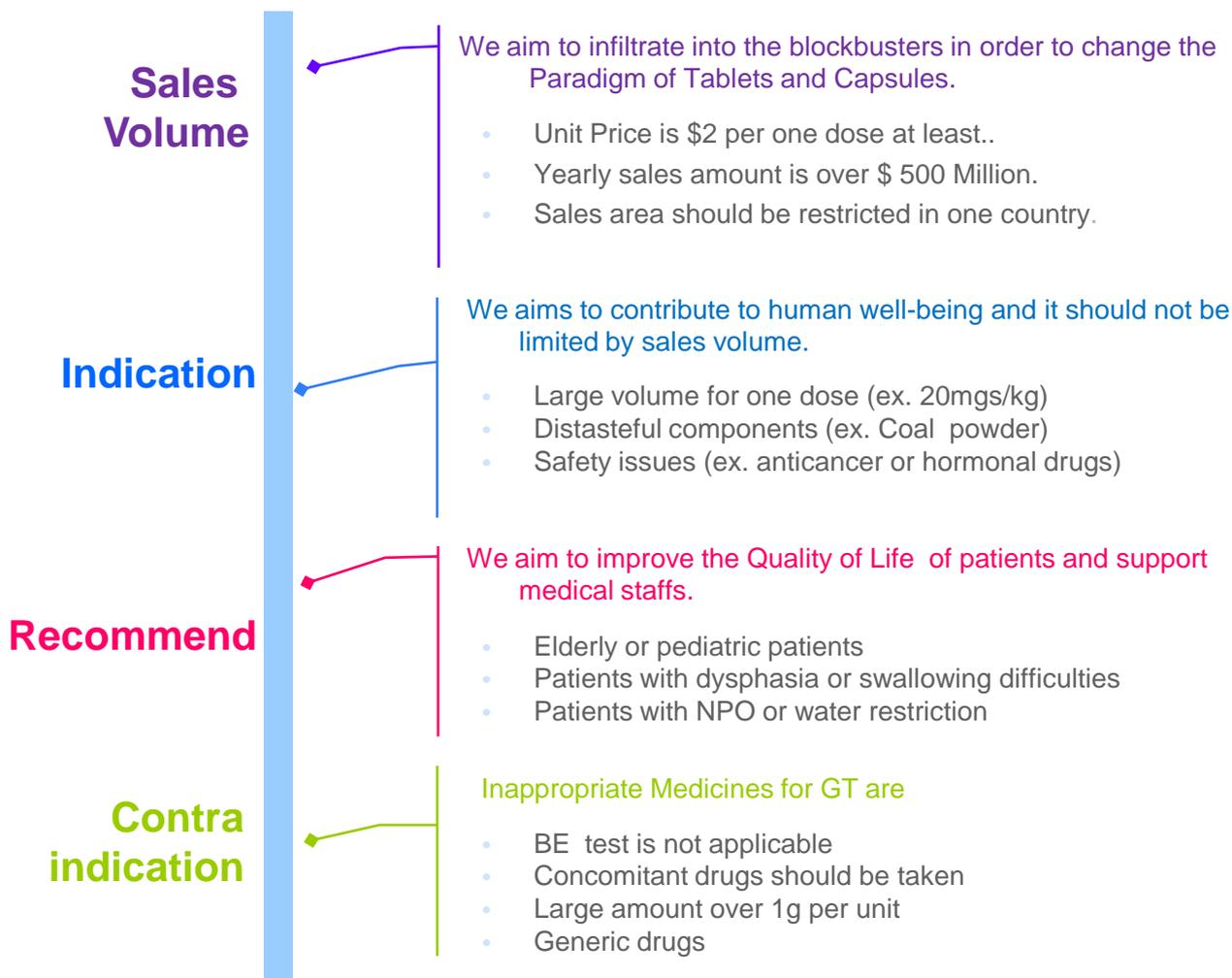




About us



● ● Licensing Policy



Current status of Licensing

GT has been applied to the blockbusters which are already on the market in order to contribute to the Product Life Cycle Management..

| Company | Indication | Expected on market |
|---------|------------------|--------------------|
| A | Senile dementia | not OPEN |
| B | Infection | not OPEN |
| C | Cancer | not OPEN |
| D | Water limitation | not OPEN |
| E | Geriatrics | not OPEN |
| F | OTC drug | not OPEN |
| G | Health food | not OPEN |

Morimoto Pharma Group



Our Philosophy

Contribute to development for Innovative, and high valued pharmaceutical products for human well being.

Our Mission

- We aim to develop a new pharmaceutical product by innovative technique.
- We elaborate a new formulation technology as a research venture.
- We pursue the sterile power filling technology.

