Compounding paediatric medicines from adult preparations may result in poor content uniformity

January 7 2014

More standardised methods are needed for the extemporaneous preparation of paediatric medicines,according to a doctoral dissertation examined at the University of Eastern Finland. Hospital pharmacies modify adult medicines for children when there are no suitable paediatric medicines available. Medicines intended for adults can be modified for children into oral suspensions, oral powders or capsules the contents of which are emptied for use. However, the study showed that the quantity of the active ingredient per dosage can vary widely in these preparations, depending on the dosage form and handling of the product.

A positive European trend in the approval of safe and efficacious medicines for children seems to be in progress, but achieving this goal takes time. Age-appropriate dosage forms formulated at different strengths containing harmless excipients are routinely needed.

Ms Minna Helin-Tanninen, Lic.Sc. (Pharm.), examined the content uniformity as well as the chemical and physical stability of different dosage forms of nifedipine, a drug used for treating pulmonary hypertension in children with bronchopulmonary dysplasia. The study focused on extemporaneous nifedipine capsules, powders and oral suspensions.

Oral suspensions require vigorous shaking

A remarkable variation in the nifedipine amount per dose, even tens of percents, was discovered in oral suspensions packed in multi-dose bottles when not shaken thoroughly. Not only the amount of shaking but also the excipients used in the suspension had an impact on content uniformity. It was observed that sophisticated suspensions mixed uniformly and easily, but contained excipients that are not recommended for neonates. Good uniformity was achieved in unit-dose suspensions that were prepared in the pharmacy with non-toxic excipients.

Opened capsules represent an alternative

The study also showed that when nifedipine was administered in powder form and the total mass of the oral powder was kept low for easy administration, the amount of nifedipine obtained by the paediatric patient was too low, less than 80% of the targeted amount. Most of the missing amount remained in the emptied powder sachets. On the other hand, nifedipine capsules, the contents of which were emptied for use, proved a good alternative to oral powders and multi-dose suspensions. Small capsules contain low amounts of excipients while the amount of nifedipine remains sufficient. The use of water-soluble lactose as an excipient prevents the occlusion of the small-bore nasogastric feeding tube.

According to Ms Helin-Tanninen, more research on extemporaneous preparation is required. "The medicines prepared in hospital pharmacies are useful to many patients. Although the tradition of pharmaceutical compounding can be traced back hundreds of years as part of the professional skill set of pharmacists, the quality of the compounded products has been inadequately studied when compared to manufactured medicines." Ms Helin-Tanninen presented the results in her doctoral dissertation.