Quantification in Solid Mixtures

the minispec Form Check

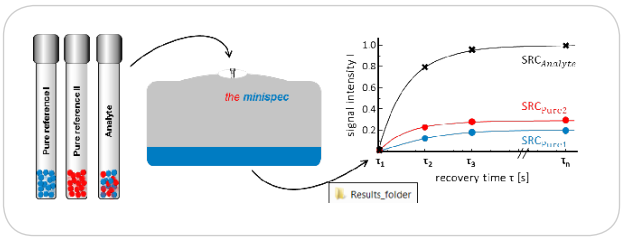
Quantification of components in complex solid mixtures like formulated pharmaceuticals (drug product) is crucial for the pharmaceutical industry and generally in materials science.[1] However, the quantification of relative amounts of API polymorphs and the corresponding amorphous forms in the presence of excipients is not a straighforward proposition. Current methods include spectroscopic, thermometric and x-ray techniques and often require laborious calibrations, are expensive or may lack the required accuracy. Designed to overcome these obstacles, Bruker's new the minispec Form Check enables easy and affordable quantification of API polymorphs, drug loading and amorphous content in solid mixtures. For the patented approach Bruker makes use of the minispec mq20 Time-Domain NMR benchtop instrument combined with the well established Dynamics Center software.

[1]Stueber D. and Jehle S., Journal of Pharmaceutical Sciences, Volume 106 , Issue 7 , 1828 - 1838.

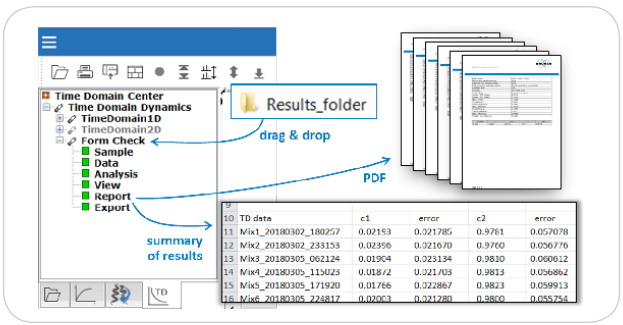
the minispec Form Check Benefits

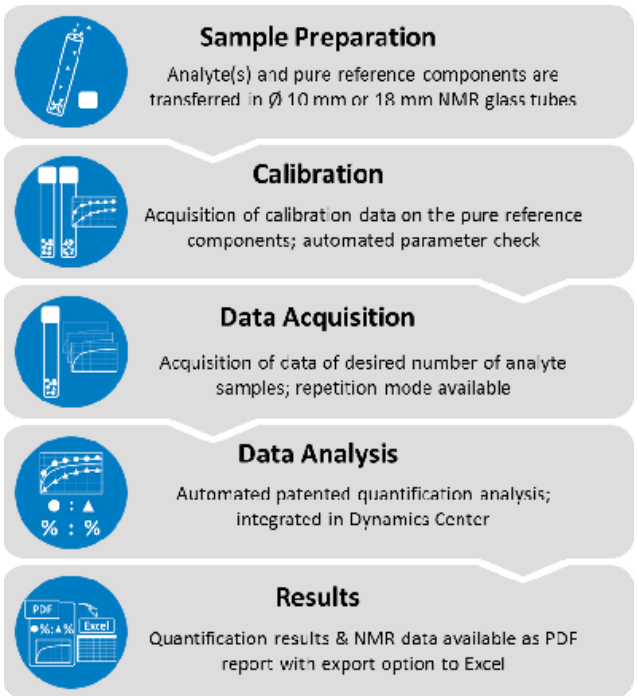
- the minispec mq20: small footprint, cryogen-free, versatile, low cost of ownership
- Accurate quantification of the API lead form in the presence of other polymorphs, amorphous material or excipients
- No requirements regarding sample texture or homogeneity (tablets, gels, polymers)
- Ease-of-use: non-expert workflow
- Minimal sample preparation & calibration
- Automated & patented quantification analysis
- Non-destructive & non-invasive: samples can be re-used for other purposes

the minispec Form Check enables quantification by comparing ^{1}H or ^{19}F Saturation Recovery Curves (SRCs) of pure components or even excipients with those of the analyte of interest. As the SRCs of the pure components are only used as fingerprints, the method is independent from different T_1 contributions, allowing also to investigate more complex mixtures like API and excipients.



In the Dynamics Center, the SRCs are automatically fitted using the patent-pending linear-combination approach to reveal the relative mass percentages of the reference components in the analyte.
This new benchtop solution supersedes excessive calibration, delicate sample preparation and a high level of expert knowledge.





Options at a Glance

- ^{1}H or ^{19}F
- 10 mm or 18 mm diameter glass tubes
- Variable temperature (+5 to +65°C) options
- Upgrades to research mode and sample automation possible

Bruker BioSpin
info@bruker.com
www.bruker.com