Contact us

Company information

- Establishment: May, 2005
- Headquarter Location: Suita, Osaka, Japan
- Capital: ¥ 35 M.
- Sales: ¥150 M. in 2010,
Expected ¥500 M. in 2011

HEAD OFFICE

1-25 Matsugaoka Senriyama, Suita City, Osaka,
Japan 〒565-0843
Tel/Fax: 81-06-6380-8526
E-mail: morimoto@mijc.jp
<http://www.morimoto-iyaku.jp>

CONSULTING:

Etowaru #201 2-2-48 Matuodai inagawa-cho
kawabe-gun hyougo-ken Japan
Tel: 81-72-766-4835

TEST CENTER & MAKER:

UNITEC Co., Ltd.
1-1-60 Tuneyoshi Konohana-ku Oosaka-si
Oosaka-fu 554-0052 JAPAN
Tel : 81-06-6463-7247

TOKYO OFFICE

1-2-9, Yushima, Bunkyo-ku, Tokyo (〒 113-0034)
TEL, FAX: 03-3251-1386

Family companies

Morimoto(Tianjin)International Trade Co.,Ltd
1-2406,JINGCAI Building,No.459, DaGu South
Road,Hexi District,Tianjin,China,PRC300202
TEL : 86-22-2326-0962 Fax: 86-22-2326-0963
<http://www.morimoto.com.cn>

SHANGHAI OFFICE

Room202, NO.22 Caoyang Road, Putuo
District, Shanghai, P.R.China. 200062
Tel: 86-21-3217-0881
E-mail:yjh@morimoto.com.cn

China Morimoto Japan PHARMA CO., LTD.

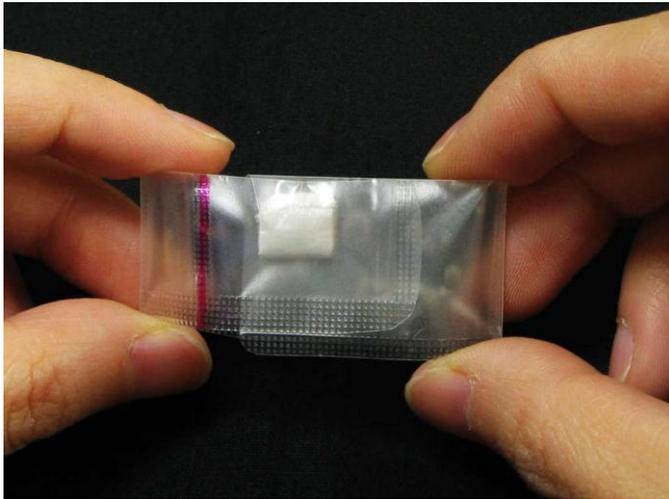
2 Beijing City Chaoyang District left house
Shonaka 号豪成大厦 1,505
Tel: 86-10-6569-6108

Morimoto Research Inc. USA

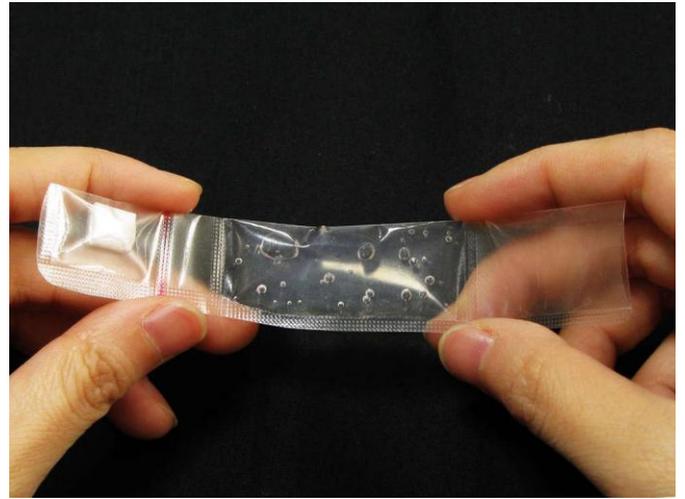
3545 Howord way, suite 220 Costa Mesa, CA
92626 Mobile: 82-10-5195-5374,
E-mail: kylee@mijc.jp



How to use GT



1. Pull the both ends out while opening it upward with both hands.



2. Hold both ends, and spread out GT in order to make flatten it out.



3. Hold GT vertically with the medicine part on top, and put Medicine Part into your mouth.



4. Press the bottom and middle of jelly by using fingertips to open seal between medicine and jelly.



5. Slide fingertips upward and push the medicine directly into your mouth



6. Hold the medicine and jelly for a second in a mouth, then swallow at one gulp.