CEOLUS™
Just Pure Performance

AsahiKASEI

Low levels of colored particles

Reduction of technically unavoidable particles (TUPs) is one of challenges for pharmaceuticals and excipients suppliers because it may increase defective products or may create negative brand perception. On the other hand, TUPs are often found in microcrystalline cellulose (MCC) because of raw materials impurities or charring during the manufacturing process.

Our MCC products Ceolus™ shows low levels of TUPs because of our efforts including raw materials quality control, manufacturing equipment cleaning, in-process monitoring, installing particle removers and finished product testing.

We performed comparison of levels of colored particles (except white particles and transparent particles) in Ceolus™ MCC vs. other MCCs. This comparison clearly showed that Ceolus™ included lowest level of colored particles.

MCC products tested

PH-101	Ceolus™ Competitor A Competitor B – Grade B-1 Competitor B – Grade B-2 Competitor C
PH-102	Ceolus™ Competitor A Competitor B – Grade B-1 Competitor B – Grade B-2 Competitor C

Formulation

Ingredients	Ratio (wt. %)
MCC	99
Magnesium stearate (Mg-St)	1

Tablet size
200 mg, ø 8.0 mm

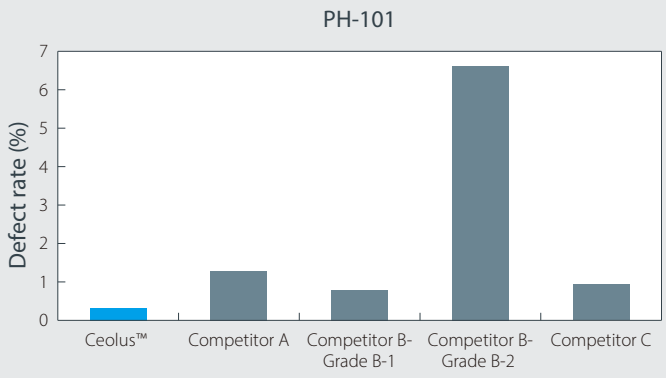
Tablet shape
Round tablets

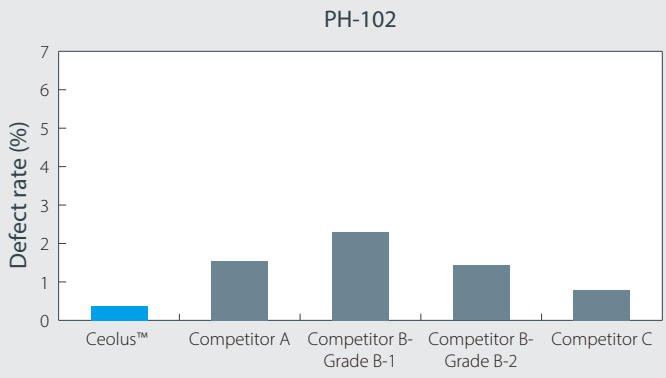
Number of tablets tested
About 11,000 per each MCC products

Date of test
October 28th, 2016

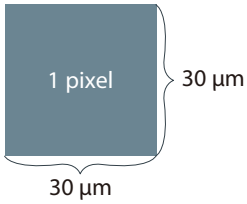
Results

Defective tablets rate
Ceolus™ achieved the lowest level of defective tablets rate.





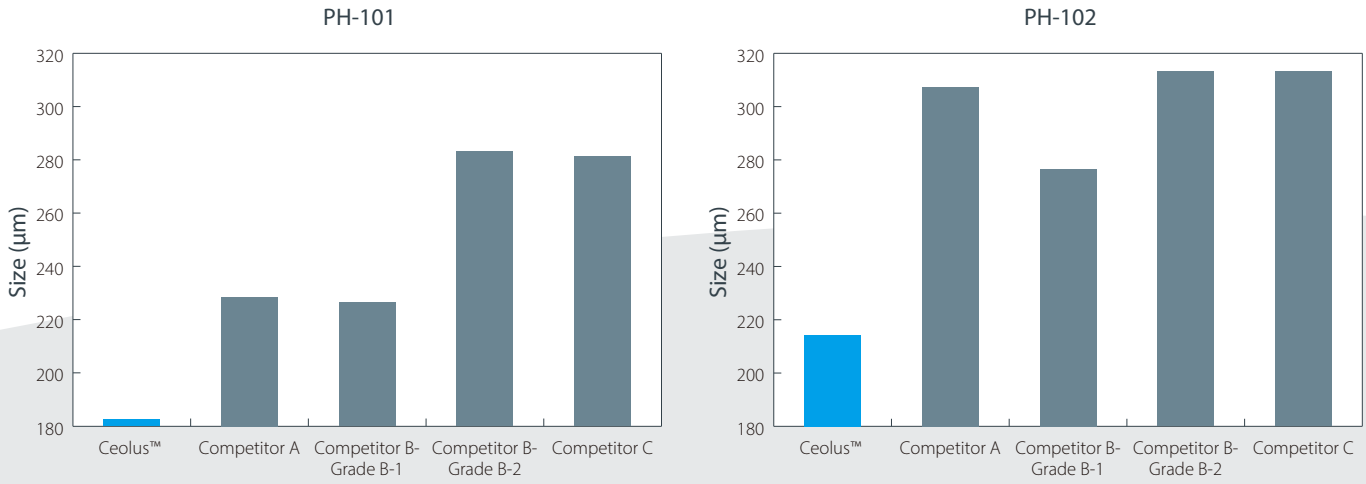
*Criteria of defective tablet
If one tablet includes 10 pixel or more colored particles, this tablet is recognized as the defective tablet.



