

Dispersible Tablets

Background:

Many medicines are only available in adult strength; therefore the administration of accurate dosage for children is critical. The taste of the medication is also an important parameter for adherence to treatment and compliance.

The adjustment of adult formulations to paediatric dosage is often done by cutting or crushing tablets, opening the capsules and using the powder to make a liquid, diluting concentrated preparations or, using injections orally, etc.

As a direct consequence, children are often given formulations that have not been developed for them. This practice can compromise the efficacy and safety of the treatment.

Over the last two years the WHO and the UNICEF have joined their efforts in promoting the development of paediatric pharmaceutical formulations for children of various ages, including dispersible tablets which disintegrate in water or a small amount of breast milk.

Age classification of paediatric patients

Paediatric medicines must allow accurate administration of the dose to children of varying age and weight. In addition, the formulation must be acceptable for the child in terms of taste and easy to administer for the care-giving adult.

During childhood, there are significant changes in the ability to handle different dosage forms. The WHO has proposed the following age classification:

- Pre-term newborn infants (<37 weeks gestation)
- Full-term newborn infants (0 to 28 days)
- Infants and toddlers (1 month to 2 years)
- Children, pre-school (2 to 5 years)
- Children, school (6 to 11 years)
- Adolescents (12 to 16-18 years -dependent on region-)

Oral medication is the preferred route of administration to children.

Small-volume liquid medicines are appropriate for use in the younger age groups.

Children less than 5 years of age usually have problems with swallowing tablets and capsules (= dysphagia).

Dysphagia may be overcome by developing solid dosage forms (dispersible tablets) to be dissolved, dispersed or mixed with food, milk or water prior to administration.

Dispersible tablets are a convenient formulation for infants, toddlers and pre-school children.

Definition

Dispersible tablets are uncoated or film-coated tablets that can be dispersed in liquid before administration giving a homogenous dispersion.

Dispersible tablets usually disintegrate within three minutes when put in water or a small amount of breast milk.

Advantages of dispersible tablets versus liquid formulations

In general dispersible tablets are:

- more convenient for active pharmaceutical ingredients with insufficient stability in water.
- more easily transportable and they generate less handling and transportation costs for the same amount of active ingredient (less volume, less weight)
- easier to produce and the production costs are less, which makes them more affordable than standard liquid formulations.

Other advantages include:

- can be used in very young children (0 – 6 months).
- are easy to dispense and: they require minimal manipulation by health professionals and parents prior to use which minimises the risk of errors.
- require a small amount of water for administration.
- can be dispersed in breast milk.

Other specificities of the dispersible formulations

- As for liquid formulations, the taste of a dispersible tablet is a crucial parameter that will condition the acceptability by the child and the adherence to treatment. Taste masking is obtained by adding flavours and/or sweeteners to the formulation.
- Dispersible tablets have less physical resistance than regular tablets; they are more sensitive to moisture and may degrade at higher humidity conditions. Each tablet must be protected from the ambient humidity.
- The quality of the packaging is critical to guarantee the conservation of the product.
- Dispersible tablets are usually packed in blisters (aluminium/PVC) or strips (aluminium).

The manufacturer guarantees the stability of the dispersible tablet in the primary packaging (blister or strip).

Recommendations for the use of dispersible formulations

- To be dispersed in a small amount (5 to 10ml) of liquid (clean water or milk).
- Use of a clean and appropriate container is recommended to disperse the tablets.
- The liquid can be softly stirred to aid dispersion before swallowing.
- As a proportion of the active substance may remain in the container after swallowing, it is advisable to rinse it with a small amount of water or milk and swallow again.
- The dispersible tablets should not be divided or chewed.
- Careful handling of dispersible tablets is necessary as, they are much more fragile than the regular tablets (more friable, less resistant to rubbing).

Dispersible tablets must be used immediately after removal from the blister packaging. Their stability outside of the blister cannot be guaranteed.

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