

# 技術資料

Technical data

顆粒コンス

Granulated Corn Starch



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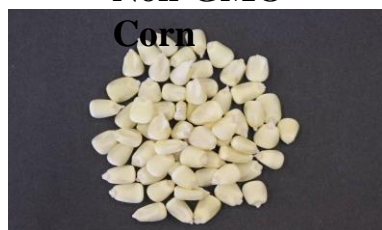
# 顆粒コンス

**医薬品添加物規格「トウモロコシデンプン造粒物」に適合**  
 Meets the specifications of "Granulated Corn Starch" listed  
 in Japanese Pharmaceutical Excipient (JPE) Compendium

1. 非遺伝子組換えトウモロコシで製造した「局方コーンスターチ」100%の顆粒

Granules composed of 100% Japanese Pharmacopoeia Corn Starch, which is made from non-GMO Corn

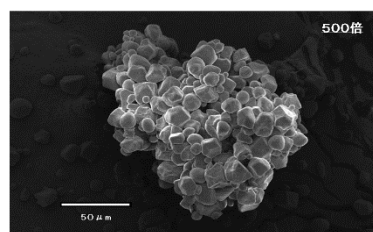
Non-GMO



Japanese Pharmacopoeia Corn Starch (JPCS-W)



Granulated Corn Starch (EGCS-W)



2. デンプンの粒子構造を保持し、顆粒内部には空隙を有する、多孔構造  
 Porous granules with intra-particle void agglomerated from individual starch particles
3. 良好な流動性と直打成型性を有し、更に口腔内崩壊性に優れた添加剤  
 Pharmaceutical additives with good flowability, direct compressibility, and excellent oral disintegration properties
4. セルロース系添加剤には無い、崩壊時のとろける舌触りと喉越し感  
 Good mouth and tongue feeling similar to chocolate, which is not able to be acquired by cellulose additives
5. 口腔内崩壊錠 (OD錠) での賦形剤、結合剤、崩壊剤として配合可能  
 Acts as a filler, binder, and disintegrant in orally disintegrating (OD) tablet formulation

# 性状、特性

## Appearance, Solubility, Characteristics

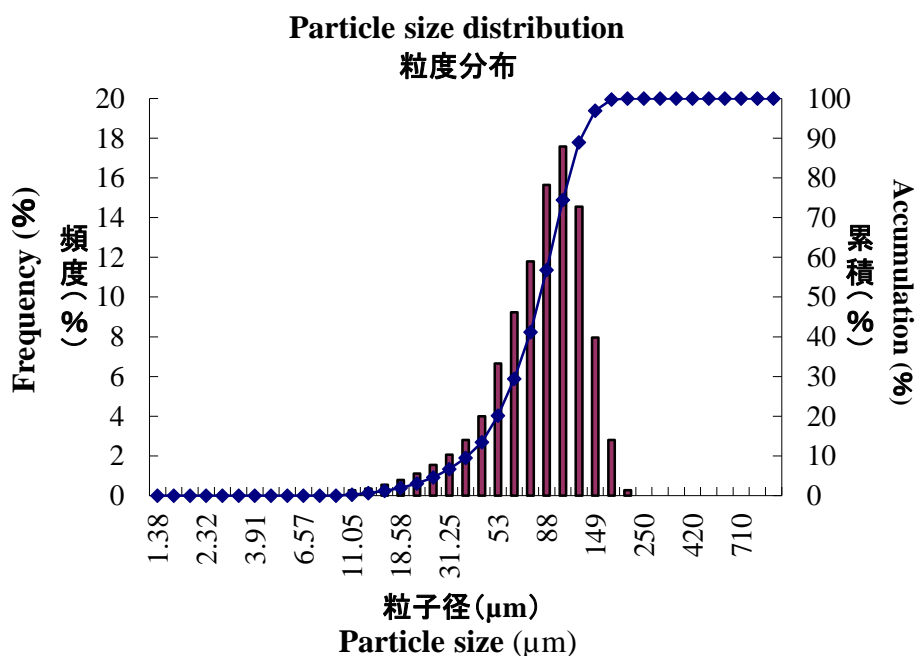
- 性状**                      本品は白色～帯黄色の粉末又は粒で、におい及び味はない。

