



REVIEW ARTICLE

## PHARMACEUTICAL DILUENTS AND THEIR UNWANTED EFFECTS: A REVIEW

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**Diluents are chemically inactive excipients, mostly used to make up the required bulk of solid dosage form and used up to 80% in a formulation. Various studies reported that diluents used in the solid dosage forms shows unwanted effects in body on long term and some time in short duration therapy. So, it is necessary to study the unwanted effects of diluents by researchers and production chemists before preparation of a pharmaceutical formulation to reduce the unwanted actions. Present review provides toxicological data of commonly used pharmaceutical diluents and summarizes the unwanted effects of pharmaceutical diluents on public health.**

**Key words:** Diluents, Solid dosage form, Tablets, Unwanted effects.

### INTRODUCTION

Diluents or fillers are pharmaceutical ingredients which lack pharmacological activity but are desirable or necessary in pharmaceutical preparations. Diluents comprise of heterogeneous groups of substances, designed to make up the required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk (Nahata, 2009). In order to facilitate tablet handling during manufacture and to achieve targeted content uniformity, the tablet size should be kept above 2-3 mm and weight of tablet should be above 50 mg. The range of diluent may vary from 5-80% in a pharmaceutical formulation (Pandey *et al* 2009). Diluents are often added to tablet formulation for secondary reason like to provide better tablet properties such as, to allow direct compression, provide improved cohesion, enhance flow and adjust weight of tablet as per die capacity (Chaudhari and Patil, 2012). Ideally Diluents should not show any effect on the other excipients used in the formulation

(Allen, 2000). Diluents should be able to mill into small sized when needed (Steinberg *et al* 2001). It should not support microbial growth in the dosage form, should not affect the dissolution of the product, should not interfere with the bioavailability of active ingredients. It should not affect the pharmacological activity of active ingredients (Fathima *et al* 2011).

### Classification of diluents

Diluents are classified on the basis of chemical nature and solubility:

#### Chemical nature

Diluents are further divided into three subtypes on the basis of their chemical structure: as organic, inorganic and co-processed.

#### Organic materials

Carbohydrates and modified carbohydrates are the major examples of this category *i.e.* lactose, starch and pre-gelatinized starch, sucrose, mannitol, sorbitol, powdered and