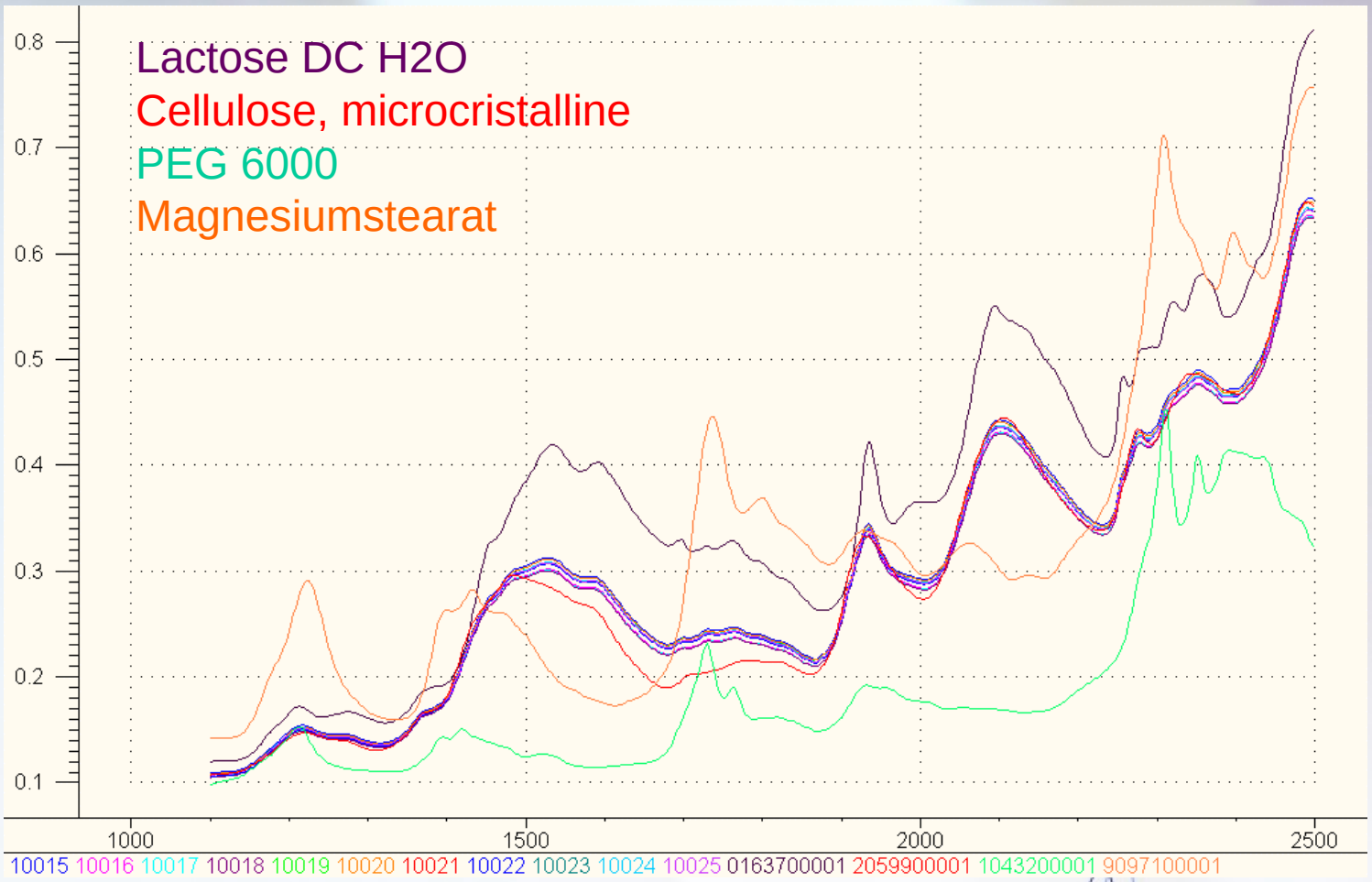
Verification of content uniformity in *Hypericum perforatum* powder blends

