

# NS-300<sup>®</sup>

Listed in 3Ps Name listed in JP : Carmellose  
 Name listed in USP-NF : Carmellose  
 Name listed in EP : Carmellose

US DMF Registered No. 19767  
 China DMF Registered No. F20180001743

## NS-300

- ▶ is a cellulosic disintegrant delivering superior Wicking performance.
- ▶ becomes water passage to impregnate water quickly into the inside of drug products.
- ▶ has no fear of residual solvents, as no organic solvent is used in the manufacturing process.
- ▶ is effective to shorten the disintegration time of OD tablets.

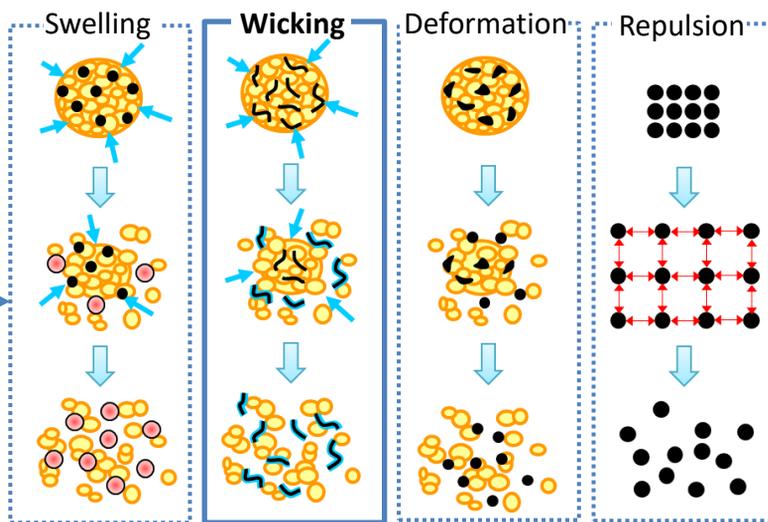
## The fundamentals of disintegration

References : Pharmaceutical Technology 5163 (1984)  
 : Pharmaceutical R&D, Vol.12 Drug material [1] 185-191P

Four types of disintegration mechanisms

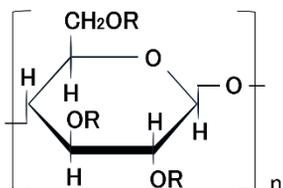
- Swelling -
- Wicking -
- Deformation -
- Repulsion -

NS-300 is a Wicking-type disintegrant.



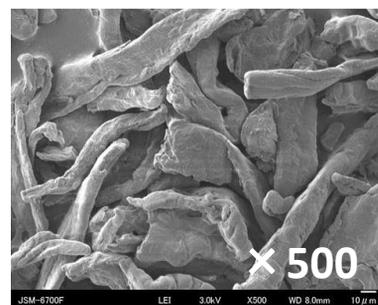
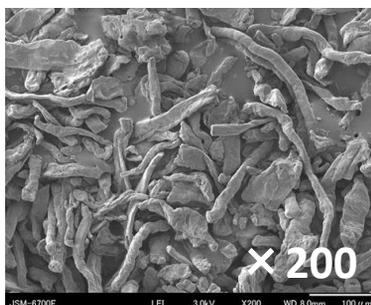
## Properties

### Chemical formula



$$R = (\text{H})_{3-x} \text{ or } (\text{CH}_2\text{COOH})_x$$

### SEM photos



### Standard values ▪ Physical properties of the powder

Loss on drying (%)	≤ 8.0	Particle size distribution *2	≤ 45μm (%)	39
pH	3.5~5.0		≤ 75μm (%)	67
Residue on ignition (%)	≤ 1.5		≤ 106μm (%)	83
Others: JP Test	Pass	Average particle diameter (μm) *2	54	
Loose bulk density (g/L) *1	387	Angle of repose (°) *1	45	
Tap density (g/L) *1	561	Hausner ratio *1	1.5	

\* 1 reference values, \* 2 Reference values (Laser diffraction measurement)

# An example of use : Application to OD tablets

Comparisons of disintegration were made between NS-300 and a Swelling-type disintegrant (E.C.G-505) by using excipients for direct tableting.

