

Formulation, particle size and rheological characterisation of a paediatric suspension of prazosin for the treatment of post-traumatic night terrors.

M. Cristofoli¹, P. Espi³, C. Moreau², C. Paillet², C. Marchand¹, C. Merienne¹, F. Pirot¹

¹ Unité de Préparation et de Contrôle des Médicaments, plateforme FRIPHARM, Pharmacie à usage intérieur, Groupement Hospitalier Edouard Herriot - Hospices Civils de Lyon

² Pharmacie à usage intérieur, Groupement Hospitalier Edouard Herriot - Hospices Civils de Lyon

³ Service de pédopsychiatrie, Hôpital Femme Mère Enfant - Hospices Civils de Lyon et Université Claude Bernard Lyon 1, Lyon, France

COM22-35647

Background and objective

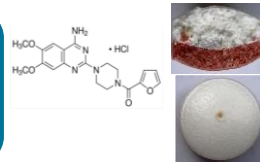
Post-traumatic stress disorder (PTSD) is a psychiatric affection characterized by stimulation of $\alpha 1$ -adrenergic receptors that cause sleep disturbances and night terrors. Recent studies report an improvement of PTSD in pediatrics by initial oral administration of 1 mg prazosin (i.e., $\alpha 1$ -adrenergic antagonist) at bedtime.

The discontinuation of immediate-release oral form of prazosin led to a feasibility study of a pediatric magistral preparation of prazosin (PM2P, 1 mg/mL) for oral and enteral administration.

Materials and methods

Formulation
(according to UPS-
NF monograph)

- An oral osmotic controlled release prazosin hydrochloride speciality in the form of **Alpress® LP 5 mg**
- Mixture of complex excipients: **Ora-Blend®**



Production

- Simultaneous grinding and slurring (using a dispersion, homogenisation, agitation and grinding system)



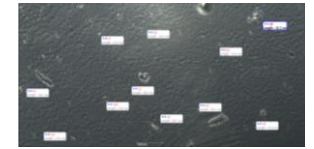
Analyse

- A particle size and stability analysis of the resulting suspension was performed by optical microscopy and light scattering measurements, as well as a rheological study and flow tests of PM2P were conducted in a paediatric enteral tube (NG CH08 and CH06).

Results and discussion

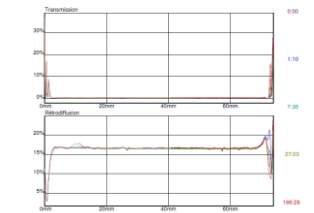
Optical analysis

- Particle size < 100 μm



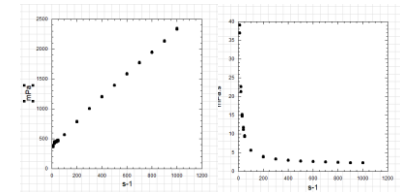
Diffusion analysis

- Identical transmission and backscatter profiles
- No suspension deflection



Rheological analysis

- Rheofluidic behaviour
- Facilitates oral intake after shaking the pack and flow



Conclusion

In the absence of a commercially available speciality for the paediatric treatment of night terrors, a magistral formulation was developed taking into account the physicochemical properties of the AP and the biopharmaceutical aspects of the administration route.