Background

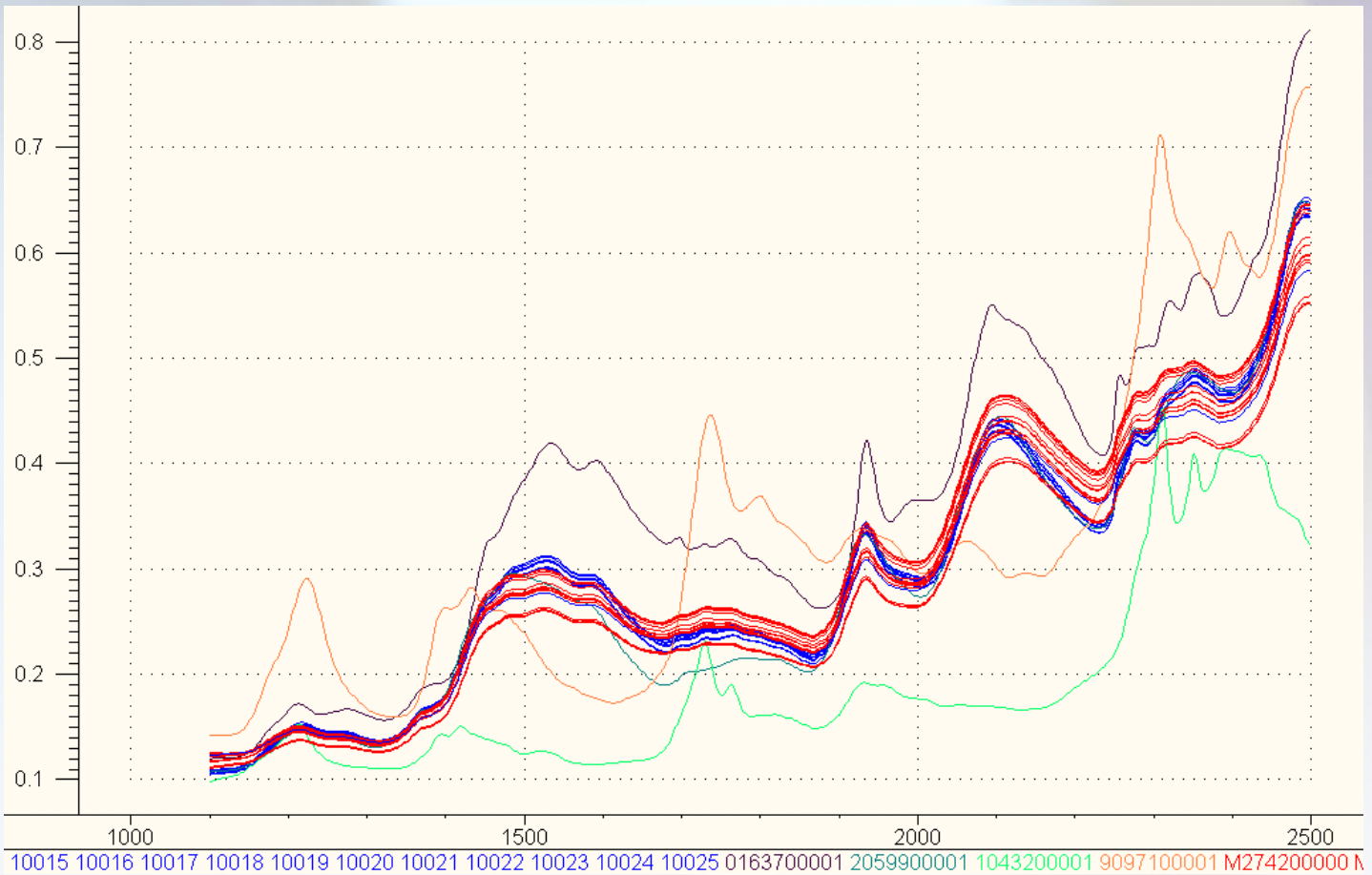
Example formulation of Hypericum perforatum tablets:

Hyperici herba	463,00
Lactose	225,90
Cellulose	285,20
PEG 6000	18,5
Magnesiumstearat	7,40
Σ	1000,00

