Tricalcium Citrate - A New Brittle Tableting Excipient for Direct Compression and Dry Granulation with Enormous Hardness Yield

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Introduction: Brittle materials usually lead to tablets of inferior mechanical strength compared to plastic deforming materials. A brittle material exhibiting a high tabletability with the ability to retain that behaviour during recompression would represent a valuable alternative to the commonly used microcrystalline cellulose (MCC).

Aims: Tricalcium citrate (TCC) was characterized as a tableting excipient for direct compression (DC) and dry granulation (DG).

Methods: Powder properties of TCC were measured. Tablets of TCC and other common fillers were directly compressed for the purpose of compression analysis including speed dependency. Work hardening during DG was determined by roller compaction of TCC and subsequent tableting.

Results: TCC appears as an excellent flowing powder of large agglomerates consisting of lower micron to submicron platelets. Despite the brittle deformation mechanism (identified in a Heckel analysis; data not shown), TCC demonstrated a very high mechanical strength up to 11 MPa in conjunction with an astonishingly low solid fraction of 0.85 at a compression pressure of 400 MPa (data not shown). This was seen along with hardly any speed and lubricant sensitivity. Nevertheless, disintegration time was very short. TCC tablets suffered only a little from the re-compression: a slight loss in tensile strength of 1 - 2 MPa was observed for granules produced via roller compaction at meaningful process parameters. **Conclusions:** TCC was found to be suitable for DC as a predominantly brittle deforming filler, nevertheless demonstrating an enormous hardness yield while being independent of lubrication and tableting speed. TCC furthermore retained enough bonding capacity after DG to maintain this pronounced tabletability.

Keywords: Tricalcium citrate, material characterisation, direct compression, dry granulation, compression analysis, roller compaction, tabletability

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