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GRAVIMETRIC AND SPECTROPHOTOMETRIC QUANTIFICATION OF PRAVASTATIN SODIUM SALT EXTEMPORANEOUS SOLUTIONS ADMINISTERED THROUGH FEEDING TUBE: EFFECT OF PREPARATION METHODS.

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BACKGROUND

Most drugs are available only as solid oral dosage forms. Patients with swallowing difficulties supplied by enteral nutrition (EN) are not able to assume these pharmaceutical forms. Therefore, to improve the management of their drug therapy, it's often necessary to handle original drug to prepare an extemporaneous liquid dosage form.

PURPOSE

Aim of this work was to evaluate two different extemporaneous preparations (prepared starting from dissolved and crushed tablets) containing Pravastatin sodium salt (PraNa) that are administered through feeding tube for EN. Results were compared with a PraNa standard solution.

MATERIAL AND METHODS

Standard solution (A) was prepared dissolving standard PraNa and parabens in sodium bicarbonate 8.4% solution. Galenic preparation (B) was obtained using 20mg PraNa tablets (Pensa S.p.A.), parabens and sodium bicarbonate 8.4% solution. Extemporaneous preparation (C) was prepared crushing tablets of PraNa in a mortar and then the obtained powder was dispersed with water. The final concentration of all the three preparations was 4mg/ml. 10ml of each solution were administered through an enterally syringe into the feeding tube and then collected downstream of the tube. After each administration, tube was flushed with distilled water (10ml). The total volumes, weights and absorbance (238 nm) were measured to determine the drug concentration and the total amount of PraNa delivered through the tube. Statistical analysis (T-test or Anova) was performed to evaluate the obtained results.

RESULTS

Gravimetric results showed a reduction of the amount of solution effectively delivered in the range of 6-8%, although such differences were not statistically significant when the different preparation methods were compared (Anova). When the amount of PraNa was quantified downstream, slight differences were observed both in term of absolute values than between the different preparation methods. Statistical analysis (T-test and Anova) did not highlight any statistically significant differences. Even though the above results, the standard deviations (SDs) represented in Figure 1 showed a larger range (about twice) in extemporaneous preparation than in the standard and galenic ones. Instead in Figure 2, SD in standard solution revealed a smaller range (about 6 times) compared to those of the galenic and extemporaneous preparations.

CONCLUSION

Comparing the different preparation methods, no significant differences were found, neither when the comparison was between them nor with standard solution. Therefore, all the three methods could be safely used to manage drug therapy and to assure compliance in dysphagic patients.

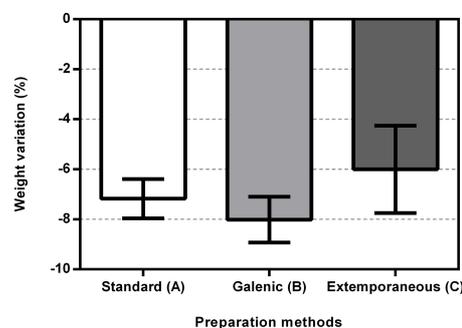


Figure 1: Weight variation (%) between upstream delivered and downstream collected preparations

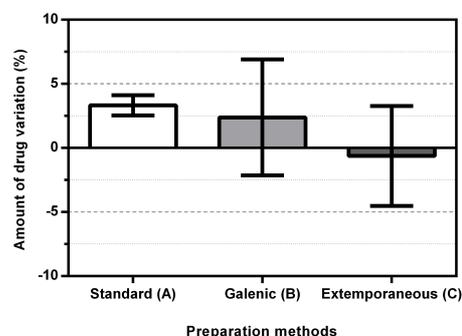


Figure 2: Amount of drug variation (%) in the three different preparation methods