**Appearance**              White to pale yellowish white powder or granule

**Odor, Taste**              No smell, no taste
- 溶解性**                    水又はエタノール(95)にほとんど溶けない。

**Solubility**                Practically insoluble in water or in ethanol (95)
- 粒度**                        平均粒子径(D50): 81.58  $\mu\text{m}$  (レーザー回折散乱法)

**Granularity**              Average particle diameter (D50) : 81.58  $\mu\text{m}$   
(Laser diffraction scattering method)



レーザー回折式粒度分布測定

Laser diffraction type particule size distribution measuring

焦点距離: 300 mm、取り込み時間: 2.0秒、平均化回数: 3回

Focal length: 300 mm, Taking-in time: 2.0 seconds

The number of times of equalization: 3 times

- 安息角**                      38度 (トウモロコシデンプン: 48度)

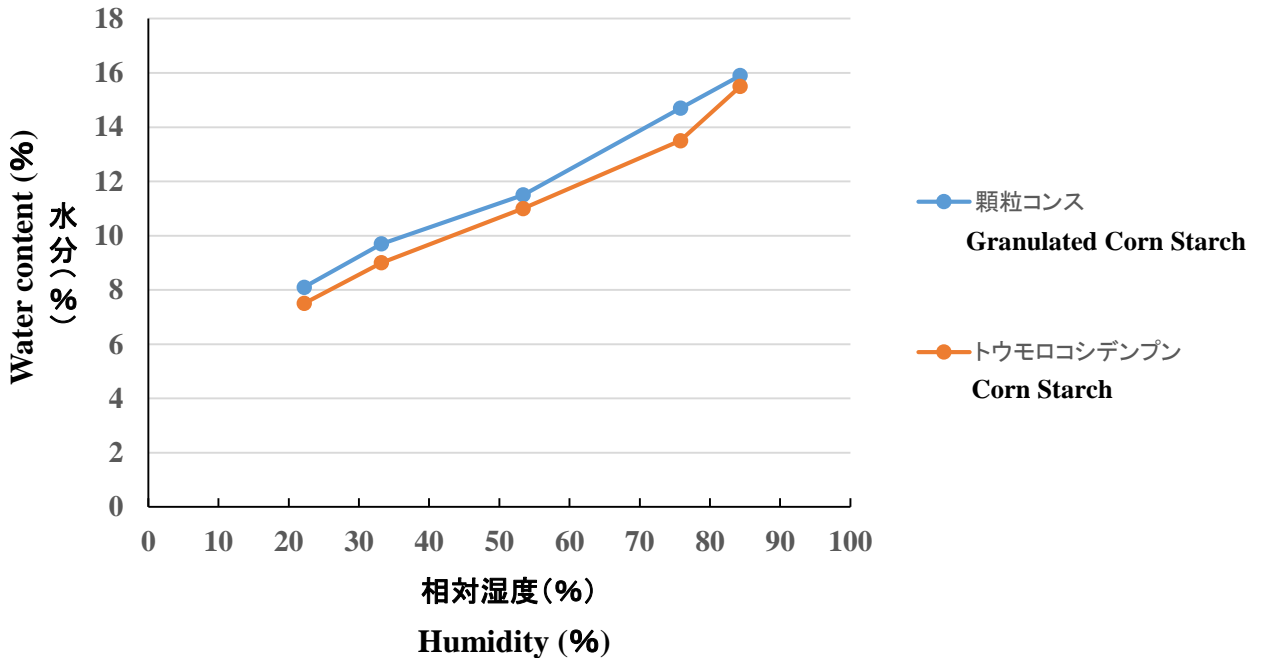
**Angle of repose**              38 degrees (Corn Starch: 48 degrees)
- 水分**                        11% (トウモロコシデンプン: 12%)

**Water content**              11% (Corn Starch: 12%)

## 6. 吸湿平衡 Equilibrium moisture absorption

### Equilibrium moisture absorption curve (37°C, 2 weeks)

吸湿平行曲線 (37°C, 2 weeks)



