administration, for example, must be the oil-in-water type. However, a good stability is required. The aim of the present study is the formulation of emulsion based on paraffin oil and to evaluate the influence of gum arabic content and mixing rate on the stability of emulsions.

Material and methods Distilled water was used as a dispersant phase (75%) and paraffin oil as a dispersed phase (20%). Tween 80 and Span 80 served as mix surfactants (60/40). The formulation was performed according to the Lipophilic Balance-Hydrophilic (HLB) method. Gum arabic concentrations ranging from 2.5%–10% w/w were used. The stability of the emulsions was evaluated by centrifugation at 4000 rpm for 15 min. The creamer index (IC) was used for the interpretation of the results. The emulsions thus prepared are mixed at 4000, 8000 and 16000 rpm for 10 min.

Results The IC of emulsions ranged from 29%–30% with a HLB of 10.72. High levels of gum arabic (10, 7.5 and 5% (w/w)) increased the creaming, therefore the stability was decreased. After addition of 2.5% (w/w) of gum arabic, 1.6% creaming was observed. In 3% (w/w) gum arabic-containing emulsion, no creaming was observed. Microscopic images of emulsions mixed at 4000, 8000 and 16000 rpm, showed that emulsion prepared at 16000 rpm had homogeneously distributed individual small droplets with no sign of flocculation compared to the others.

Conclusion The present experiment has shown that a concentration of 3% w/w gum arabic, and a mixing rate of 16000 rpm provided the optimum stability of oil-paraffin emulsion.

REFERENCE AND/OR ACKNOWLEDGEMENTS

Ramin L, et al. Soy protein isolate and gum arabic composite affects stability of beverage emulsion. *Iran J Chem Eng* 2009;6.

No conflict of interest.

3PC-045 FORMULATION AND STABILITY STUDY OF EXTEMPORANEOUS ORAL LIQUID DOSAGE FORMS CONTAINING FLECAINIDE ACETATE 2 MG/ML FOR PAEDIATRIC USE

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Background Flecainide acetate (FlecAc) is an antiarrhythmic drug, effective in children and fetal tachyarrhythmias. FlecAc is commercially available as 50 mg–150 mg oral tablets or intravenous injectable solutions, approved only for use in adults. For paediatric use, an extemporaneous preparation has to be compounded, using the pure active principle or, when this is lacking, the ground tablet. Few examples of extemporaneous FlecAc preparations are reported in the literature, normally at a dose of 20 mg/mL. Nevertheless, in the case of neonates and infants, a lower concentration is useful.

Purpose The aim of this work was to compound FlecAc oral liquids (2 mg/mL) using pure powder (API) or ground commercial tablets (GCT) and to evaluate the chemical stability of the active principle.

Material and methods Oral solutions were compounded using either a preserved simple syrup (PSS) with the addition of a suspending phase or a ready-to-use commercial suspending

vehicle, ORA-Plus ORA-Sweet (OPOS), to be stored at 4°C or 25°C, respectively. Four types of aqueous solutions were compounded following hospital standard operating procedures. In three different pharmacies, seven hospital pharmacists compounded a total of 28 preparations (n=28): 1) PSS-API, 2) PSS-GCT, 3) OPOS-API and 4) OPOS-GCT. The samples were stored at 4°C (PSS), 25°C (OPOS) and 40°C (both) for 42 days. The FlecAc content was determined using a stability indicating the high-performance liquid chromatography method.

Results At time t=0, the mean FlecAc content of all samples was 1.82 ± 0.10 mg/mL, against a labelled content of 2.00 mg/mL. A significant difference in FlecAc content was observed only in the case of GCT preparations (OPOS-GCT: 1.87 ± 0.07 mg/mL; PSS-GCT: 1.79 ± 0.15 mg/mL, $p=0.03$). Based on these results, duration and method of stirring were further investigated and improved in a second batch, which showed a higher mean content and reduced variability (1.92 ± 0.06 mg/mL). FlecAc was stable over the entire period.

Conclusion FlecAc is completely solubilised in the proposed vehicles and stable for 42 days. A suspending agent is therefore necessary only to mask the excipients of the tablet, if not completely solubilised. Normally suggested storage in a refrigerator when PSS is compounded should be carefully considered, because of the influence of the reduced temperature on FlecAc solubility.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-046 STUDY OF STABILITY OF TWO LIQUID FORMULATIONS OF OMEPRAZOLE ELABORATED IN THE PHARMACEUTICAL SERVICE

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Background As many medicines are not available for paediatric use they have to be elaborated in the pharmacy service. Generally, there are different formulations described in the bibliography.

Purpose To compare two liquid formulations of omeprazole elaborated in the pharmacy service of a tertiary hospital evaluating physicochemical stability and organoleptic characteristics (OC) with the aim of defining the most ideal formulation.

