CONTENT UNIFORMITY OF SODIUM BENZOATE CAPSULES: VALIDATION OF A METHOD USING QCPREP®

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3PC-012

CONTEXT

Pediatric formulation of **sodium benzoate** for patients with urea cycle disorders:
250 mg **capsules** of pure active ingredient (AI), without excipients **made in our pharmacy**

AI content control is mandatory

OBJECTIVE

Develop and validate a **dosage method** of active ingredient to perform routine capsule content testing using **UV/Raman spectrophotometry**

MATERIAL AND METHOD

According ICH-Q2-R1 criteria:

Preferred absorption band
Maximum correlation between absorbance and linearity

Linearity
Detection limit: 2.5 and 50.0 mg/mL
Validation criteria:
- linear regression of the calibration curve
- correlation coefficient (r^2) > 0.999

Repeatability
6 analysis for the routine dosage concentration (RDC): 25 mg/mL
Validation criteria: CV < 2%

Intermediate precision
Repeated analysis (n=3) on 3 different days for the RDC (25mg/mL)
Validation criteria: CV < 5%

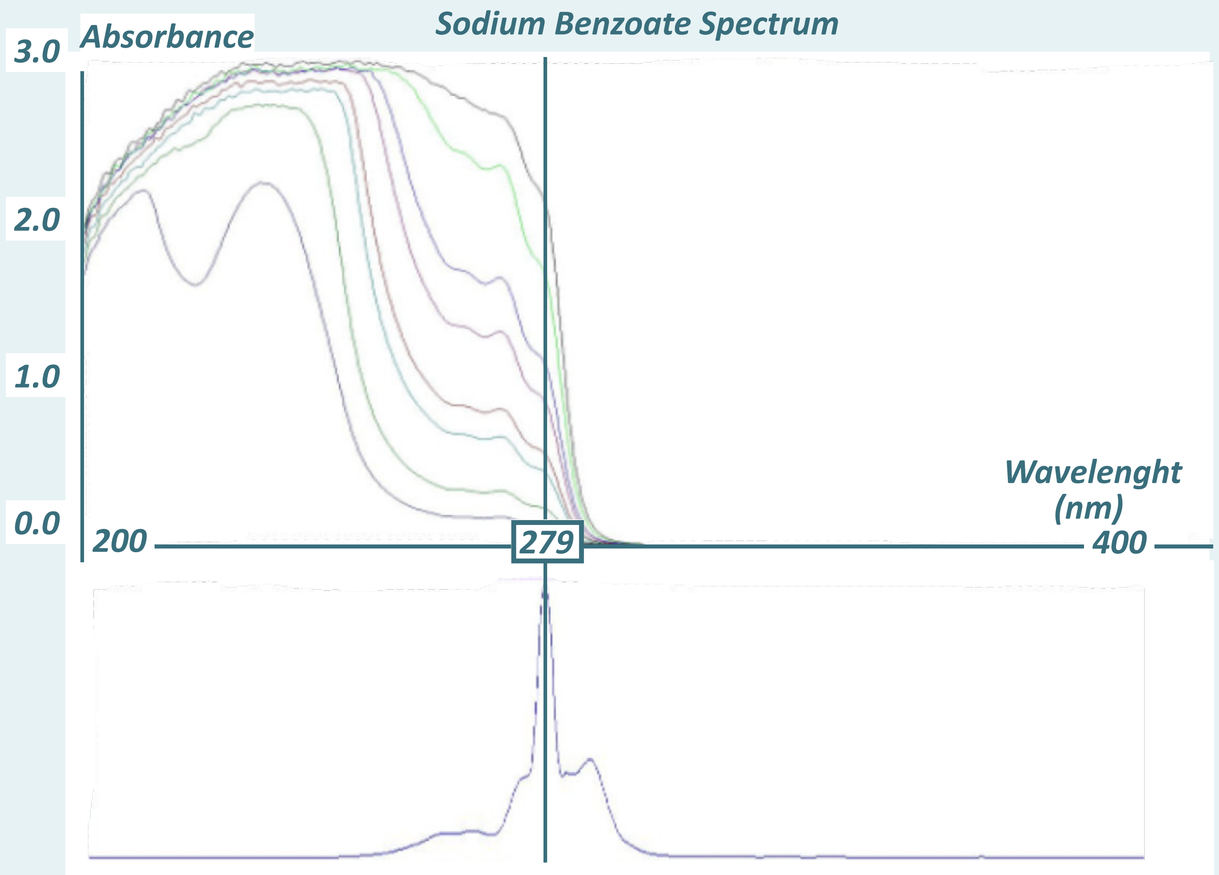
Accuracy
3 concentrations: 75%, 100%, and 125% of the RDC (n=3 per concentration)
Validation criteria: Deviation < 5% of the expected value

