

# TECHNOLOGY OF THE NEW TYPE OF ORAL DOSAGE FORM FOR CHILDREN: **GEL T** OGETHER (GT™)



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# STUDY PURPOSE

- ① The newly-developed dosage form: GT™ (Gel Together), is an elegant package containing a drug wrapped in an edible film and viscous liquid (jelly) in separate compartments.
- ① GT was evaluated for **package design, in vitro dissolution, and filling precision** for pediatric use.



GT™

# GT: GOOD TASTE & GEL TOGETHER

- ◎ GT which is a premix type of drug dosage form containing a drug and jelly in separated compartments

## Oral Dosage KIT



IP protected

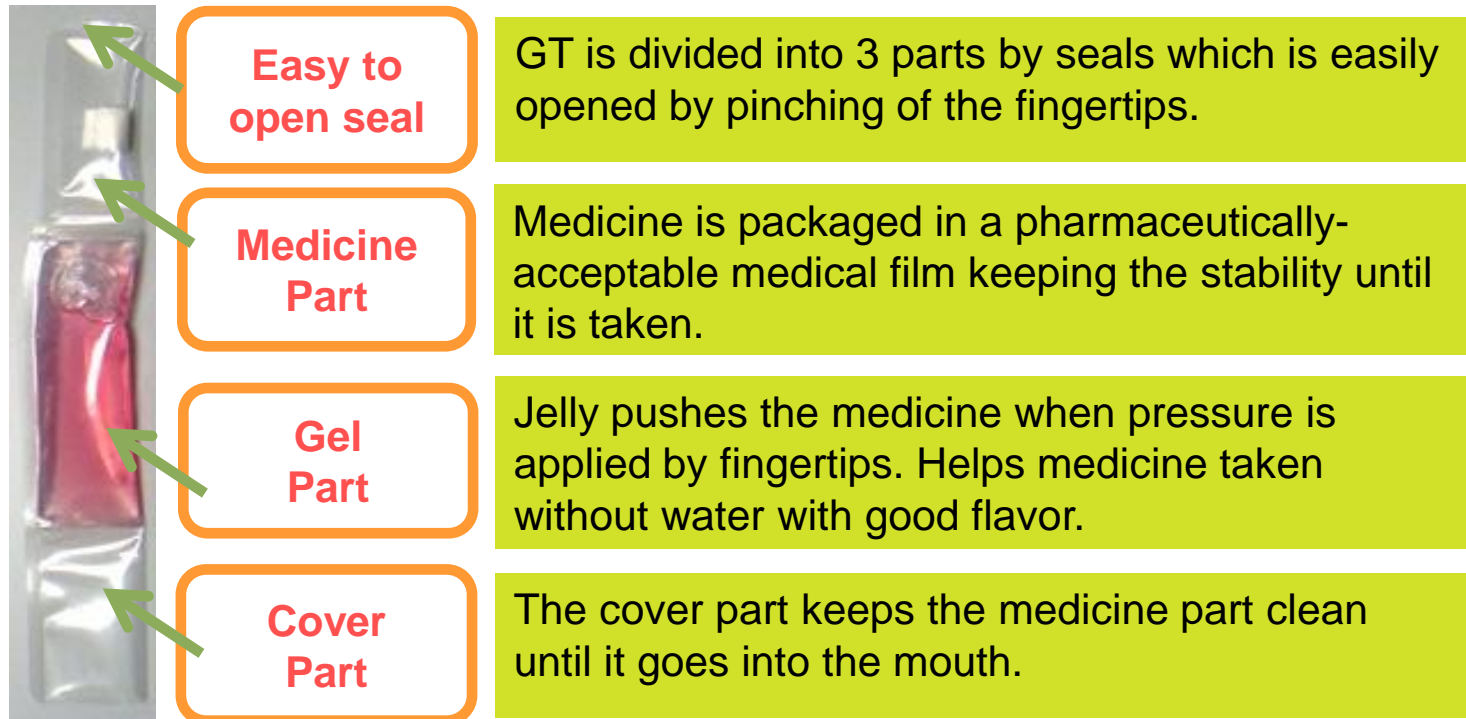


## Injection Kit



# GT: GOOD TASTE & GEL TOGETHER

- ⊙ GT is divided into 3 parts by seals produced with different applied pressure, heat and time levels.



GT™

# HOW TO USE

A large, downward-pointing arrow with a light green fill and a dark green outline. The text "Caregiver Administration" is centered within the arrow's shaft.

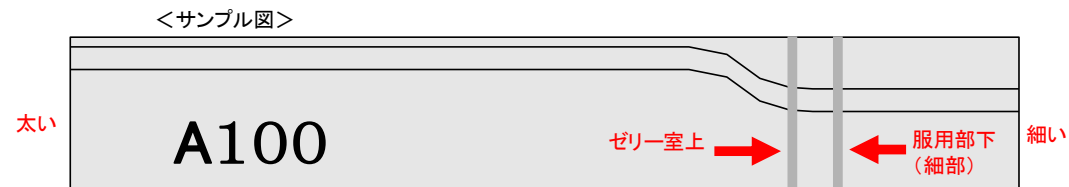
Caregiver  
Administration

A large, upward-pointing arrow with a light green fill and a dark green outline. The text "Self Administration" is centered within the arrow's shaft.

