

CaSO₄ - 2 H₂O as a tableting diluent

What properties should a tableting diluent exhibit?

Many drugs are prescribed in very small quantities. These tiny amounts have to be diluted, so that the pharmacist and the patient can handle them properly; this is the purpose of a diluent.

Thus, most tablets consist mainly of diluents and other tableting additives and contain only a small proportion of the actual drug.

The most important property for a diluent can be deduced from this large proportion; it must be physiologically safe even in large quantities. It must not produce side effects either in the digestive tract or in any other organ.

Moreover, there must be no interaction between the diluent and the other components of the tablet. The components of the tablet should remain unchanged even in long-term storage. The effect of the diluent on the liberation of the drug and its resorption in the digestive tract is also of importance. The diluent should contribute to a reproducible and, as far as possible, predictable behaviour of the tablet after consumption. The diluent should allow the adjustment of the hardness and disintegration time which are the most important properties for its behaviour. Tablet diluents must naturally allow of processing with the normal technical installations. This extends from the flow properties of the diluent to its mixability with the drug and other additives, the granulation of the mixture and its pressability on the tableting machine.

The process of tableting is particularly dependent on the recipe and on the available plant. A harmonization of the properties of the diluent to these parameters is essential, since the diluent constitutes most of the tablet and influences the properties of the tablet to a very large extent.

Storage stability under extreme climatic conditions is necessary if the diluent is to achieve widespread use. Storage stability includes the chemical, physical and microbiological stability.

Tablets are oral medicaments and must be manufactured with low microbial counts. Naturally this also applies to raw materials. Thus, raw materials that do not constitute a nutrient medium for bacteria and fungi are advantageous for the maintenance of a proper microbiological purity during long-term storage. The required properties of a tablet diluent can be described under the following headings:

- harmless to the health even in large doses
- inert with predictable behaviour towards drugs and in terms of drug release,
- trouble-free manufacture
- good storage properties
- long term, trouble-free microbiological status.