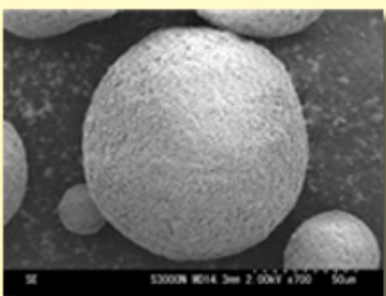




Neusilin® US2 is a fine ultra light granule of magnesium aluminometasilicate and is widely accepted as a multifunctional excipient that improves the quality of pharmaceuticals. Due to its large surface area and porous nature, US2 adsorbs high loads of oils or water and can be mechanically compacted into high quality tablets. Furthermore, Fuji's unique manufacturing expertise makes US2 neutral unlike traditional Magnesium aluminum silicates whose pH is alkaline. In this newsletter we introduce you to the best disintegrant combination with **Neusilin® US2** for tableting.

Neusilin® US2 (X700)



Chemical formula: $Al_2O_3 \cdot MgO \cdot 1.7SiO_2 \cdot xH_2O$

Chemical Abstract Service (CAS) Number: 12511-31-8

U.S. Drug Master File (DMF) filed

Typical Properties

PROPERTY	Grade US2 (Granule)
Loss on Drying (%)	1.4
Bulk Density - Loose (g/ml)	0.15
Bulk Density - Tapped (g/ml)	0.19
True Specific Gravity (g/ml)	2.2
BET Specific Surface Area (m ² /g)	300
Mean Particle Size (µm) (Agglomerate)	60 - 120
Angle of Repose (Degrees)	30
Oil Adsorbing Capacity (ml/g)	3.2
pH of 5% Slurry	7.4
Packaging (Kg)	10

Among excipients, disintegrants play an important role in disintegration and dissolution of tablets. This factor is critical for drug absorption *in vivo*. In order to give the

formulators the best choice of disintegrating agent in combination with **Neusilin® US2**, eight most common disintegrants were selected and their ability to quickly disintegrate compressed tablets was evaluated.

Disintegrants Used in Tableting

Carboxy methyl starch sodium (Explotab)	Croscarmellose sodium (Ac-Di-Sol)
Corn starch	Cross-link polyvinylpyrrolidone (Kollidon-CL)
Carmellose calcium (ECG-505)	Rice starch (Microperl)
Hydroxy propyl cellulose (LH-21)	Carboxy methyl cellulose (NS-300)

