

Draft Guidance on Talc

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Active Ingredient:	Talc
Dosage Form; Route:	Powder; intrapleural
Strength:	4 gm/vial
Recommended Study:	One option: in vitro

In vitro option:

Bioequivalence of the Test product may be established based on comparative in vitro characterization of three batches of both the Test and Reference Standard products.

1. Particle morphology. It is recommended that a suitable method for qualitative determination be used to allow observation of particles, including in the size range in which talc particles are expected to fall. Representative micrographs should be submitted. These data are supportive, and formal statistical testing is not applicable.
2. Particle size distribution. Particle size distribution should be compared using the population bioequivalence (PBE) statistical procedure (95% upper confidence bound) based on D50 and SPAN [i.e., (D90-D10)/D50]. Refer to the product-specific Guidance on Budesonide inhalation suspension for additional information regarding PBE. The applicants should provide no less than 10 datasets from 3 batches each of the Test and Reference products to be used in the PBE analysis.

Dissolution test method and sampling times: Not applicable.