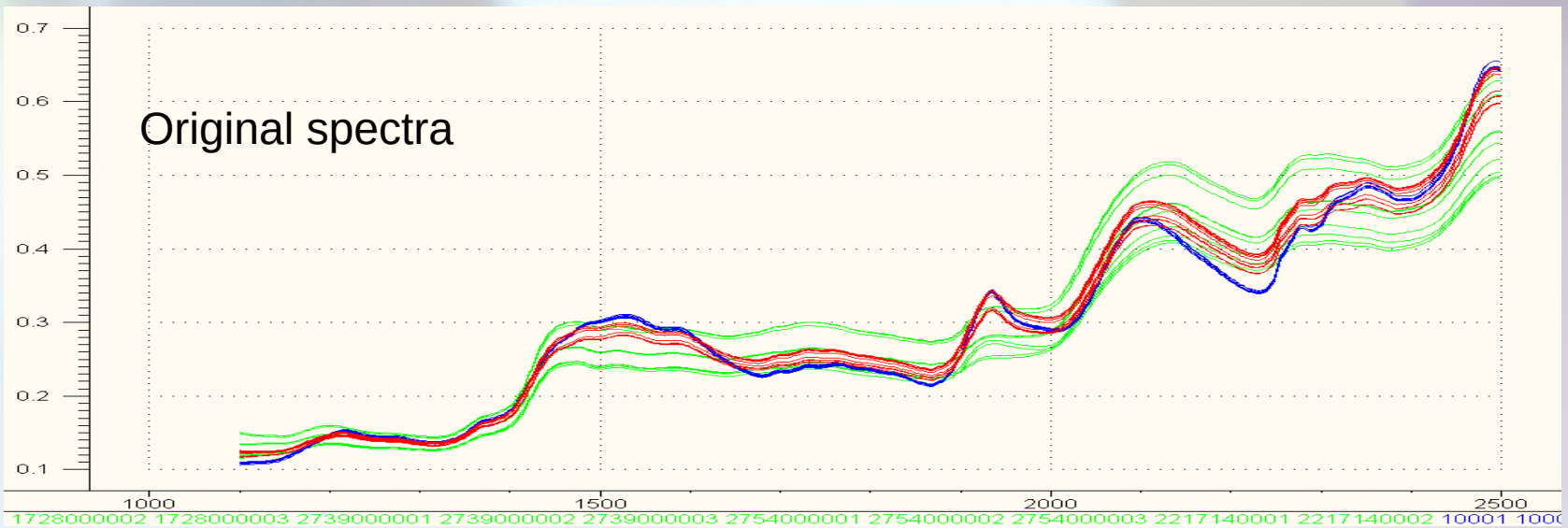
Spectra of the excipients and a „placebo“ powder blend

