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Development and validation of an analytical method for the dosage of clonidine capsule by HPLC-UV

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Introduction

- Clonidine used to diagnostic of growth hormone deficiency in child
- Not any commercially available oral dosage forms allowing to perform adequate dosing in this population (0.15 mg/m²)
- Compounds clonidine capsules from powder

Objective → Develop an analytical method to perform uniformity of content assay of compounded clonidine capsules

Materials and Methods

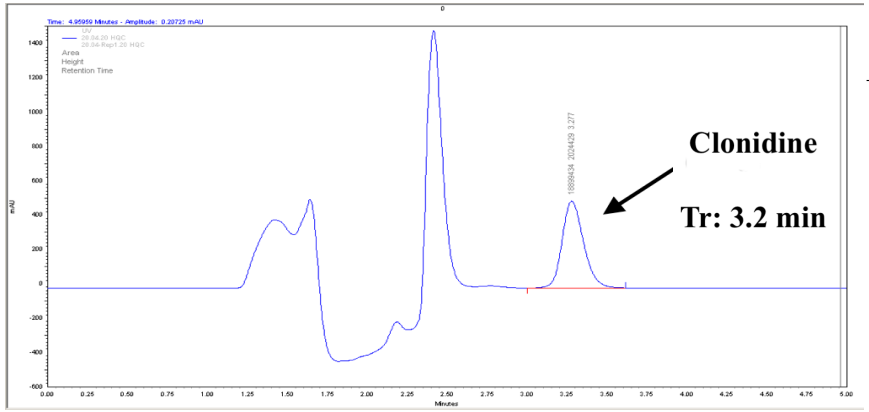
- Chemical analysis by HPLC-UV:

Mobile phase	Flow rate	Column	Wavelenght
acetonitrile/ultrapure water (25/75; v/v) with 0.1% TFA	1mL/min	Purospher® STAR RP-18 endcapped (5µm) 150x4.6 mm	210nm

- Validation of method: ICH Q2 R(1) international guideline:
  → linearity, accuracy (precision and trueness)
- Range: 3.125 to 50µg/mL
- 3 levels quality controls (Low: 3.125µg/mL; Medium: 12.5µg/mL and High: 50µg/mL)
- The analytical method was applied on a batch of clonidine capsules according to the European Pharmacopeia (2.9.40)

Results & discussion

- **Equation of the regression line Y= 386566(±10851)X + 63579 (± 52891)**



	QC Low	QC Medium	QC High
Repetability (CV%)	2.73	1.66	3.22
Intermediate Precision (CV%)	4.65	2.71	3.34
Trueness intraday (CV%)	0.57	-0.86	2.76
Trueness interday (CV%)	0.15	0.33	0.98

- Application of the analytical method showed that our batch did not meet the criteria of the EP, demonstrating the interest in developing this analytical method to avoid dosing errors
- Choice of our calibration range → allows us to dose the capsules that we produce the most (0.15 and 0.03mg)

Conclusion

- The analytical method showed adequate linearity and accuracy
- The method was successfully applied to the routine estimation of clonidine due to its **simplicity**, **rapidness** (analysis time less than 5min), and **high precision**
- This will allow to perform control on our clonidine capsules and improve the quality of our preparations