The advantages of UV-Raman spectroscopy for checking the strength of nalbuphine preparations

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Objectives :

To check paediatric nalbuphine formulations with a simple, fast and reliable method by using UV-raman spectroscopy.

Methods :

In order to validate a method using the QC-prep (a UV-raman spectrometer, Icones Society, France), we prepared three concentration ranges, prepared by diluting three different samples of nalbuphine reconstituted in 0.9% NaCl. Each range was composed of **5 points of calibration**.

The **linearity** was validated from the average of the three ranges.

The **fidelity** of the method is tested by **repeatability** (one solution was sampled five times by QC-prep) and **reproducibility** (five different solutions were sampled at one time).

The method is considered as valid if :

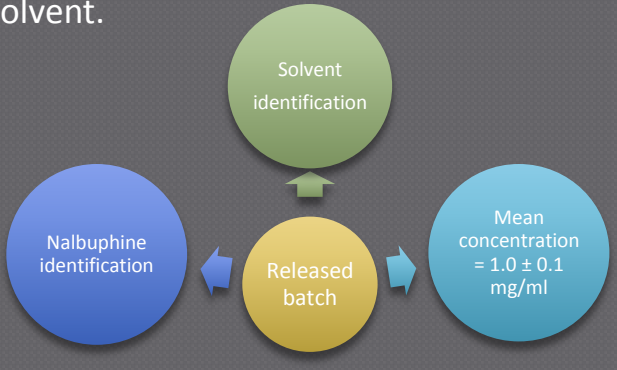
- ✓ the linearity is good enough **($r^2 > 0.999$)**
- ✓ the coefficient of variation (CV) and relative error (RE) of repeatability and reproducibility are **below 5%**.

Results :

The QC-prep method for nalbuphine 1 mg/ml in 0.9% NaCl is **valid** in terms of :

Linearity	Linear from 0.2 to 2.0 mg/ml (r^2 = 0.9997)
Repeatability	CV < 0.25 %
Reproducibility	CV < 2.5 %
Accuracy	CV < 5 %

Seven different batches have been checked in routine work. No mistakes have been identified, either in the concentration of the drug (quality control and sample), or in identification of the solvent.



Conclusions :

Calibration of the QC-prep is simple thanks to easy-to-use software. This is a powerful tool that enables us to determine the concentration of nalbuphine more quickly, easily and safely than the HPLC method previously used. The UV-Raman spectroscopy method could be extended to the analysis of other formulations such as paediatric antibiotics preparations.

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