**製造、保管工程で、トウモロコシデンプンと同等の取扱い可能**  
**Manufacturing process, as well as the storage process, can**  
**be handled the same as Corn Starch**

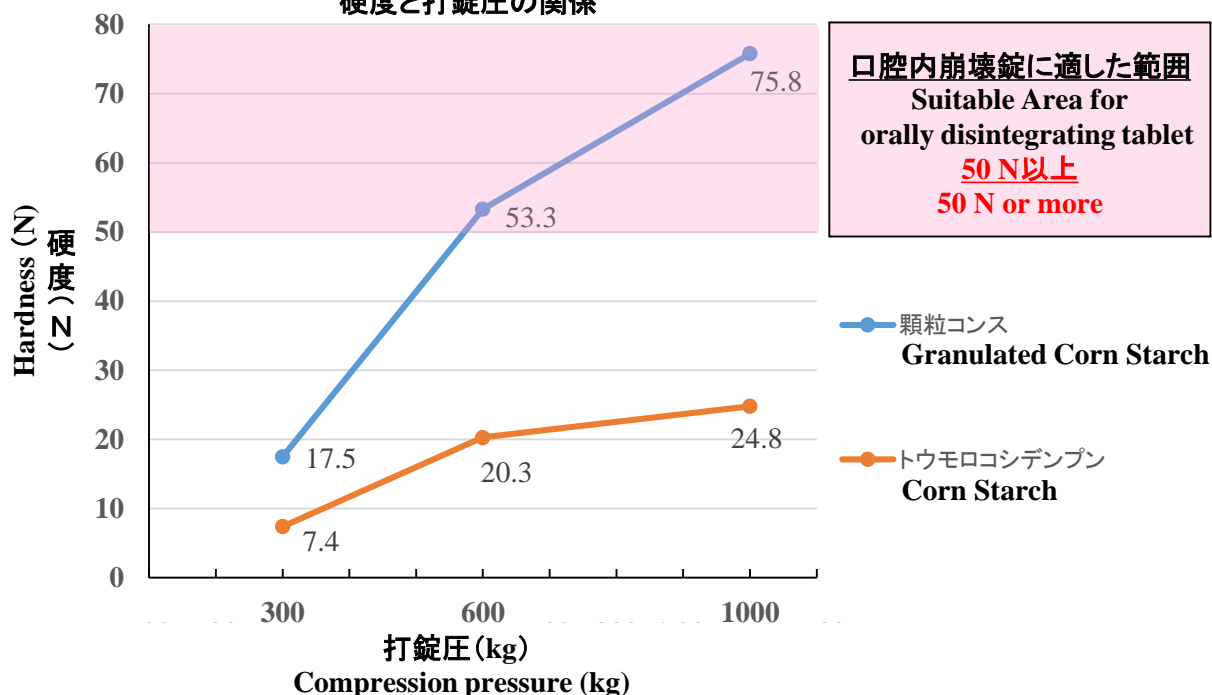
# 顆粒コンス直打錠の錠剤特性

Compression properties of Granulated Corn Starch in the direct tableting process

## 1. 硬度 Hardness

Hardness vs. Compression pressure

硬度と打錠圧の関係



|                      |  |
|----------------------|--|
| 打錠成型                 | フルオート単発式打錠機 AUTOTAB-500 (市橋精機 株式会社)<br>顆粒量: 200 mg, φ: 8 mm  |
| Making tablet        | Full auto single punch tableting AUTOTAB-500<br>Granules: 200 mg, φ: 8 mm (ICIHASHI SEIKI Co., Ltd.) |
| 硬度測定                 | ポータブルチェッカー PC-30 (岡田精工株式会社)  |
| Hardness Measurement | Portable Checker PC-30 (OKADA SEIKO Co., Ltd.)   |



顆粒コンスの直接打錠成型で、その後の包装、輸送、病院・薬局での取扱いに必要な十分な硬度の錠剤を製造可能

By compressing “Granulated Corn Starch” directly, it is possible to manufacture a tablet of sufficient hardness required for packing, transportation, and handling at a hospital or a pharmacy.