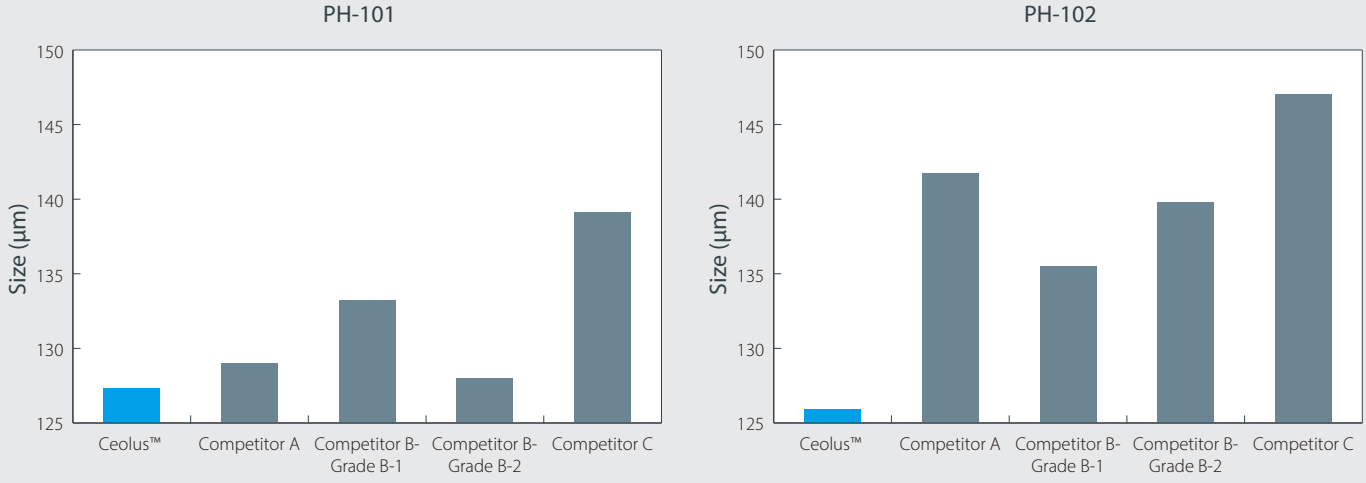
Size of colored particles in tablets

Tablets with Ceolus™ showed the lowest size of colored particles in tablets.

Maximum size



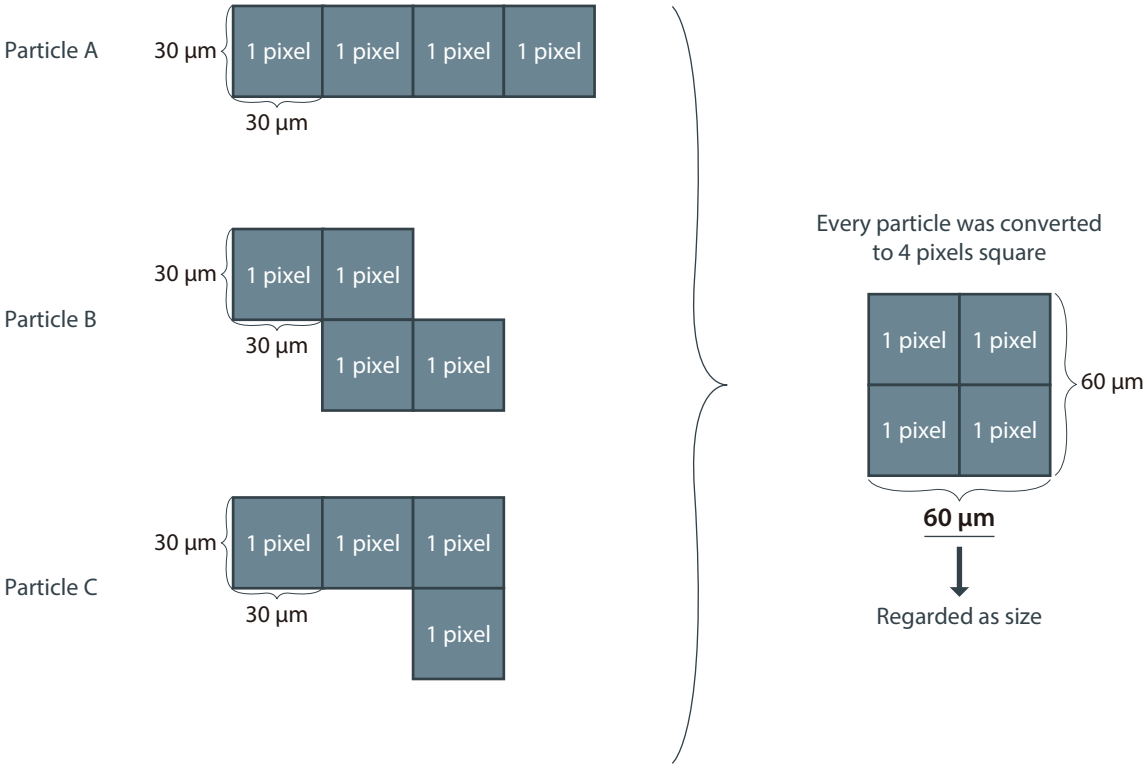
Average size



*How to calculate size

Total areas of colored particles detected were converted to one square and the length of one side on this square was regarded as the size.

e.g., 4 pixel particles



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