

# INDIGO CARMINE SOLUTION AND ADRENALINE IN SUBMUCOSAL CHROMOENDOSCOPY

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## OBJETIVES

- ✓ Description and galenic validation of a solution of indigo carmine (IC) and adrenaline in colloid plasma expander derived from gelatin for use in submucosal chromoendoscopy.
- ✓ Establishing the period of validity according to the Guide to Good Preparation Practices (GPP).

## MATERIALS AND METHODS

Development of the composition of the formula and review of its pharmacological and physicochemical characteristics.

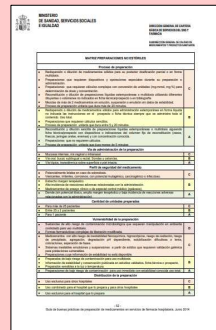
Determination of the risk of the preparation and its expiration date according to the GPP.

Galenic validation: physical stability due to color change, pH stability and microbiological control.

### ELABORATION

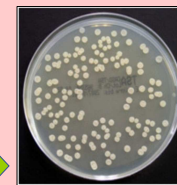


### CONSERVATION



- FRIDGE: 2-8 °C
- 14 days.

### OBTAINING RESULTS



Trypticase Soy Agar



pH



Color Change

## RESULTS

- There was no color change in any sample except at t45.
- There was no microbiological growth in any sample.
- A medium risk level and a validity period of 14 days between 2-8°C were established according to the GPP.
- After its use, the endoscopists consider that the preparation meets the demanded requirements, and it has not been necessary to vary the formulation composition.

Time	Color Change	pH potentiometry	Microbiology Trypticase Soy Agar
T0	(-)	6,65 ± 0,02	(-)
T15	(-)	6,83 ± 0,02	(-)
T30	(-)	6,57 ± 0,03	(-)
T45	(+)	6,70 ± 0,02	(-)

## CONCLUSION

- ✓ The IC solution is physically, chemically, and microbiologically stable for 14 days at 2-8°C.
- ✓ The final concentration of IC used and the association with adrenaline allow, in the opinion of the endoscopists, the adequate differentiation and distinction of the areas susceptible to endoscopic resection.

