



EARLY DEVELOPMENT API CHARACTERISATION

Need help to understand the functional properties of your Active Pharmaceutical Ingredient (API)? Want to know how to apply this information to help you formulate better? Look no further, read on to find out how the scientists at Merlin Powder Characterisation can help

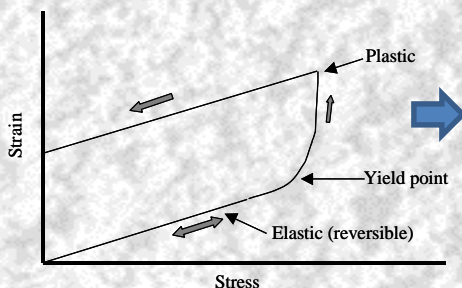
We can help you improve your tablet formulations by:

- Using 3-5 g of API to assess the key functional properties of your API: compressibility, compactability and true density.
- Categorising the material to help the formulator understand: key risks to successful development and barriers to scale-up.

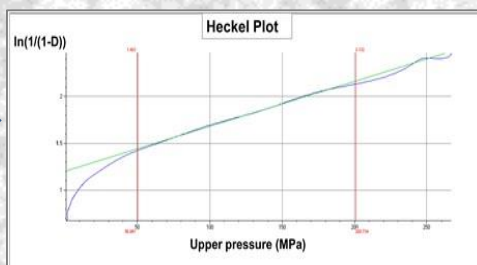
How do we do it?

Compressibility Tests:

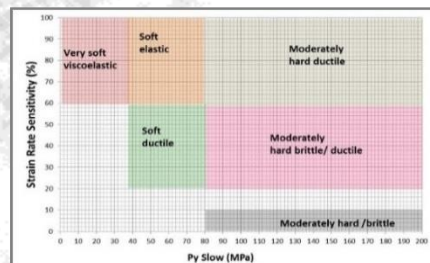
- Heckel Analysis at slow compression speed and production punch speeds to calculate yield pressures.
- Strain Rate Sensitivity (%) measures the change in yield pressure between slow compression speed and production punch speed.
- True density of API measured using Helium Pycnometry.



Particle Deformation – the test compresses the API or excipient until it yields.



Heckel Analysis – calculates the average yield pressure of the API or excipient.



Strain Rate Sensitivity (SRS) – gives an indication of the risk of scale-up on the material characteristics of the API. Categorise the API according to yield pressure and SRS to compare properties with other materials.

So how does this help you as a formulator?

- Once you know how the material behaves, you can assess the different methods of tablet formulation e.g. direct compression, roller compaction, wet granulation and rule out any incompatible methods up front.
- You can formulate with excipients to compliment the API properties i.e. balance properties and limit problem characteristics
- Flag early if the material is susceptible to speed sensitivity. This will need to be reduced if successful scale-up is to be achieved during the development process.

References

R.W. Heckel, 1961, Transactions of the metallurgical society of AIME, 221, Oct, pp1001-1008
R. Roberts & R. Roe, Chemical Engineering Science V42, 4 903-911 (1987)

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