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INTRODUCTION

Solution of trichloroacetic acid (TCA) dosed at 33% (w/w):

- Indications = Xanthomas and inflammatory granulomas of the inner ear
- Hospital preparation (HP) → final content control¹

Objective: Validate the titrimetric (acid-base) assay method for the TCA solution

MATERIALS ET METHODS

Materials:

- Automatic titrator Mettler Toledo T5
- Glass electrode DGi-115-SC
- Titrating solution of NaOH at 0.1 mol/L
- Trichloroacetic acid at 33 %



Méthods^{2,3,4}:

- **Accuracy:** relative difference (RD) between the measured concentrations and the theoretical concentrations
- **Precision:** relative standard deviation (RSD) between the measured concentrations
→ validation if RD and RSD < 3 % on 3 different concentrations (80, 100 and 120 % of the target concentration)
- **Linearity:** 5-point range covering 80 % to 120 % of the target concentration
→ validation if the determination of the coefficient $R^2 > 0.995$
- **Reproducibility:** titrations on 3 different days
- **Limit of quantification (LOQ):** titration of 6 samples at different concentrations
→ last concentration obtained with RSD < 3 %

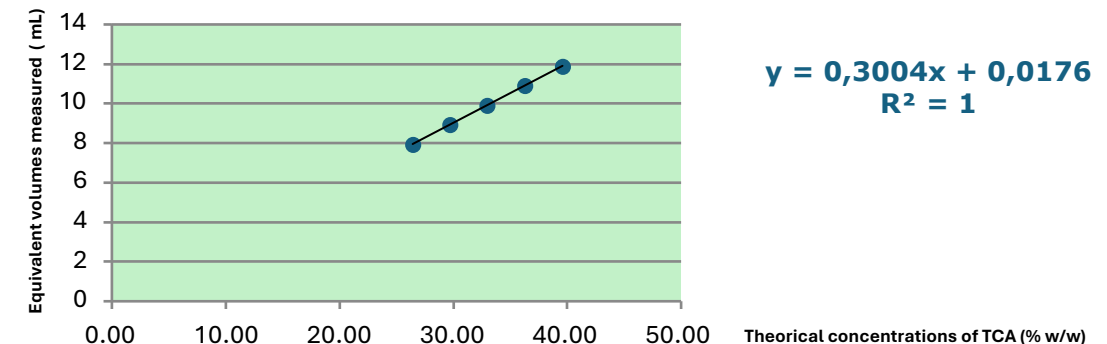
- Automated titrimetric assay method is validated
- Optimisation of the control time of the operator
- Traceability of the assays performed

RESULTS

Accuracy, precision:

		DAY 1	DAY 2	DAY 3
80%	Theoretical concentration (% w/w)	26.44	26.04	26.39
	Average concentration measured (% w/w)	26.14	25.72	25.91
	RD (%)	1.12	1.20	1.82
	RSD (%)	0.24	0.49	0.24
100%	Theoretical concentration (% w/w)	33.00	32.53	32.45
	Average concentration measured (% w/w)	32.52	31.83	33.00
	RD (%)	1.45	2.16	1.79
	RSD (%)	0.30	0.36	0.22
120%	Theoretical concentration (% w/w)	39.63	39.34	39.60
	Average concentration measured (% w/w)	39.01	38.71	38.82
	RD (%)	1.56	1.59	1.96
	RSD (%)	0.27	0.06	0.05

Linearity:



LOQ: 0.83 % w/w

DISCUSSION - CONCLUSION

Routine use to control the hospital preparation of TCA at 33 %