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.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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%.

The ophthalmologists order the drug/s through the online list, then the pharmacist prepares it/them. When the patient leaves the hospital, the pharmacist gives the drug to the patient, along with a leaflet with details about product storage and possible side effects.

Results In the study period, 68 patients received prescriptions for five categories of ocular formulations: antibiotics, antimycotics, immune-suppressors, immune-modulators and oncologic drugs. The hospital pharmacists recorded patient responses to these formulations. Of the 12 patients who received antibiotics, 11 responded positively while one did not provide a response. Antimicotics were prescribed to 25 patients: 20 responded favourably, four unfavourably and one did not provide feedback. Of the 25 patients prescribed immune-suppressors, 10 responded positively, two negatively, two did not respond and 11 are still in treatment. Three patients received immune-modulators, with two responding favourably and one still in treatment. Anticancer formulations were provided to three patients, all of whom responded positively.

This system facilitated analysis of the outcomes of the various treatments.

Conclusion Most of the patients responded to the drug treatment positively and all gave positive feedback about the leaflet. The online prescription system streamlines the work of the pharmacist and the ophthalmologist.

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No conflict of interest.

3PC-036 COMPARISON OF METABOLITE LEVELS IN SERUM AND TEARS: IMPLICATIONS FOR THE DILUTION OF AUTOLOGOUS-SERUM-EYE-DROPS

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Background No general standards exist for the optimal dilution factor of autologous-serum-eye-drops (ASED) to treat dry eye syndrome (DES).[1 2] While dilution reduces patient burden, simplifies logistics and potentially decreases anti-proliferative effects from TGF-δ, better epithelial healing with non-diluted ASED in Sjögren Syndrome, but not in non-Sjögren DES have been reported.[2].

Purpose The ratio of serum to tear concentration for a range of metabolites in ASED after prolonged storage time was determined to define dilution that maintains metabolite concentrations equal or above those in tears.

Material and methods After autologous whole blood donation, unit dose ASED were prepared and stored at −20°C for 9 months. Concentration changes of 14 sphingolipids (SLs), 14 lysophosphatidylcholines (LPCs) and 76 phosphatidylcholines (PCs) were determined in ASED on day 0 and day 273 by LC-MS/MS using the Absolute/DQ-p180-Kit (Biocrates Life Sciences) and compared to those in tears of the same person.

Results The concentrations of all SLs in ASED increased by 30%–80% within 9 months. Compared to tears, the concentrations were 10-fold (day 0) to 14-fold (day 273) higher. The concentrations of all LPCs decreased by 50%–75%, with 20 and five times higher levels on day 0 and day 273 in ASED compared to tears. Most PCs showed a less than two-fold increase, while PC ae C30:1/C38:1/C38:2 increased by five–six-fold. In sum, all PC-concentrations were about 16–19-fold higher in ASED (day 0–day 273) than in tears.

Conclusion We observed an increase in SLs probably through the release of sphingosine-1-phosphate from platelets during blood clotting. The decrease in LPCs may be linked to a shift from LPCs to PCs through the presence of LPC-acyltransferases. After 9 months at −20°C, the LPC levels still exceeded those in tears by five-fold. These data support a dilution up to five-fold as suggested by others (reviewed in [2]). Because certain patient populations may benefit from less diluted ASED, an individual approach seems indicated until more clinical information stratified by cause and severity of DES is available.

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No conflict of interest.

3PC-037 DEVELOPMENT OF VIRTUAL DRUG INFORMATION CENTRE FOR PHARMACY COMPOUNDING AREA

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Background Professional use of web 2.0 digital tools is increasing recently in the hospital pharmacy field.

Symbaloo (www. symbaloo.com) is a free web-based tool that allows users to create a virtual desk to organise key information sources (links or documents) in a user-friendly and personalised page for free.

Purpose The main objective of the study was to develop a Symbaloo digital desk for the pharmacy compounding area of a tertiary-level hospital.

Material and methods A descriptive study was carried out in May 2018.

A Symbaloo 'webmix' called 'Farmacotecnia' was created with a pharmacy department profile. The next step was to add links to the web, following the criteria shown below:

- Virtual documents, links and other web resources recommended by healthcare organisations, scientific associations or hospital pharmacy departments.
- Websites that comply with the basic recommendations of reliable health websites of the Health Quality Agency of Andalucia or have any web–quality seal such as 'Health on the Net Code' seal.
- Only Spanish– or English–speaking websites.

Update up to 24 months before its inclusion on the webmix. Links of own documents were obtained to share from Google Drive web service.

The webmix was published open access, after the pharmacy department checked the links and information.