

Certified child-resistant packaging for pharmaceuticals

An estimated 500,000 accidental child poisonings occur in Europe every year. Affected are mostly small children up to three years old and the poisoning occurs mainly with pharmaceutical products. Child-resistant packaging, representing the last barrier, as it were, between the infant and the packaged content has an important part to play in solving the problem. Although the industry's awareness for this type of safety packaging has increased, knowledge about differences and subtleties is often lacking. Independent of the child-resistant packaging's system and material, a review of the safety function is necessary to ensure that it works correctly before being put to use. A standardized certification procedure can bring about clarity; it can vouchsafe for the packaging's quality and product safety at that time.

Legal framework

In Europe, such packaging certification of pharmaceutical products is done in compliance with the ISO 8317 for reclosable and EN 14375 for non-reclosable packages (www.ivm-childsafe.com). Tests are conducted with small children between 42 to 51 months and senior citizen between 50 to 70 years and serve as a basis for this certification. In international comparison, the United States were the first to create standards that made child-resistant packaging mandatory for the vast majority of drugs (see US 16 CFR § 1700).

Today, comparable requirements and standards are in place in Germany as well as internationally (requirements according to § 28 AMG, BtMVV § 12). The company bringing the product to market bears the responsibility of compliance with these norms and standards. There is a sound reasoning behind this, since it's always the entire product which is being certified, not the individual components.



Fig: pills are easily confused with candy

Towards a child-resistant packaging

In the development of child-resistant packaging, it is important to create hurdles which are difficult for children to overcome, but easy enough for senior citizens to solve and operate. To get this balance between child-resistance and suitability for senior citizens right, appropriate packaging concepts are based on the following skills, for example: motor, fine motor skills, logic, experience, patience and intuition. A basic distinction is made between reclosable and non-reclosable child-resistant packaging.

Reclosable child resistant packaging can be closed again in a child-resistant way after opening and removing part of the contents. Many systems are based on an opening trick that is not known to toddlers and also very challenging for their level of motor



Fig: Reclosable child resistant packaging with push-lock closing mechanism

coordination. The most well-known examples are types of packaging with a screw on cap, which can be opened only by pushing down and turning simultaneously. Another well-known variant can only be opened by pushing sideways and turning simultaneously.

With non-reclosable child resistant packaging, the units are individually packaged and removed. Their best-known forms are pharmaceutical blisters with individually wrapped pills or tablets. They offer good protection, ensure prolonged shelf life and at the same time provide a form of prevention against tampering. While in Europe the majority of producers still prefer push blisters with multilayer laminated films, reinforced to meet the requirements of EN 14375, in the United States more complex systems are gaining traction. These distinguish themselves through the necessity of an additional effort in form of cognitive and motor hurdles (such as peel-push blisters). A child-resistant solution which meets the certification criteria needs to combine the interaction of various factors, such as the lidding foils' properties as well as those of the formable foil, or by perforations. Even small deviations, such as variations in cavity size, can lead to a loss of the child-resistant functionality.



Fig: Blister with child resistant non-reclosable packages

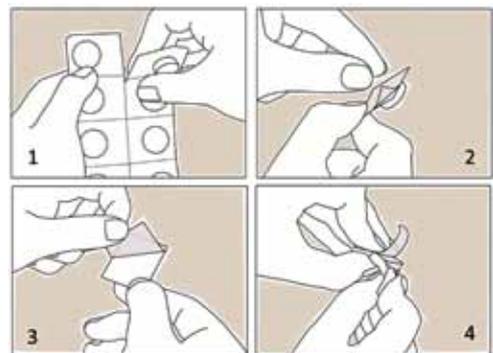


Fig: Blister with child resistant peel-push-mechanism

Testing the function

Child-resistant packaging's functionality must be tested in order to be described as child resistant. To give an example, a safety mechanism based on the "push and turn" principle is no evidence that the opening and the removal of the contents by small children is really prevented. It often happens that safety mechanisms are designed to be technically complex and include the interaction of different factors to prevent the opening by small children, but still fail in practical use.

In Europe tests on pharmaceutical packaging are conducted in the majority of cases in compliance with ISO 8317 for reclosable and EN 14375 for non-reclosable packaging. To test child-resistance, infants aged 42 to 51 months will be asked twice to open the package for a five minute period (with and without a demonstration of the opening procedure). The certification requirements are fulfilled if, within the first five minutes, no more than 15 percent of the children manage to open the package and no more than 20 percent of children access the contents of the package throughout the entire ten minute period.

At the same time, a review of the packaging's suitability for older adults form part of the test procedure. To ensure access to the contents for senior citizens and

guarantee that there will be no restrictions in their medication, despite the obstacles designed for children, the package is tested with individuals between 50 and 70 years of age. After a preparation time of five minutes at least 90 percent of the test subjects have to be able to access the content and close it again properly within a minute, provided the packing is reclosable. Through this double test method, child- and senior-friendly packaging is guaranteed in compliance with European standards.

Working together to ensure safety

To summarize, the following points need to be taken into consideration for the packaging of medical drugs. If there is danger to the health of small children, child-resistant packaging must be used and this packaging must be tested to establish that it works satisfactorily. The testing of child-resistant packaging for pharmaceutical products is subject to the standards ISO 8317 and EN 14375, compliance is proven through certificates. Certification is handled by accredited institutions (www.ivm-childsafe.com) complying with EN 45011 in order to be recognized internationally by government agencies, industry and consumer protection organizations. The development of suitable



packaging materials should be planned well in advance, a key to success being communication between all the partners involved, i.e. pharmaceutical companies, packaging manufacturers and testing laboratories. Working together, they can guarantee compliance with the safety requirements, keeping the children's best interest in mind.

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