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Development and validation of an analytical method for the assessment of methyl and propylparaben by HPLC-UV

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Introduction

- Parabens are the most common preservative agents.
- Although they are endocrine disruptors, these compounds are found in many commercialized medicines and pharmaceutical preparations, leading to safety concern when these medications are administered.
- Maximum Acceptable Daily Intake (MADI): 10mg/Kg/day

Objective: Develop an analytical method to perform content assay of methylparaben (MP) and propylparaben (PB) in pharmaceutical to ensure the lowest possible content.

Materials and Methods

- Chemical analysis by HPLC-UV:

Mobile phase	Flow rate	Column	Wavelenght
acetonitrile/ultrapure water (50/50; v/v)	1mL/min	Purospher® STAR RP-18 endcapped (5µm) 150x4.6 mm	254nm

Table 1 : Chromatographic conditions

- Validation of method: ICH Q2 R(1) international guideline:
  → linearity, accuracy (precision and trueness) and specificity
- Range: 0.03 to 1µg/mL
- 3 levels quality controls (Low: 0.03µg/mL; Medium: 0.125µg/mL and High: 1µg/mL)

Results & discussion

- **Equation of regressions lines :**
  - MP : y = 311.47(±8.22)x + 0,474 (± 0.485)
  - PP : y = 3254.71(±4.95)x + 0,546 (± 0.223)

	QC Low		QC Medium		QC High	
	MP	PP	MP	PP	MP	PP
Repetability (CV%)	3.59	3.56	5.33	2.44	2.52	2.61
Intermediate Precision (CV%)	6.43	6.13	5.74	3.91	3.96	3.94
Trueness intraday (CV%)	6.18	2.11	1.52	0.38	1.08	3.51
Trueness interday (CV%)	2.56	-0.41	0.64	0.31	-1.05	2.50

Table 2 : Validation parameters of the methods

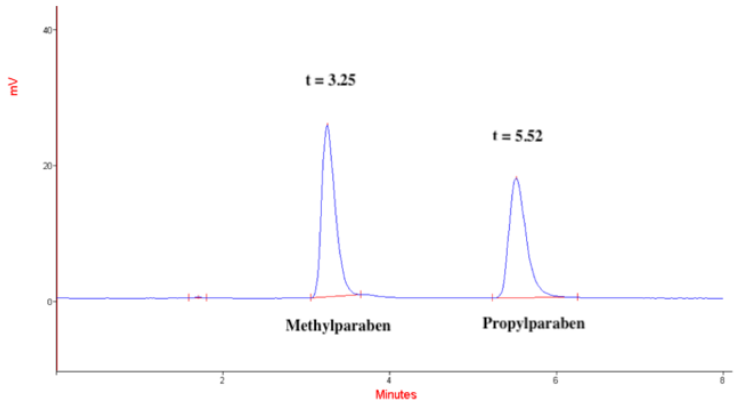

figure 1 : Chromatogram of a solution of MP and PP at 1 µg/mL

- Interest in developing our assay method in order to control the paraben content of preparations that are released.
- MP and PP were chosen because they are the most commonly found.

Conclusion

- The analytical method showed adequate linearity, accuracy and specificity.
- The method was successfully applied to the routine estimation of MP and PP due to its **simplicity**, **rapidness** (analysis time less than 7min), and **high precision.**
- This will allow to perform control on our compounded and improve the safety of our preparations.