Self  
Administration

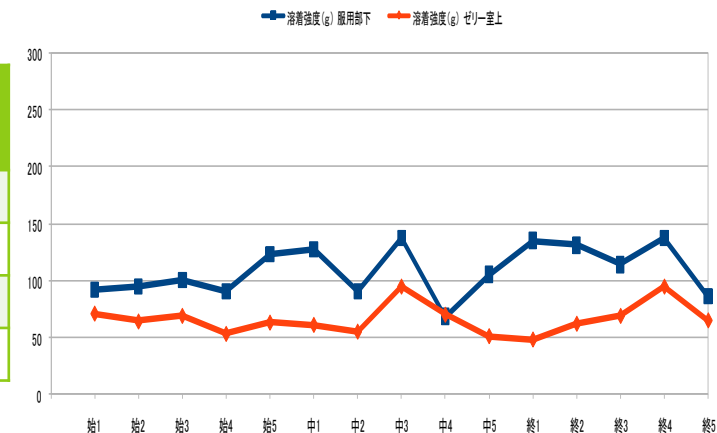
# EVALUATION FOR PACKAGE DESIGN 1) SEAL STRENGTH

- ◎ The pressure was 70kg maximum vertically, and the package was easily operated by 2kg of pinch power.



## [Seal Strength test]

Minimum	Maximum	Mean	Standard Deviation
15.0	25.0	19.0	2.4
15.0	26.0	20.3	3.4
32.0	42.0	36.2	2.9
28.0	43.0	36.5	4.6



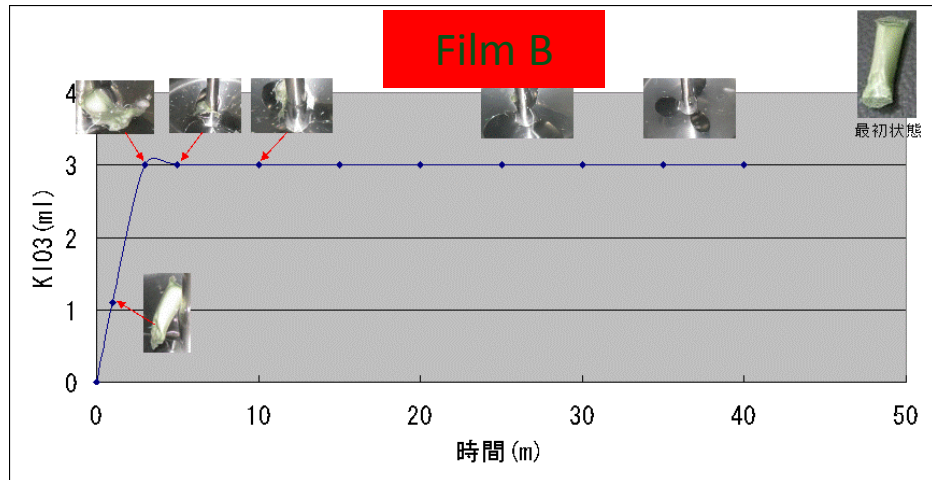
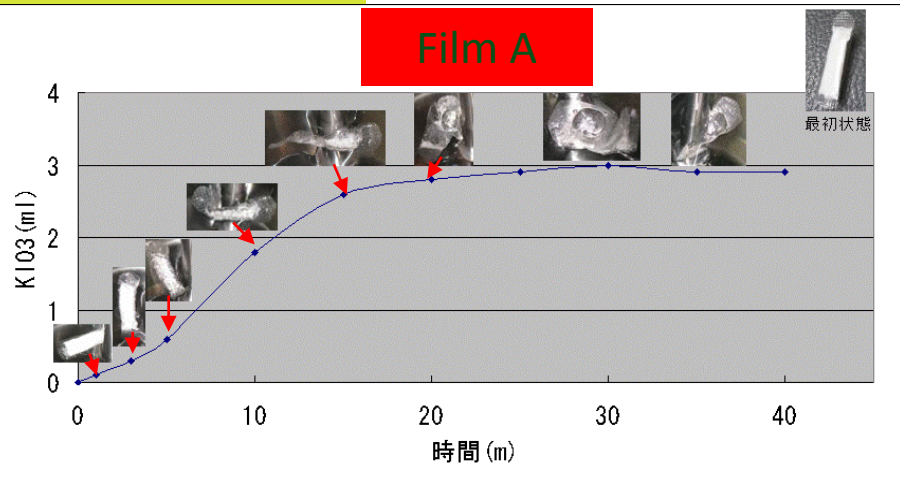
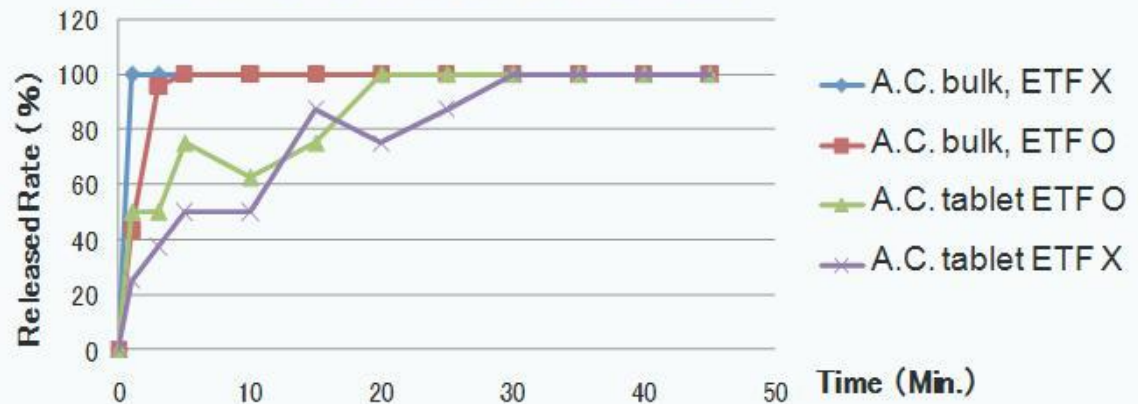
# EVALUATION FOR PACKAGE DESIGN 2) INTEGRITY TEST