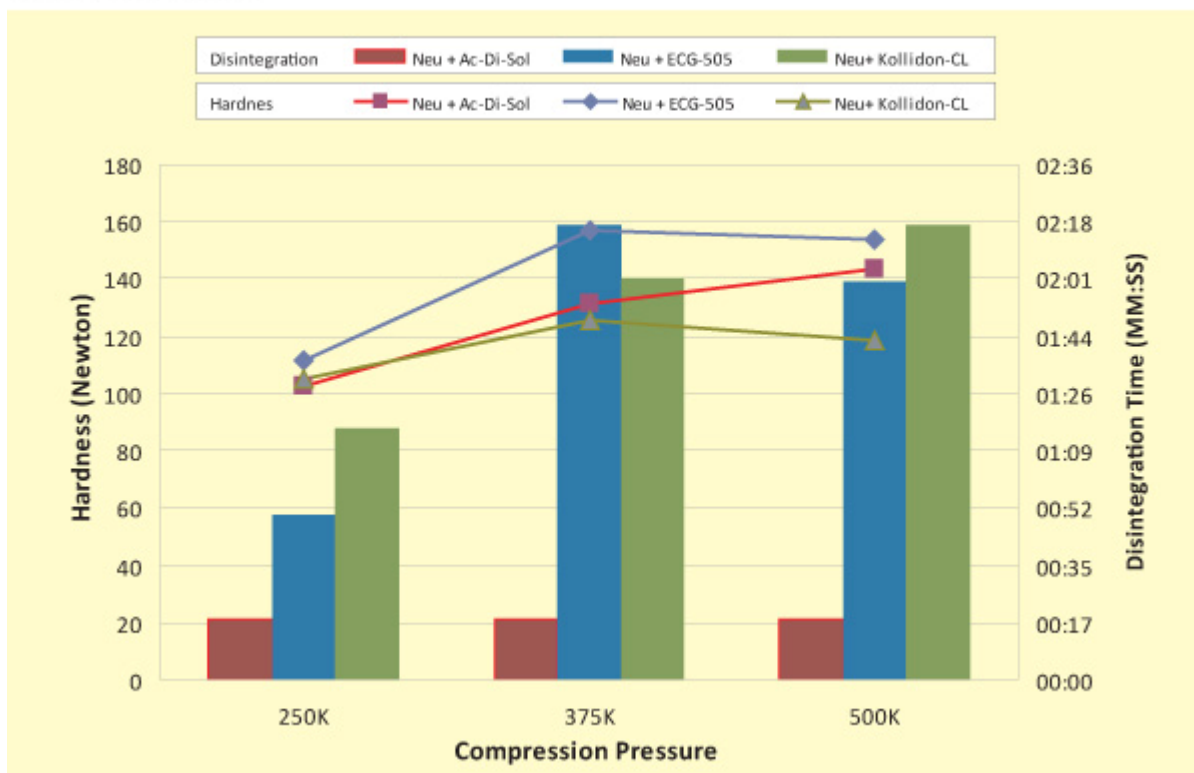
Formulation

Neusilin® US2 was compounded with 5% disintegrant and 1% Magnesium stearate. The mixture was compressed into tablets of 11 mm dia and 200mg weight in a rotary tableting machine. Disintegration test was carried out as per JP. To measure the disintegration time, one tablet is placed in each tube in the basket rack assembly containing six glass tubes, 7.75 cm long, open at the top and with a 1.8–2.2mm mesh, attached to the bottom. The assembly is positioned in a 1-liter beaker of water and maintained at 37°C. The basket rack is moved up and down at constant speed and the disintegration time was calculated as the time taken for the tablet to disintegrate and all the particles pass through the mesh screen. The results are summarized in the table given below.

Compression Pressure	Hardness (Newton) at			Tablet thickness (mm)at			Disintegration time (min:sec)		
	250K	375K	500K	250K	375K	500K	250K	375K	500K
Neusilin alone	108.7	142.1	161.3	5.191	4.559	4.187	> 30:00	> 30:00	> 30:00
Neu* + Explotab	95.9	130.1	144.8	5.064	4.478	4.12	> 30:00	> 30:00	> 30:00
Neu+ Corn Starch	107.5	105.8	94.7	5.033	4.483	4.126	> 30:00	> 30:00	> 30:00
Neu + ECG-505	111.4	156.9	154	5.022	4.493	4.124	00:50	02:17	02:00
Neu+ LH-21	105.8	119.1	135.5	5.027	4.47	4.108	15:47	25:11	19:47
Neu + Ac-Di-Sol	102.7	131.4	143.2	5.022	4.478	4.105	00:18	00:18	00:18
Neu+ Kollidon-CL	105.1	125.3	118.7	5.078	4.514	4.151	01:16	02:01	02:17
Neu + Microperl	94.8	115.4	134.3	5.084	4.501	4.131	>30:00	>30:00	>30:00
Neu + CMC	97.8	128.9	144	5.103	4.496	4.133	26:52	18:30	18:45

*Neu=Neusilin

Fig. 1. Disintegration time and Hardness of three best combination of disintegrants with Neusilin US2.



Among the common disintegrants used, the most compatible disintegrant with **Neusilin® US2** was found to be Croscarmellose sodium (Ac-Di-Sol) followed by Cross-link polyvinylpyrrolidone (Kollidon-CL) and Carmellose calcium (ECG-505). The Characteristics (large surface area and porous nature) of US2 and the cross linking of Croscarmellose sodium act synergistically allowing the tablet to swell and absorb many times its weight in water leading to quick disintegration. **Neusilin® US2** improves flowability and makes sufficiently hard tablets at low compression forces. Increase in hardness and compression pressure did not affect the disintegration time or tablet conformity when Croscarmellose sodium was used as a disintegrant.

As most of the starch type disintegrants does not go well with **Neusilin® US2**, Croscarmellose sodium is your best choice when you choose **Neusilin® US2** in your formulations.

Dosage and Safety:

Neusilin® is extremely safe with no reports of adverse reactions and is listed in the US Pharmacopeia/ National Formulary and Japanese Pharmaceutical Codex. Please consult Fuji technical sales team for your specific requirements.

Neusilin® is available in various grades to meet the diverse requirements of complex actives that can be converted to oral solid-dosage forms. To obtain a sample or to find your local distributor, please contact us at pharma@fujichemical.co.jp. For more technical information, please visit www.fujichemical.co.jp/english/neusilin.html

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