## 2. 口腔内崩壊性 Disintegration in the oral cavity

### A) ヒトでの試験

Studies in humans

口腔内崩壊時間: 25 秒

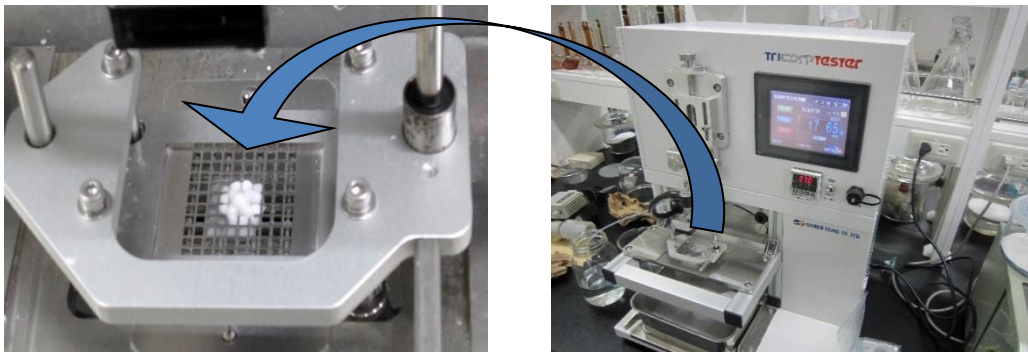
Oral disintegrating time: 25 seconds

口腔内崩壊後の舌触り、喉越し感: 良好

Texture after the collapse in oral cavity and throat sensation: Favorable

### B) 口腔内試験器での試験

Studies in oral disintegration tester



トリコープテスタ: 岡田精工(株)

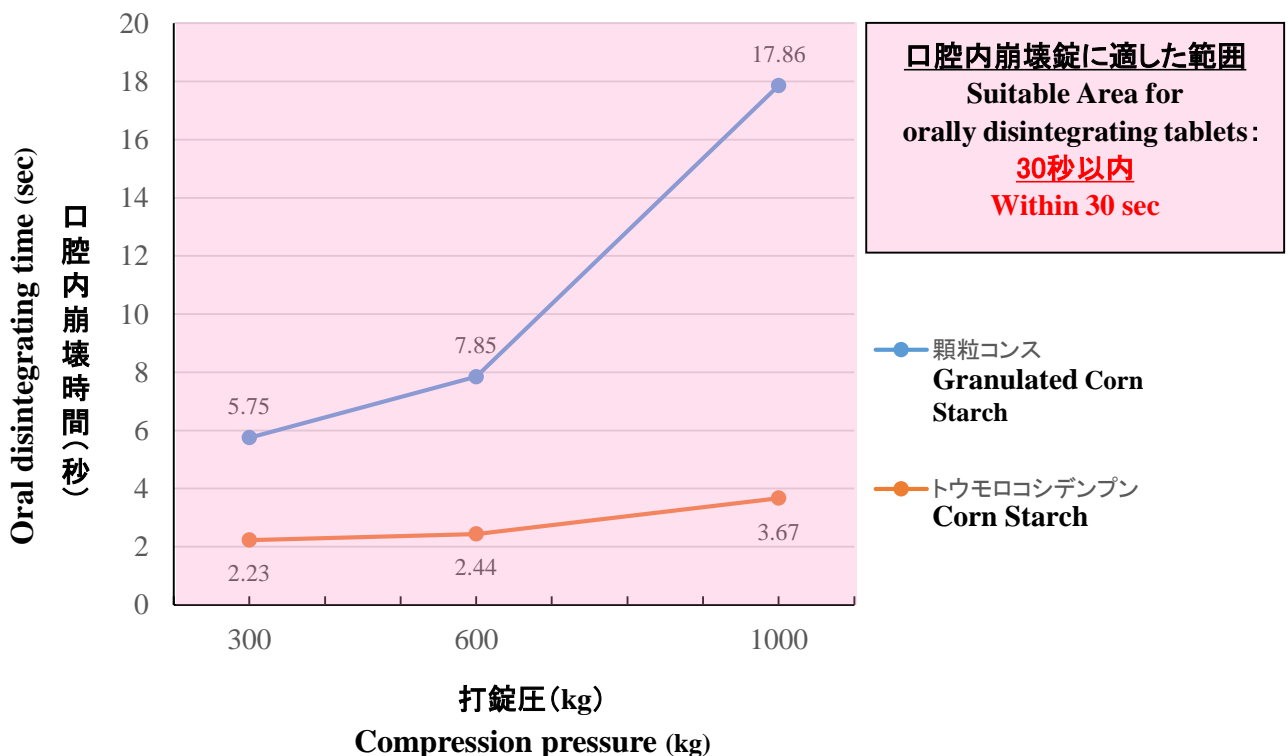
TRICORPTESTER: OKADA SEIKO Co., Ltd.

