3PC-019 EVALUATION OF THE IMPACT OF MACHINE-AIDED DEBLISTERING IN UNIT DOSE BLISTER PRODUCTION ON THE FUNCTIONALITY OF TABLET COATING

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Background and importance Deblistering of medication is a critical step in unit dose blister production. In our setting, large quantities of push-through packs are processed by manually operated deblistering machines. Visibly damaged drugs are removed. However, it has not been investigated whether mechanical stress by deblistering machines can cause minimal, hardly identifiable damage with negative effects on functional coating.
Aim and objectives The influence of machine-aided versus manual deblistering on drugs with modified release was studied to rule out negative effects on functionality of coating. Purposely damaged tablets with tiny superficial defects served as positive controls. Enteric coating and extended release were investigated in tablets chosen for their high deblistering volume and critical active agent, respectively.
Material and methods Thrombo ASS 100 mg (acetylsalicylic acid; enteric coating) and Quilonorm retard 450 mg (lithium carbonate; retardation of release) were deblistered (A) manually, (B) with deblistering machines and (C) manually and then minimally damaged on the surface with a pointed item. Ten tablets of each group were analysed in two ways. (1) Disintegration testing was performed based on the methods of the European Pharmacopoeia. (2) Tablets were immersed into a methylene blue dye bath to visualise intactness of coating as well as damaged areas.
Results Manually and machine deblistered Thrombo ASS tablets met the required 2 hours of acid stage duration in 0.1 N HCl. The minimally damaged fraction started to disintegrate within seconds. When transferred to neutral buffer solution, manually and machine deblistered tablets showed identical disintegration behaviour. All three groups of Quilonorm retard tablets showed acid stability and disintegrated the same way in a pH-neutral environment. Cavities and grooves were visible on damaged tablets immersed into the dye bath. Tablets deblistered by hand and machine showed identical, even dying of their surfaces.
Conclusion and relevance Although minimal damage can lead to a loss of coating functionality, machine-aided deblistering showed no negative effects on coated tablets. Neither differences in disintegration tests nor in the dye bath were detected compared with manually deblistered tablets. These results were examined during a good manufacturing practice (GMP) inspection by the Austrian authority, support machine qualification and the validation of this important step in the unit dose blister process and may therefore be of interest for other production sites.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-020 CHEMICAL STABILITY AND PHYSICAL COMPATIBILITY OF INSULIN EYE DROPS USED IN CLINICAL PRACTICE

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Background and importance Insulin eye drops are an effective treatment for corneal neurotrophic ulcers due to the action of insulin as a tissue growth factor. Owing to the lack of studies on the stability of this eye drops, in clinical practice it is not possible to give them for more than 7 days of use. The purpose of this study was to assess whether the stability could be increased, making the preparation and dispensing by the Pharmacy Service easier, as well as making it more comfortable for the patient.
Aim and objectives The objective was to study the chemical stability and physical compatibility of eye drops of human insulin (Humulina and Actrapid) at 1 UI/mL, diluted in Systane, Liquifilm or 0.9% sodium chloride (0.9% NaCl), in polyethylene bottles, protected from light, at 24°C or 4.5°C, for 30 days.
Material and methods Three preparations were prepared for each condition. At the time of analysis, one sample for each preparation was analysed by high performance liquid chromatography. The time at which human insulin retained 90% of the initial concentration (T90) was obtained for each preparation. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual inspection, gravimetric analysis and pH measurement.
Results Humilina preparations, T90 was: (a) with Systane: 9 days at 4.5°C, 7 days at 24°C; (b) with Liquifilm: 9 hours at 4.5°C, 10 hours at 24°C; (c) with 0.9% NaCl: 1 day at 4.5°C, 15 hours at 24°C. Actrapid preparations, T90 was: (d) with Systane: 10 days at 4.5°C and 24°C; (e) with Liquifilm: 17 hours at 4.5°C, 6 hours at 24°C; (f) with 0.9% NaCl: 4 days at 4.5°C, 3 days at 24°C. During the study, neither changes in colour nor losses of weight were observed in the preparations assayed: variations of pH were higher than 5% from day 2 in all preparations with Humulina and Actrapid in 0.9% NaCl.
Conclusion and relevance Eye drops of human insulin (Humulina or Actrapid) at 1 UI/mL diluted in Systane, in polyethylene bottles and protected from light, can be used in clinical practice.

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3PC-021 DESIGN AND ELABORATION OF METRONIDAZOLE 1% TOPICAL SOLUTION FOR TREATMENT OF ULCERS INFECTED BY ANAEROBIC BACTERIA

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Background and importance The scientific literature was reviewed in order to investigate metronidazole 1% topical solution for treatment of ulcers infected by anaerobic bacteria, and whether refrigerated storage is recommended. However, the samples formulated in the Hospital Pharmacy Department presented a crystalline precipitate, which could not be redispersed. Therefore, a compounding improvement was necessary.
Aim and objectives Design and analyse, by galenic validation, different compounding improvement to increase the solubility of metronidazole in water in three storage environments.