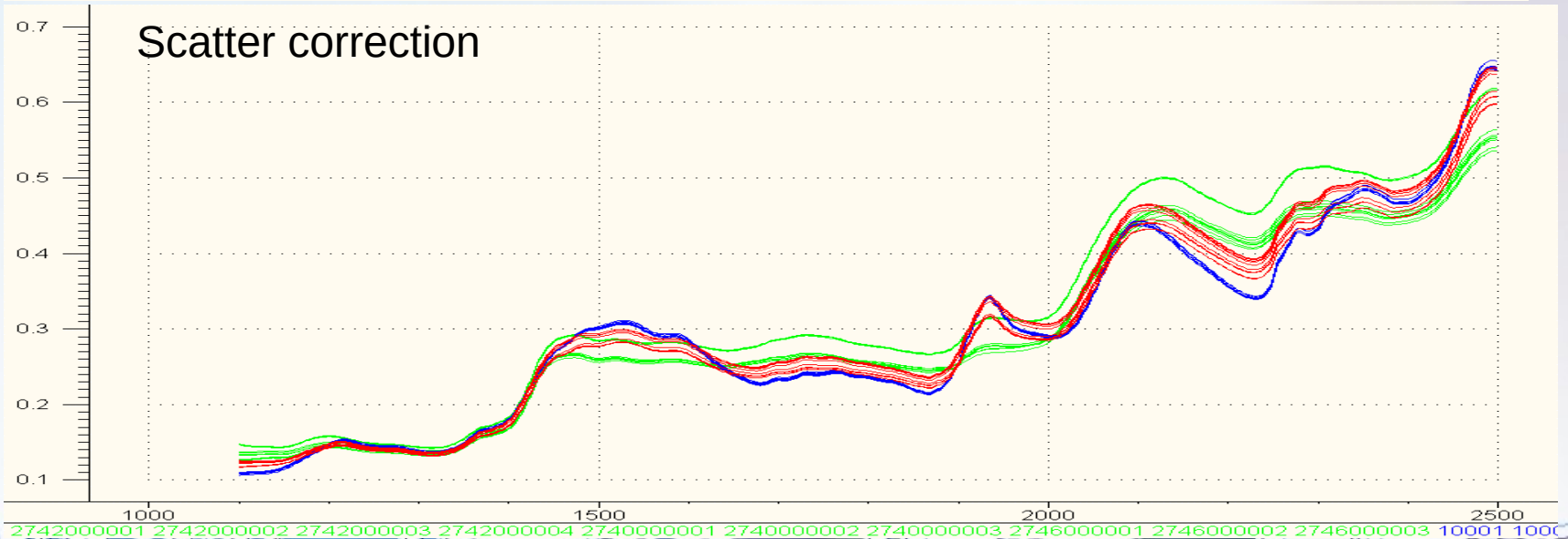


Original spectra: Excipients, placebo blend and complete compaction blend



NIR spectra: extracts, placebo blend, compaction blends

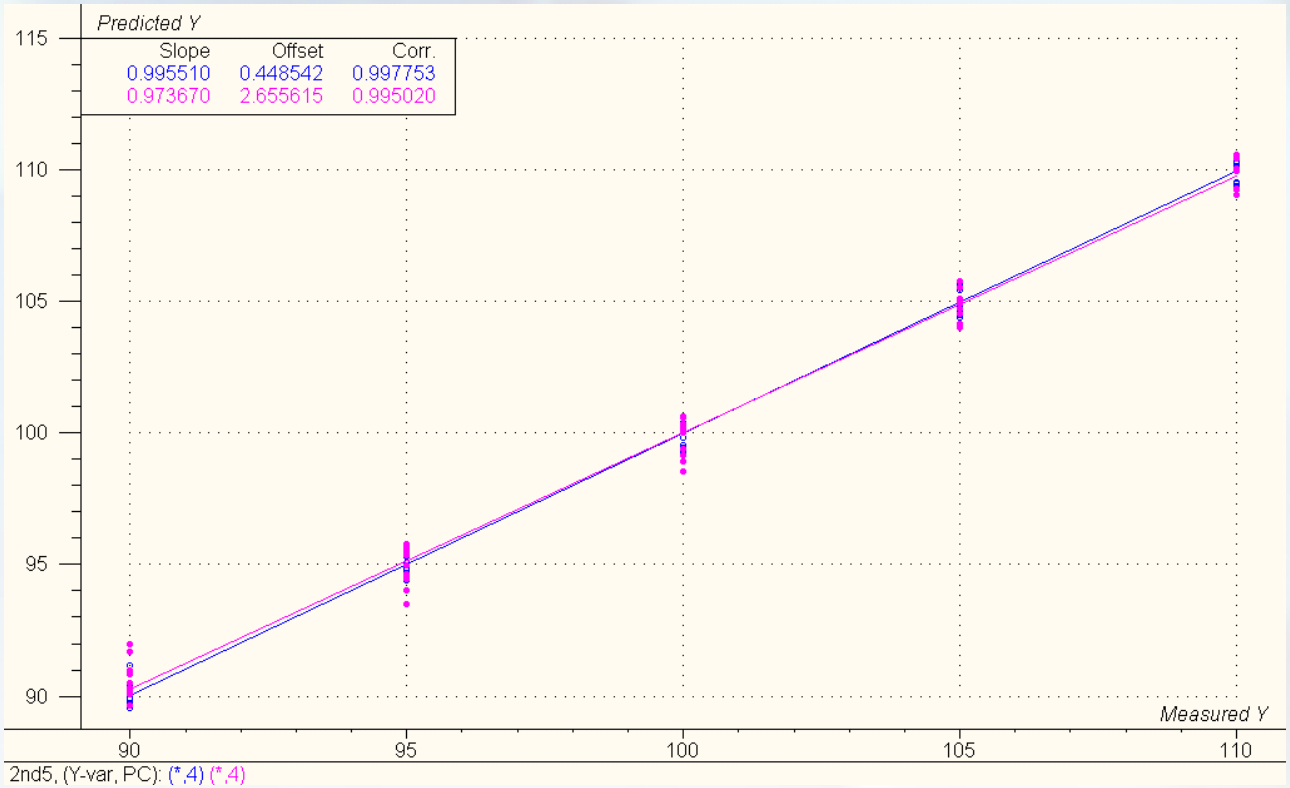




Example: **Verification of content uniformity for 11 *Hypericum perforatum* powder blends**

- Configuration of a simple calibration model:
  - Three different *H. perforatum* extracts
  - Five point calibration (90, 95, 100, 105 and 110 % content of extract compared to the original compaction blend
- Prediction of the content for another eight extracts
- Comparison to the original values

Calibration model for different compaction blends



RMSEC: 0.4714
RMSEP: 0

PLS; 4PC

Prediction of new powder blends

	Predicted (%)	Deviation	Original (%)
1	97.673	1.529	98.2
2	99.658	1.858	100.0
3	99.293	1.619	99.4
4	100.234	1.316	99.8
5	100.832	1.596	100.1
6	103.817	1.435	100.9

Conclusion and Outlook

- By means of NIRS we can quantify „mixtures“ within „mixtures“
- Due to the short measurement time, many samples can be analysed
- The training set has to cover the whole expected determination range

- Next step:

  creating a calibration model for the tablets!

Where are the limits?

- Every calibration model can be applied only to those samples that are characterised in the training set
- The model has to be „cultivated“
- We need a new model for every step in the production process

BUT:

One routine measurement should require 1 minute!