samples. An important increase in the number of isoforms even with changes in their masses, including the main isoform, was detected.

Conclusion and relevance Exposure to light may cause modifications in the nivolumab isoform profile which suggests protein degradation. This work shows the importance of protecting opened vials of the medicine Opdivo from light (and by extension, bags for infusion) when they are at room temperature (up to 25°C).

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Conflict of interest No conflict of interest

3PC-066 COMPOUNDING AN EYE DROP FORMULATION OF TOPICAL INSULIN FOR CORNEAL DEFECTS REFRACTORY TO PREVIOUS TREATMENT: EXPERIENCE IN REAL CLINICAL PRACTICE

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Background and importance Recent studies suggest the use of topical insulin on the ocular surface to accelerate cicatrisation of corneal lesions in diverse ocular pathologies, such as postoperative corneal epithelial erosion, neurotrophic keratitis and refractory corneal ulcers. However, its use has not been extended into real clinical practice.

Aim and objectives To describe an eye drop formulation of insulin 1 UI/mL for use in corneal defects refractory to previous treatment, and to evaluate its possible application in regular practice.

Material and methods A bibliographical search was performed in Pubmed using the following keywords: topical insulin, corneal ulcers and epithelial defects refractory; 9 results were found. Five references were selected with the most recent publication dates (2017–2020).

The pharmacy and ophthalmology departments reached an agreement to compound an eye drop formulation of topical insulin 1 UI/mL. The preparation was carried out in the pharmacy department in a horizontal laminar flow cabin following an aseptic compounding technique using regular insulin (100 UI/mL) and artificial tears with a polyethylene glycol base. The dilution was then filtered and packaged in light protected eye drop bottles. The risk matrix of sterile preparations of the Sociedad Española de Farmacia Hospitalaria was applied obtaining a low level of risk, which established a validity period of 14 days refrigerated or 48 hours at room temperature.

Results The formulation obtained was a transparent sterile liquid, adequate for ocular use. A visual control was performed during the validity period, with no physical alterations of the product. Currently, nine patients with neurotrophic corneal ulcers or epithelial defects, refractory to medical and/or surgical standard treatment, have been treated. Mean number of days of treatment was 21±7 days. Improvement in pain was observed in every patient and total healing of the lesion was reported in 66% of patients. No adverse reactions were reported.

Conclusion and relevance Compounded topical insulin was adequate for ocular use, with no alterations during the validity period. Acceptance by patients was good, achieving quick relief of pain in every patient and total healing of the cornea in most patients. This preparation can be used as a treatment option in corneal defects refractory to previous treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-067 KEY ROLE OF THE HOSPITAL PHARMACY IN A NON-PROFIT STUDY INVOLVING RUXOLITINIB 5 MG CPS: IMPLEMENTATION AND QUALITY ASSURANCE OF AN INVESTIGATIONAL MANUFACTURING PRODUCT

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Background and importance Ruxolitinib is a JAK inhibitor indicated for myelofibrosis and polycythaemia vera in adults. The department of haematology started a non-profit study to evaluate ruxolitinib 5 mg in patients affected by Hodgkin's lymphoma. Because the company patent holder was not interested in sponsoring this study, the investigators used their research funds to meet the cost of Jakavi 20 mg tablets, which were cheaper than the other dosages.

Aim and objectives The aims of the hospital pharmacy were to improve the pharmaceutical formulation of capsules of ruxolitinib 5 mg, starting with Jakavi 20 mg tablets, consistent with department financial resources, and to conduct uniformity of mass and stability studies of compounding.

Material and methods The first step was to measure the volume of a tablet of Jakavi 20 mg to calculate the amount of starch needed to produce 100 capsule size 3 (0.30 mL) ruxolitinib 5 mg. For each batch of 200 capsules, 50 tablets of Jakavi 20 mg and 6 mg of starch were used; 80 samples were allocated to conduct uniformity of mass single dose preparations and stability studies. For the stability test, three samples of 20 capsules for each one, in amber glass bottles at storage temperatures of 25°C to 2°C for 12 months were prepared. Every month, ruxolitinib concentrations were determined by reverse phase HPLC.

Results In total, 102 packs of ruxolitinib 20 mg were purchased, instead of 408 packs of ruxolitinib 5 mg. Uniformity of mass studies demonstrated that no more than two of the individual capsule masses deviated from the average mass by more than 10% and none deviated more than twice that percentage. Regarding the stability test, the first 6 months of data showed that the percentage of ruxolitinib has not changed significantly. Therefore, all the aims of the study were achieved.

