Abstract 3PC-024 Table 1 Impact of temperature cycling on SB5 critical quality attributes

<table>
<thead>
<tr>
<th>Category</th>
<th>Test item</th>
<th>Test method</th>
<th>Baseline (reference) (%)</th>
<th>Following 3 thermal cycles (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurities</td>
<td>High molecular</td>
<td>Size exclusion HPLC</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Impurities</td>
<td>Weight aggregates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purity</td>
<td>Total purity</td>
<td>CE-SDS (non-reducing)</td>
<td>96.8</td>
<td>96.6</td>
</tr>
<tr>
<td>Biological</td>
<td>TNFα binding</td>
<td>Competitive binding assay (FRET)</td>
<td>92</td>
<td>98</td>
</tr>
<tr>
<td>Biological</td>
<td>TNFα neutralisation</td>
<td>Cell based, NF68</td>
<td></td>
<td>94</td>
</tr>
</tbody>
</table>

CE-SDS, capillary electrophoresis—sodium dodecyl sulfate; FRET, fluorescence resonance energy transfer; HPLC, high performance liquid chromatography.

Results

A total of 132 syringes underwent three freeze–thaw cycles, exposing each syringe for a total of 144 hours to 30°C and 144 hours to −5°C. Following exposure, 66 syringes were used for the analysis and 66 were retained. The effects of this thermal cycling on the critical quality attributes of SB5 from baseline is shown in table 1.

Conclusion and relevance SB5 was stable in the immediate pack when exposed to multiple freeze–thaw cycles. These results may help hospital pharmacists assess the impact of temperature excursions during shipment or storage on product quality of SB5.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest

Corporate sponsored research or other substantive relationships:

HE is an employee of, and holds stock in Biogen, responsible for the commercialisation of SB5. JK, JY, DP, SJH and SJP are employees of Samsung Bioepis, the marketing authorisation holder of SB5.

3PC-025 MAGISTRAL FORMULATION FOR A PATIENT WITH MULTIPLE FOOD ALLERGY

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Background and importance

Multiple food allergy (MFA), in its severe stage, is a pathology with nutritional and pharmacotherapeutic restrictions. Drug intolerance to available medicines and lack of alternatives can lead to magistral formulations.

Aim and objectives

To compound oral liquid formulations of iron, zinc and sirolimus by eliminating all preservatives, antioxidants, colourings and flavourings, and evaluate their use in a paediatric patient with MFA.

Material and methods

We made a literature review including physicochemical characteristics of the active principles studied and the compounding magistral formulations described. We also compared the composition between these commercialised drugs and simple syrups.

We accomplished all of the controls described in the pharmacopeia for oral liquid forms on days 1 and 30.

Efficacy was evaluated by clinical monitoring from the patient’s birth in 2017.

Results

According to our bibliographic review, three active principles were formulated with an adjuvant free vehicle: 64% preservative free simple syrup (PFSS).

The final composition was:

- Sirolimus 0.5 mg/mL oral suspension: sirolimus in 1% preserving free carboxymethylcellulose and PFSS. It was compounded using as a pattern the formulation of a tacrolimus suspension, based on molecular similarities.
- Zinc 5 mg/mL oral solution: zinc acetate dihydrate in sterile water 20% and diluted PFSS, based on existing formulations. We used the best tolerated salt.
- Iron 30 mg/mL oral solution: ferrous sulfate heptahydrate in sterile water 20% and diluted PFSS. We chose the salt with the highest absorption and solubility.

Quality controls: the solutions showed clarity and absence of precipitates and the suspension, re- dispersibility and homogeneity after stirring. The organoleptic characteristics were not optimal for the taste. The results for microbiological controls were negative.

Due to the physicochemical and microbiological characteristics, a period of validity of 30 days in refrigerated amber glass was considered.

Zinc and iron deficiency were corrected and blood levels of sirolimus were within the adequate range. Currently the patient continues with treatment and an exhaustive follow-up is being carried out.

Conclusion and relevance

Our oral liquid formulation was appropriate for the pathology of our patient and contributed to his growth and health. The comprehensive pharmaceutical care and an individualised compounding for the MFA was essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-026 FORMULATION AND GALENIC CHARACTERISATION OF A TACROLIMUS ADHESIVE GEL FOR TREATMENT OF ULCERATIVE PROCTITIS

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Background and importance

Ulcerative proctitis is associated with faecal incontinence, pain, itching, bleeding and purulent discharge, and is often managed with topical salicylates or steroids. However, treatment can be refractory in some patients. Rectal administration of tacrolimus may be effective in difficult to treat ulcerative proctitis1. Some patients find it difficult to retain rectal pharmaceutical forms, suppositories or enemas, which lead to painful administration and inadreosification.

Aim and objectives

To develop a tacrolimus adhesive gel and its galenic validation, to improve and extend contact time of tacrolimus with rectal mucosal surfaces.