Specificity
Not assessed due to the exclusive composition of the capsules with the AI

Qc-Prep®
UV/Raman spectrophotometer

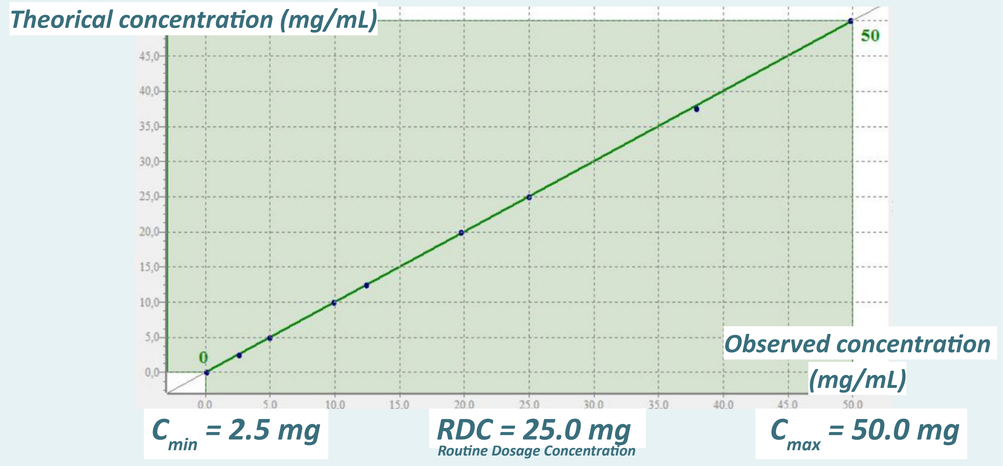
RESULTS

Preferred absorption band

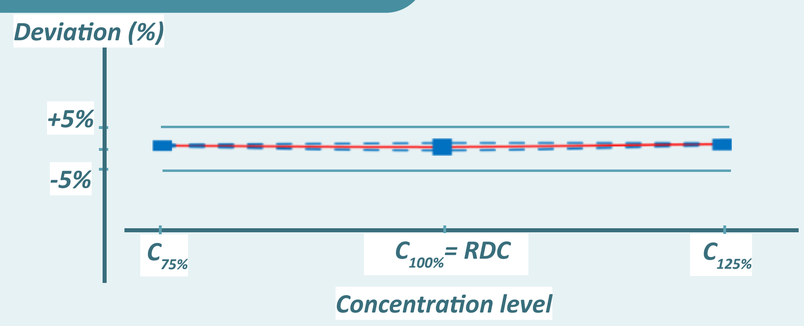


Absorbance and linearity correlation curve

Linearity



Accuracy profile



Linearity	Repetability	Intermediate Precision	Accuracy
r^2 = 0,99993	CV = 1.94 %	CV = 0.99 %	$c_{75\%}$ = 0.7 % $c_{100\%}$ = 0.5 % $c_{125\%}$ = 1.1 %

Table of method validation criteria

CONCLUSION / DISCUSSION

Dosage Method Validated
Has demonstrated linearity, repeatability, intermediate precision, and accuracy

Qc-Prep®
User-friendly, fast, and reliable for the routine content uniformity control of our preparations

Perspectives
Implementation of this pre-release control will be continued for other preparations