Material and methods A bibliographic check of the different formulations of omeprazole was carried out and two liquid magistral preparations were elaborated in triplicate. Formulation 1 was prepared from omeprazole monohydrate salt, using as excipients: simple syrup, mixture conservans and purified water. Formulation 2 was prepared from omeprazole capsules using bicarbonate 1 M as excipient. Conditions of refrigeration and of light protection were established. As an indicator of physicochemical stability, the pH was selected. For its determination a pH measurer, Mettler Toledo SevenMulti was used. The data was analysed using an Excel 2010 spreadsheet. The results were expressed as average $\pm$ SD. Also colour, smell and taste (OC) were evaluated, as well as homogeneity of the formulations. Thirty days was established as a period of study. The determinations were carried out on days 0,10,17,24 and 30 post-elaboration.

Results The pH was stable with barely any oscillations during the period of study. The data obtained for formulation 1 was: 8.476 ± 0.012 (sample 1), 8.544 ± 0.01 (sample 2) and 8.547 ± 0.018 (sample 3). For formulation 2 it was: 6.777 ± 0.026 (sample 1), 6.373 ± 0.005 (sample 2) and 6.382 ± 0.003 (sample 3).

The homogeneity of the formulations remained stable. The OC fluctuated significantly during the period of study. The colour of formulation 1 evolved from amber and opaque to dark brown, and the smell evolved from sweet to metallic and the taste (bitter-sweet) remained stable. In formulation 2 the opaque white colour and the disagreeable metallic smell remained unchanged. The taste changed, from very bitter to salty.

Conclusion In both formulations the pH remained stable.

The formulation based on raw material presents significant changes in OC, mainly in colour.

With regard to the formulation whose elaboration is made from capsules, the OC remained more stable.

As a result of this, it was decided to establish formulation 2 as a preferential formula in spite of its more disagreeable taste.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-047

EVALUATION OF THE EFFECTIVENESS AND SATISFACTION OF THE MASTER SUSPENSION FORMULA FOR MUCOSITIS ELABORATED IN A TERTIARY HOSPITAL

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Background Mucositis is a complication arising from chemotherapy that reduces the quality of life of a cancer patient. Its prevention and treatment are important.

Purpose To evaluate the effectiveness and satisfaction of the suspension for mucositis elaborated in the pharmacy service, destined for patients with mucositis as a consequence of cytostatic treatment, in order to identify where improvement is needed.

Material and methods Observational descriptive study for 1 month. Patients who attended the oncohematological day hospital to receive treatment and to pick up the suspension for mucositis were included. The master formula was composed of nystatin, methylprednisolone, mepivacaine, gentamicin and 1/6 M bicarbonate.

All the patients who agreed to participate in the study were given an anonymous questionnaire. It included information about demographics, pathology, (degree of mucositis according to the World Health Organisation), tolerability, effectiveness and patient satisfaction. The replies referred to qualitative dichotomous or polytomous variables, with nominal or ordinal gradations. The replies were analysed via an Excel 2010 spreadsheet.

Results Sixty-nine questionnaires were collected.

Twenty-six were men and four were excluded from the study for lack of information. The average age of the patients was 63 ± 10.83 years old.

The patients were classified based on the degree of mucositis: 21 patients grade 0, 19 grade 1, 23 grade 2, one grade 3 and one grade 4.

Fifty-six patients (86.15%) indicated a considerable improvement in symptoms after the use of the master formula after 2–4 days of use. In five (7.69%) patients there was no improvement.

As for the taste, the valuation of the majority (64.68%) was that it was disagreeable.

In general, the valuation of the master formula was: 1 (3.07%), 2 (9.23%), 3 (40%), 4 (36.92%) and 5 (10.77%), 1 being nothing, 2 being a little, 3 being quite a bit, 4 being a lot and 5 being totally satisfactory.

Conclusion The master formula for mucositis elaborated in the pharmacy service is effectiveness in the control of the symptoms of mucositis in more than 90% of patients.

The patients showed a high degree of satisfaction globally, palatability being the factor that required improvement. As an opportunity to improve we found the study of flavourings compatible with the formula and that they did not interfere with the therapeutic effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-048

ORAL MUCOADHESIVE DEXAMETHASONE 0.1% (M/M) GEL: A STRATEGY FOR MOTOR INHIBITORS MUCOSITIS

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Background Stomatitis is the most referred adverse reaction during everolimus treatment (in metastatic breast cancer). In a post-commercial study (n=92) the prophylactic administration of an oral solution of dexamethasone resulted in an important reduction in incidence and severity of stomatitis.

In Portugal, there is not any formulation on the market that permits a topical administration of dexamethasone.

Purpose Development, characterisation and stability studies of a new oral mucoadhesive gel of dexamethasone (DEX) at 0.1% (m/m) for prophylaxis/treatment of oral mucositis with an effective topic action, good palatability and ease of use by our patients.

Material and methods A gel was developed without sucrose to obtain chemical and physical properties suitable for the administration, storage and therapeutic compliance.

Full pharmaceutical quality testing was carried out (rheology and adhesion tests). Appropriate stability-indicating analytical methodology was developed to quantify DEX. The microbiological and stability tests were performed during 180 days. The *in vitro* release study of DEX was performed by using Franz diffusion cells. An observational study of its clinical use are still ongoing.

Results A stable formulation of gel was obtained with a period of use of 180 days at $25^\circ\text{C} \pm 3^\circ\text{C}$.