37°C 6 mL/min (人工唾液)

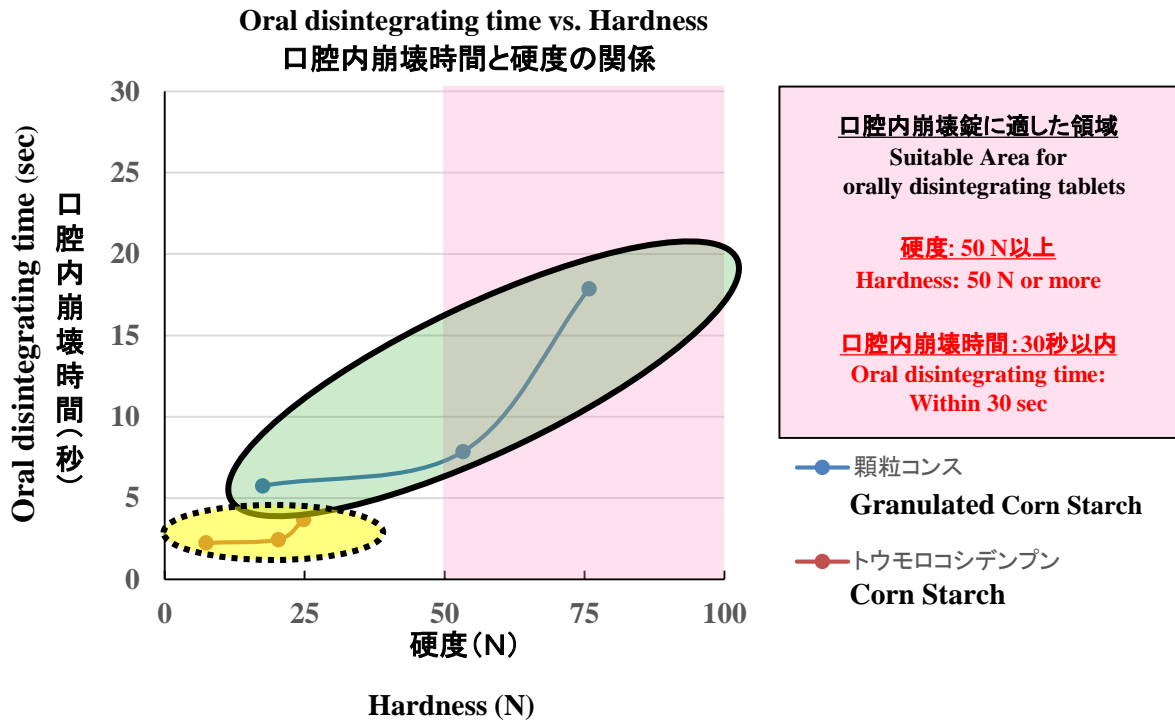
37°C 6 mL/min (Artificial saliva)

### Oral disintegrating time vs. Compression Pressure

口腔内崩壊時間と打錠圧の関係



### 3. 硬度-口腔内崩壊性 Hardness-Disintegration in the oral cavity



顆粒コンスは、直接打錠で十分な硬度と短い口腔内崩壊時間を実現し、口腔内崩壊錠の製造に適している。

Tablets of direct compressed "Granulated Corn Starch" realizes sufficient hardness and short collapse time in the mouth, therefore "Granulated Corn Starch" is suitable for manufacturing orally disintegrating tablets