- ◎ Confirmed no leak after leaving for 10 minutes using Ageless seal check by Mitsubishi Gas Chemical



# EVALUATION FOR IN VITRO DISSOLUTION

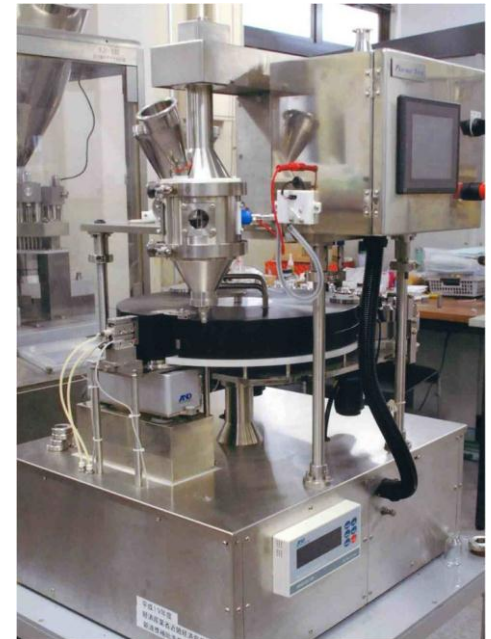
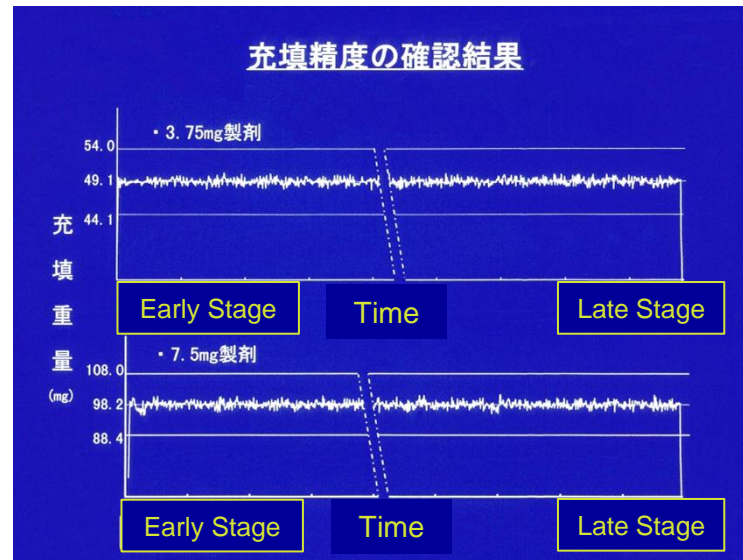
Figure 1. Fast dissolved drug, Ascorbic acid





# EVALUATION FOR FILLING PRECISION

- ◎ Filling accuracy and precision was measured by Automatic Weight Control: accuracy was +/- 5 of target and precision typically less than  $\pm 1\%$  CoV.
- ◎ Powder filling was weighed on-line from 10mg to 1,500mg and rejects were removed if they did not meet acceptance criteria.



# CONCLUSION

- ⊙ According to “EMA reflection paper 2006”, most solid dosage forms are not preferred by pre-school children, and there are few existing products containing jelly.
- ⊙ In a preliminary study, it was found that more than **80% of pre-school children** (age 2~6) preferred GT for easy administration using flavored jelly. GT has a great potential to deliver drugs to pediatric patients.

