

Preventing the tableting issues and making very hard tablet of high dose Metformin HCl in direct compression using the most highly compactible microcrystalline cellulose (MCC) Ceolus™ KG-1000

OBJECTIVE

Ceolus™ KG-1000 is the most compactible Microcrystalline Cellulose (MCC). KG-1000 is useful for preventing the tableting issues such as capping and making very hard tablet (high hardness and low friability). It is more effective for high dose formulation of poorly compactible API. Metformin HCl is very popular as such kind of API.

The objective of this study is to investigate the effect of KG-1000 on the tablet characteristics in high dose Metformin HCl formulation in direct compression.

WHAT IS CEOLUS™ KG-1000?

KG-1000 has the world highest compactibility in all MCC grades.

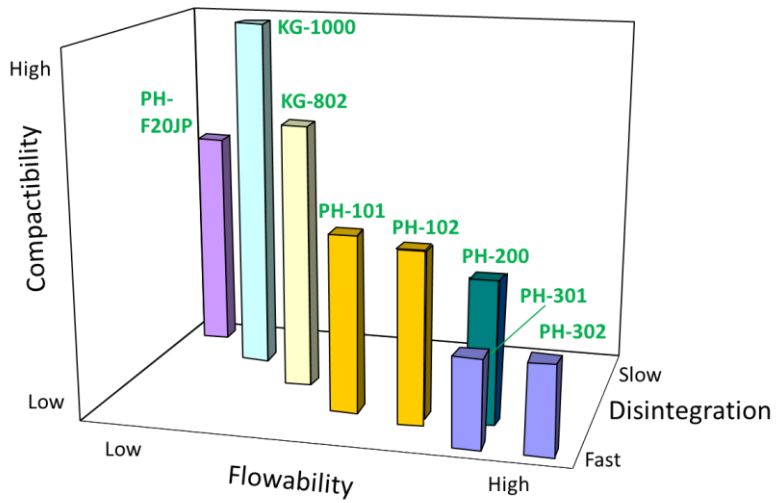
KG-1000 has the lowest bulk density which facilitates plastic deformation effectively.

KG-1000 particles have extremely large L/D value, the ratio of length to width of particle. These particles easily arrange perpendicularly to the applied force upon compaction.

Therefore, the contact area of the MCC particles is increased.

Powder properties

Fig.1 Powder properties of Ceolus™ grades

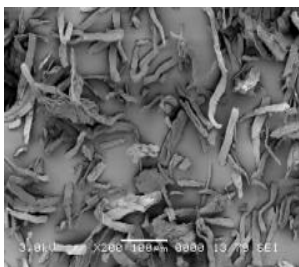


Tab.1 Powder properties of Ceolus™ grades

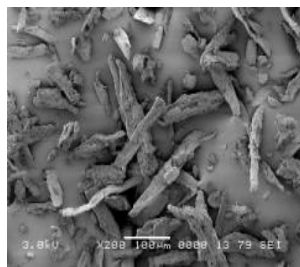
	Bulk density (g/cm ³)	Av. particle diameter (μm)	Repose Angle (°)	Oil absorbing capacity (wt%)
KG 1000	0.12	50	57	270
KG 802	0.21	50	49	200
PH F20JP	0.23	50	>60	180
PH 101	0.29	50	45	190
PH 102	0.30	100	42	180
PH 301	0.41	50	41	120
PH 302	0.42	100	38	120
PH 200	0.35	170	36	150

Particle morphology

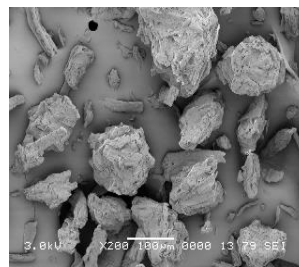
Fig.2 Powder morphology of Ceolus™ grades



