

Method Development and validation for assessment of sulfadoxine and pyrimethamine by HPLC-UV

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Context

Combination sulfadoxine-pyrimethamine used in congenital toxoplasmosis.
Current problem : any pediatric pharmaceutical form of this combination is commercialised

⇒ Solicitation of the pharmacy to produce capsules.

Four different formulations according to weight and frequency of administration :

Formulation	7 days		10 days	
Capsule colour	Ivory	Red and white	Ivory	Red and white
Sulfadoxine (mg)	87,5	17,5	125	25
Pyrimethamine (mg)	4,375	0,875	6,25	1,25

Objective

Allow the discharge controls of those formulations with a quantification of drug content, by developing an analytical, separative, quantitative method by high-performance liquid chromatography with ultraviolet detection (HPLC-UV) must be used.

Material and Method

✓ Development of a calibration range with 3 calibration standards :

Standards level	CS1	CS2	CS3
Amount of sulfadoxine (µg/mL)	12,5	125	200
Amount of pyrimethamine (µg/mL)	0,625	6,25	10

✓ Validation of the range with 3 validation standards :

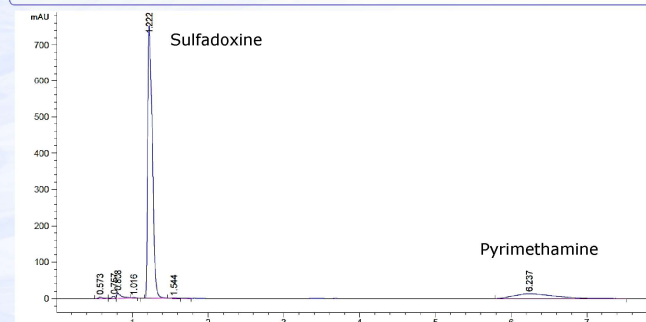
Standards level	VS1	VS2	VS3
Amount of sulfadoxine (µg/mL)	15	100	175
Amount of pyrimethamine (µg/mL)	0,75	5	8,75

✓ HPLC-UV settings :

- column C18, 2,6 µm, 100 x 4,6 mm maintained at 35°C
- Mobile phase : acidified water using acetic acid (pH=3,7) and acetonitrile (60 :40 v/v)
- Volume of injection 10 µL ; flow rate 1,2 mL/min ; detection wavelength 220 nm

✓ Use of the accuracy profile in accordance to the recommendations of SFSTP and ICH

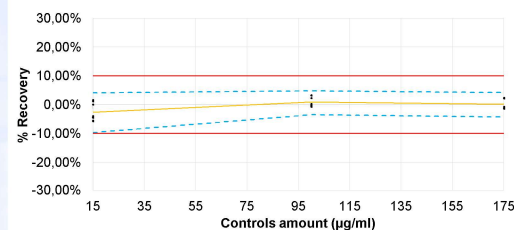
Results



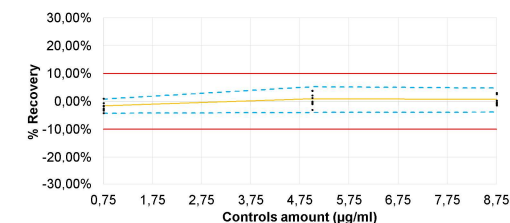
Chromatogram obtained from a validation standard VS3 :
Sulfadoxine-Pyrimethamine 175-8,75 µg/mL



Sulfadoxine accuracy profile



Pyrimethamine accuracy profile



Conclusion

The method were validated in accordance to the recommendations of ICH and SFSTP guidelines and this specific, simple and fast technic allows the achievement of the discharge quality control of the capsules.