Conclusion and relevance The results showed that the role of the pharmacist was essential for implementation of the non-profit trial. In fact, they allowed the compounding required by the study design, ensuring safety and quality, with significant cost savings. The stability test demonstrated that the compounding can be stored for up to 6 months under standard conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-068 LONG TERM STABILITY OF CO-ADMINISTRATION OF BUMETANIDE AND SCOPOLAMINE FOR THE PALLIATIVE CARE UNIT

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Background and importance Death rattle occurs in 25–90% of dying patients and is often associated with pulmonary fluid overload. Co-administration of scopolamine (anticholinergic drug) and bumetanide (loop diuretic) could be used to avoid unnecessary fluid overload at the end stage of life.
Aim and objectives The study aimed to investigate the physical and chemical stabilities of the admixture bumetanide and scopolamine, prepared in advance, by a centralised intravenous additive service (CIVAS) in the hospital pharmacy.
Material and methods Stability of minimal (min) concentration was evaluated for five polypropylene syringes of 48 mL containing the admixture bumetanide (Burinex 2 mg/4 mL, Leo, Belgium) and scopolamine (0.25 mg/mL, Sterop, Belgium) at 41.67 µg/mL and 5.21 µg/mL, respectively. The maximal (max) concentration with 125 µg/mL of bumetanide and 31.25 µg/mL of scopolamine was evaluated for five polypropylene syringes of 14 mL. All syringes were stored for 18 days at 5±3°C. Periodic samples were visually and microscopically examined to observe any particle appearance or colour change. pH and absorbance at three wavelengths (350, 410 and 550 nm) were monitored. The concentrations were measured by ultra-high performance liquid chromatography–photodiode array detection.
Results Over 18 days, there was no change in colour or appearance of opacity, turbidity or precipitation, and the pH remained stable. The relative concentrations of bumetanide and scopolamine at min and max concentrations after 18 days were unchanged, with 100.1% and 100.3% of the initial content of bumetanide and with 99.2% and 99.4% of the initial content of scopolamine. The lower limits of the 90% CI on the means of both molecules at min and max concentrations remained higher than the 90% threshold that considers the mixture to be chemically stable.
Conclusion and relevance The study is the first to show that the admixture of bumetanide and scopolamine is physically and chemically stable at two concentrations used in the palliative care unit. This combination, available in polypropylene syringes, has numerous advantages (eg, preparation under aseptic conditions by a CIVAS with decreased workload and preparation errors).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-069 IMPROVING SAFETY AND QUALITY FOR ASEPTIC TRANSFER PROCEDURES IN HOSPITAL PHARMACIES

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Background and importance Materials used in aseptic manufacturing, such as medical devices (MD), infusion bags (IB), bottles (B), infusion vials (V) and ampoules (A), usually undergo disinfection with alcohol 70%. Alcohol, however, is known not to eradicate all microbes (eg, bacterial spores).
Aim and objectives To explore the effectiveness of a sporicidal aseptic transfer approach using high speed H_2O_2.
Material and methods For 12 materials and their cardboard packaging (MD, IB, B, V and A), three samplings each at the outer and inner sides of the packaging and at the unpacked material surface were tested with contact plates (108 plates) applied for 5 s. After incubation for ≥72 hours at 20–25°C and 30–35°C, respectively, contact plates were observed for colony forming units (CFU). Unpacked materials were additionally tested, three samplings each (36 contact plates), after sporicidal disinfection using high speed H_2O_2 (wipes and foam).
Results Without disinfection, CFU appeared on 81% and 33% of contact plates for the outer and inner sides of the cardboard boxes. The surface of the materials showed contamination for 25% of the plates. The microbes found on the plates included bacteria, aerobic endospore formers (Bacillaceae) and Aspergillus. After sporicidal disinfection, microbial growth was seen on none of the plates.
Conclusion and relevance As a risk based approach to contamination control is fundamental for aseptic transfer procedures, our results reflect the strategy for minimising contamination for aseptic manufacturing. Endospore forming bacteria were found as part of the contamination flora on the surface of several material samples. Therefore, a sporicidal agent (eg, high speed H_2O_2) is required to minimise the contamination risk not only when materials are transferred to clean room classes B and A, but preferably when entering the production area (zone D).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-070 EVALUATION OF COMPATIBILITY OF ACETYLSALICYLIC ACID AND ATENOLOL WITH MEDICATIONS COMMONLY USED IN INTENSIVE CARE UNITS

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