visually inspected for turbidity after 14 days of incubation. The number of colony forming units (CFU) per plate were counted and identified.

Results The results of the KI discus test were far below the acceptance limit, demonstrating the effectiveness of laminar airflow in preventing the escape of particles from the internal areas of the robot. None of 240 media fills showed turbidity after incubation, thereby indicating no contamination with microorganisms. The working area met the grade A limit (0 CFU/sample). In the warehouse, 1 CFU was found in two samples (mean 0.2 CFU/contact plate, 0.1 CFU/settle plate). Microbial contamination was slightly higher in the loading area (mean 0.3 CFU/contact plate, 0.8 CFU/settle plate). Most of the CFUs were identified as skin related microorganisms, such as *Staphylococcus epidermidis* and *Staphylococcus hominis*.

Conclusion and relevance Extensive media fill tests and environmental monitoring during automated preparation with the robot revealed well controlled aseptic procedures and adequate sterility levels, thereby complying with the quality standard set by the hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-064 A MULTICENTRE STUDY COMPARING CHEMOTHERAPY PREPARATIONS USING DIGITAL VIDEO MONITORING

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Background and importance Preparation of chemotherapy treatment is a risky step. Therefore, the production circuit in the chemotherapy reconstitution unit (CRU) must be secured. The Drugcam digital tool is a preparation control system that guides the hospital pharmacy preparer (HPP) in their manufacturing process.

Aim and objectives A remote, multicentre and retrospective digital audit analysed qualitatively and quantitatively the practices of different CRU to find ways to optimise the preparation step for chemotherapy treatment.

Material and methods Over 1 year, data from 10 public and private healthcare institutions on three types of chemotherapy treatment, lyophilisate (pemetrexed), ready-to-use standard dose (nivolumab 240 mg) and dispenser (5-fluorouracil (5-FU)) were collected. This study analysed quantitative data extracted in Excel by pharmacists using local Drugcam data. Qualitative data obtained from audits made by pharmacists analysing 10 video recordings per chemotherapy preparation were also analysed.

Results 14 218 preparations made by 119 HPP were analysed: 2217 pemetrexed by 99 HPP, 1819 nivolumab by 90 HPP and 12827 5-FU by 110 HPP. The median preparation times for pemetrexed, nivolumab and 5-FU from all centres were 6.2, 4.2 and 4.9 min, respectively. Regardless of the three molecules, the results showed no significant difference between the experience of the Drugcam preparer and its productivity.

Qualitatively, analysis of the films showed heterogeneous practices between establishments: no compress for all stages, reconstitution by shaking of the lyophilisate as well as its mirage was not protocolled and rapid injections into the solvent were observed. The equipment used (infusion line or extension for infusion tree), the Drugcam practice (labelling of the preparation filmed or not, automatic or not automatic detection by the data matrix of the solvent/vial bags) and the organisation of each centre had a strong impact on the quality and productivity of the centres.

Conclusion and relevance If this study showed no correlation between time production, annual number of preparations and number of HPP, the analysis will allow us to recommend the practices of Drugcam for the preparation of chemotherapy treatment. Moreover, organisational modifications (series preparation, change of material reference) and practice harmonisation (standardised reconstitution of lyophilisates) will improve productivity and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-065 IMPACT OF LIGHT STRESS ON THE ISOFORM PROFILE OF NIVOLUMAB (OPDIVO) IN OPENED VIALS ESTIMATED BY (RP)UHPLC-UV-(HESI/ORBITRAP)-MS

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Background and importance Nivolumab (Opdivo) is a human IgG4 monoclonal antibody from the group of immunomodulators which bind to the programmed death receptor 1 (PD-1). As a complex protein, physical aggregation and chemical degradation can occur throughout its life, and even modest environmental stresses can cause extensive damage.¹ As indicated in its technical report,² the unopened vials can be stored at a controlled room temperature up to 25°C with room light for up to 48 hours.

Aim and objectives To assess the impact on the isoform profile of nivolumab 10 mg/mL (Opdivo) promoted by exposure to light in its own opened vial at a controlled temperature of 25°C to evaluate likely risks from unintentional mishandling in real hospital conditions.

Material and methods Nivolumab (Opdivo, 10 mg/mL) was placed in an accelerated stress test chamber to simulate sunlight (Solarbox 3000e RH, Cofomegra, Milan, Italy) for 24 hours at 25°C. Irradiation was set at 250 W/m², between 320 and 800 nm.³ A validated reverse phase ultra high resolution liquid chromatography coupled to high resolution mass spectrometry and exact mass ((RP)UHPLC-UV-(HESI/Orbitrap)-MS) method was used to analyse intact nivolumab. UV-chromatograms and total ion chromatograms (TICs) were recorded and the deconvoluted mass spectra gave the nivolumab mass isoform profile.

Results UV chromatograms and TICs suggested no degradation products after light exposure. However, isoform profiles clearly showed changes in the light submitted nivolumab

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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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 cicatrization of corneal lesions in diverse ocular pathologies, such as post-operative 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 polycythemia 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.