**Purpose** Our aim was to prepare clozapine capsules, different strengths, macroscopically not discernible.
**Material and methods** The consent of the patient and his parents had been obtained.

In the absence of pure pharmaceutical raw material, the feasibility study (Good Preparation Practices) revealed crushability of the available tablets. They were micronised with a RETSCH RM 200 mortar apparatus for 4 min, particle size <3 mm.

The initial prescription (one capsule 165 mg in the morning, one capsule 260 mg in the evening, for 15 days) led us to prepare 15 capsules of size 00 (translucent) for the morning and 15 capsules size 000 (opaque red) for the evening. Excipient (lactose) was added if required.

The dose adjustment criterion was the clinical state of the patient.
**Results** The obligations for labelling had been fulfilled except for the strength, replaced by morning clozapine or evening clozapine. The clinical evaluation induced a first increase (+12%) of the morning dose after 5 weeks.

The correct dose was found after 9 weeks with +27% of the daily dose, targeted in the morning, without the patient's fear of the changes. White blood cell counts every 4 weeks were normal. At the last dose increase, the volume of the powder necessitated to change the capsules from 00 to 000 and ivory colour (instead of translucent, not available). Nevertheless, these macroscopic changes did not have a nocebo effect.

Blinding required a double circuit of prescriptions: those given by the prescriber to the patient mentioning 'morning capsule: 1, evening capsule: 1' to be taken daily and those which were intended for us, specifying the strengths.
**Conclusion** All items required in the pharmaceutical preparations labelling must be fulfilled exhaustively to avoid any confusion. However, exceptionally and transiently, a labelling not mentioning the strength was relevant in helping the prescriber to manage a dosage adjustment and to achieve the desired clinical outcomes.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
No conflict of interest.

## 3PC-034 IMIPENEM-FORTIFIED EYE DROPS FOR THE TREATMENT OF BACTERIAL KERATITIS: DEVELOPMENT AND CHARACTERISATION

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**Background** Bacterial keratitis is an infectious ocular disease accompanied by inflammation that can cause severe visual impairment. Commercial eye drops are not effective in many cases, so it is necessary to develop fortified antibiotic eye drops with high drug concentrations in hospital pharmacy departments.
**Purpose** To develop and characterise imipenem eye drops through release and stability studies of three possible formulations for the treatment of resistant bacterial keratitis.
**Material and methods** Initially, three different vehicles were used for the development of 5 mg/ml imipenem eye drops: balanced salt solution (BSS); 0.4% hyaluronic acid (HA); and 0.84% ion-sensitive hydrogel composed of gellan gum and kappa carrageenan (ISH). Later, these three formulations were characterised. First, release assays were performed using vertical Franz cells (37°C, 100 rpm orbital shaker, 12–14 kD dialysis membrane) and artificial tears as receptor medium. The drug release was determined spectrophotometrically (298 nm). For the stability study, all formulations were stored at room temperature and at 4°C–8°C for 10 days protected from light. Each day, pH, transparency and concentration were determined.
**Results** Release studies showed that imipenem is delivered by a Higuchi diffusion in all formulations. However, ISH was more effective than BSS and HA in drug release control.

Stability studies showed that, at day 3, formulations stored at 4°C–8°C of BSS and HA maintain ≥90% of the initial concentration (IC), while in ISH it was 85%. At the same time, room temperature-stored samples preserved 60%–80% of the IC. At day 5, only BSS and HA formulations stored at 4°C–8°C maintain ≥85% of the IC. Finally, after 10 days of study, all samples stored at 4°C–8°C maintain around 70% of the IC, while those stored at room temperature only keep around 20%–30%. On the other hand, no significant pH and transparency variation were shown at both storing conditions.
**Conclusion** The ISH vehicle shows the best release characteristics. However, its poor physicochemical-stability would make its use difficult in clinical practice. For this reason, the optimal vehicles for the elaboration are BSS and HA.

It is recommended to store these eye drops at 4°C–8°C protected from light. Under these conditions, a validity period of 5 days can be established.

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No conflict of interest.

## 3PC-035 GALENIC FORMULATIONS FOR OPHTALMOLOGISTS: NEW FORMULATIONS, PRESCRIBING PATHWAYS AND PATIENT INFORMATION

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**Background** Some ocular pathologies require to be treated with special ocular solutions that are not available on the market as ready formulations, but need to be prepared in the hospital pharmacy.
**Purpose** The objective was to create: a database of pharmacopeia-validated ocular formulations that hospital ophthalmologists could prescribe; an online format to be used by hospital ophthalmologists to request the formulations; and a leaflet on each formulation to provide patients with information about the product prescribed.
**Material and methods** The current literature[1] was reviewed before choosing formulations that the hospital ophthalmologists could prescribe: Amphotericin B 1.5 mg/mL, Cyclosporine A 0.05%, Cyclosporine A 1.25%, Cyclosporine A 2%, Chlorhexidine 0.02%, Chlorhexidine 0.2%, Fluconazole 2 mg/mL, Interferon 1 MUI/mL, Interferon 3 MUI/mL, Mitomycin C 0.04%, Tacrolimus 0.1%, Tobramycin 13.5%, Vancomycin 25 mg/mL and Voriconazole 1%.