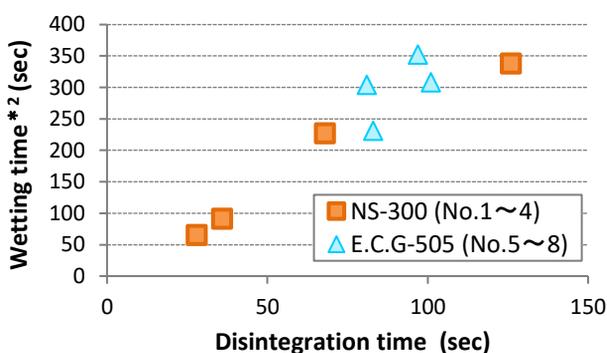
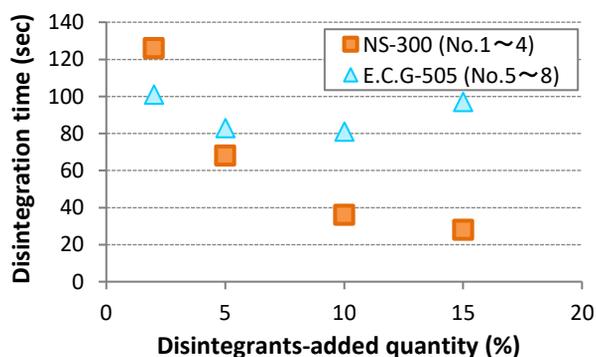
## 【 Experimental conditions 】

Raw : Mannitol (Parateck M200 Merck)  
 materials : Crystalline cellulose (CEOLUS PH-101 Asahi Kasei)  
 : Disintegrants (NS-300 & E.C.G-505 GOTOKU CHEMICAL)  
 : Magnesium Stearate (Wako Pure Chemical) \*1

Direct tableting method  
 Tablet size : 8.0 mm, R6.5  
 Tablet weight : 200 mg  
 Tableting machine : Hand press  
 Tableting pressure : 2.0MPa

## 【 Tablet composition 】

Added disintegrants	NS-300				E.C.G-505				
	Formulation No.	1	2	3	4	5	6	7	8
Mannitol	88 %	85 %	80 %	75 %	88 %	85 %	80 %	75 %	
Crystalline cellulose	10 %	10 %	10 %	10 %	10 %	10 %	10 %	10 %	10 %
Disintegrant	2 %	5 %	10 %	15 %	2 %	5 %	10 %	15 %	
Hardness (kgf)	11.0	9.8	10.3	8.8	12.5	11.8	10.1	9.6	



↳ **NS-300 shortened the disintegration time according to the increase of additive quantity.**

↳ **Disintegration time and wetting time \*2 were excellently correlative.**

★ The more the quantity of NS-300 is added, the more the contact points with water increase, which leads to the improvement of water-conducting feature of the tablet. A little larger quantity of NS-300 should be added than that of the Swelling-type disintegrant. **Approximately 10%** will be recommended.

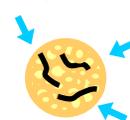
Disintegrant : **Proper quantity**



Contact points with water : Superior  
 → Conductive feature is Effective.

Contact points with water : Minor  
 → Conductive feature is Weak.

Disintegrant : **Minor**



\* 1 Adding 0.5% to the original quantity. \* 2 This means, "How long does it take after putting a tablet on a wetted sheet of paper until the tablet is wholly wetted?"

**Contact info for inquiries : Exclusive Distributor GOTOKU CHEMICAL CO., LTD.**

TEL : +81-3-3291-3331 E-mail : [contact@gotoku.co.jp](mailto:contact@gotoku.co.jp)

Stability monitoring data and SDS, etc. are available. Please feel free to request for them to us.

**Exclusive Distributor GOTOKU CHEMICAL CO., LTD.**

16-3, Kandaogawamachi, Chiyoda-ku, Tokyo 101-0052, JAPAN

TEL : +81-3-3291-3331 FAX : +81-3-3293-6577