Ceolus™ KG-1000

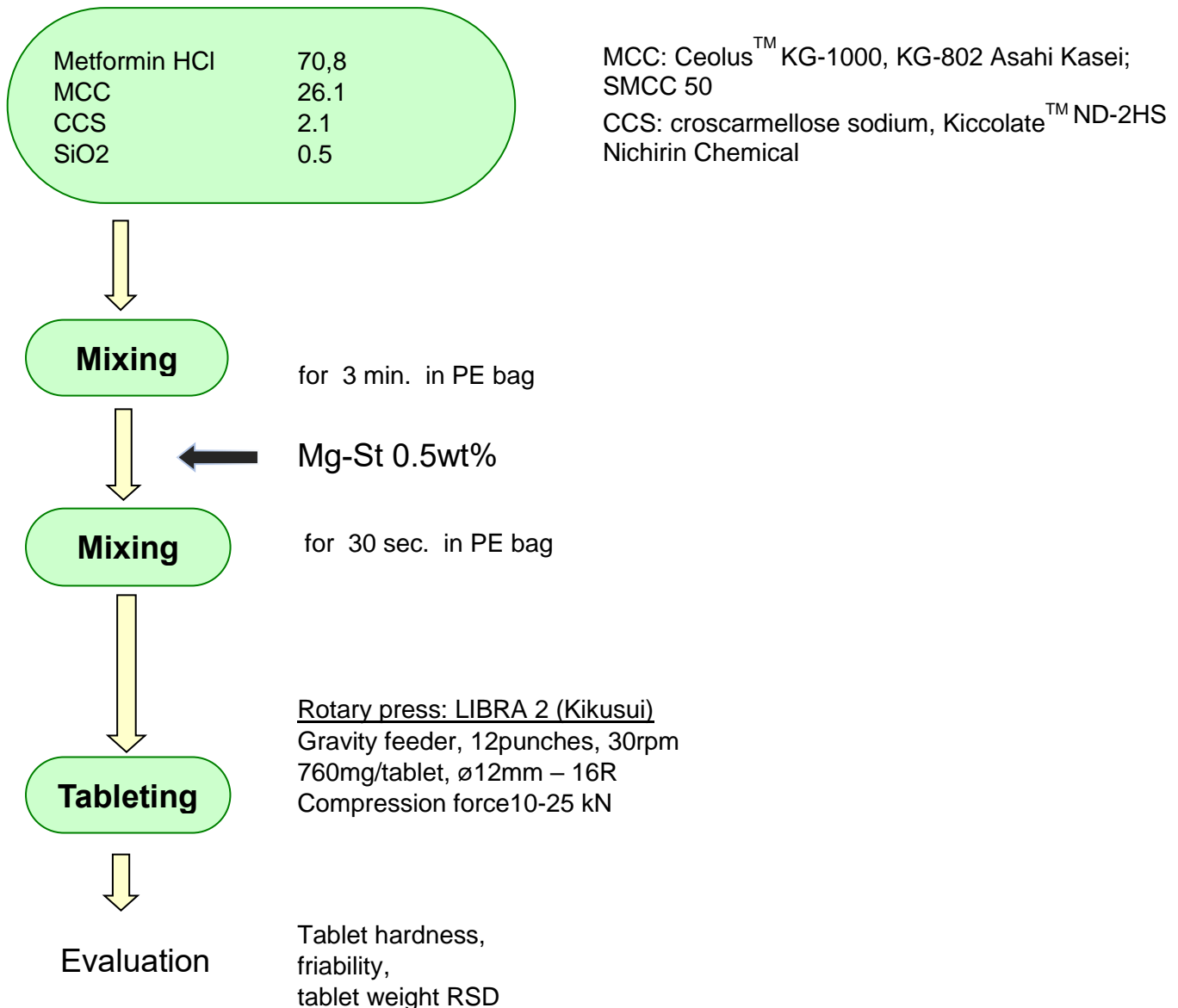


Ceolus™ KG-802



Ceolus™ PH-102

METHOD



RESULTS

- KG-1000 showed much higher tablet hardness than KG-802 and SMCC50.
- SMCC50 showed very high friability because all tablets occurred capping during friability test.
- KG-802 showed also high friability at high compression force.
- KG-1000 showed the lowest friability and reached below 0.2%, which is required in tablet coating.
- Tablet weight RSD of KG-1000 kept below 1%.

Fig.3 Force/hardness ratio

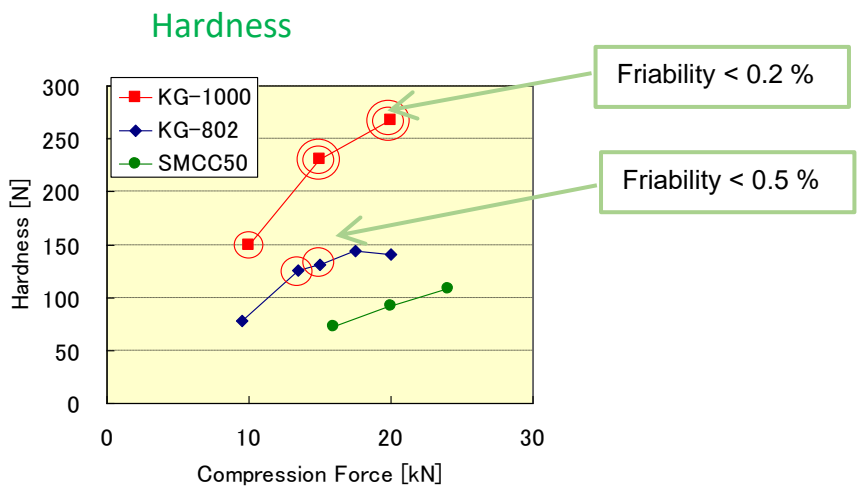


Fig.4 Tablet hardness & Friability correlation

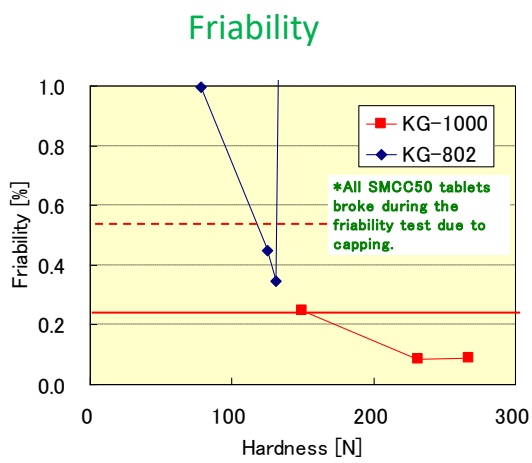
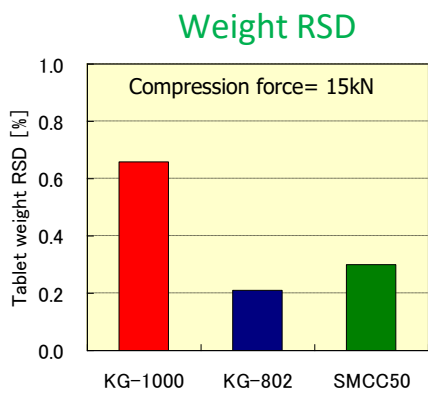


Fig.5 Weight RSD



CONCLUSION

Ceolus™ KG-1000 has the highest compactibility in all MCC grades due to its long fibrous particles.

This study investigated that Ceolus™ KG-1000 is the most effective MCC in preventing capping and making hard tablet of high dose Metformin HCl in direct compression.

REFERENCE

The data of this page is a property of Asahi Kasei Corporation.