Control of raw materials in pharmaceutical industry – comparison of pharmacopoeia regulations

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Introduction

The production of safe and effective pharmaceutical products with standard quality requires permanent monitoring, control and quality assurance of everything that is involved in the production process. To meet the stringent requirements of the pharmacopoeia regulations, it is necessary to carry out quality control tests of incoming raw materials continuously, including quality control of active substances, excipients and packaging material. A huge number of manuals, protocols, standard operating procedures, pharmacopoeia regulations and guidelines which provide additional information for monitoring and ensuring the quality of raw materials in the pharmaceutical industry are available.

Goals

The aim of this study was to compare the requirements included in the monographs of the European, American, Indian Pharmacopoeia and in the Handbook of Pharmaceutical Excipients and to estimate them as control parameters for evaluation of the quality of raw materials in production of Paracetamol tablets á 500 mg.

Results

From the comparisons made, it can be noted that the requirements included in the monographs of these three pharmacopoeias are largely similar, so we can conclude that there is compliance within the pharmacopoeia requirements. The only significant differences were observed in the part concerning the packing material. European Pharmacopoeia contains monograph specific for each type of packaging material while applications relating to packaging materials in the US and Indian Pharmacopoeia are not placed in separate monographs.

Materials

The Summary of Product Characteristics for Paracetamol tablets á 500 mg, manufactured by the pharmaceutical company Sandoz was used. The monographs for acetaminophen, sodium starch glycolate (type A), corn pregelatinized starch, stearic acid, povidone and materials based on virgin PVC used for packing dry dosage forms for oral administration included in the fifth edition of the European Pharmacopoeia (European Pharmacopoeia 5.0), the American Pharmacopoeia (United States Pharmacopeia 30th revision) and the fifth edition of the Indian Pharmacopoeia published in the 2007 (Indian Pharmacopoeia 2007) and monographs of auxiliary substances included in the sixth edition of Handbook of pharmaceutical excipients (Handbook of pharmaceutical excipients; sixth edition) were compared.

Methods

The comparative method was used.

Conclusions

In industrial conditions, the quality control specifications may also include other requirements and tests that are not included in the monographs of the pharmacopoeia, as is necessary for defining the quality of incoming raw materials. Fulfilling all the requirements included in the specifications for quality of all incoming raw materials and respecting the standards of good manufacturing practice provides assurance that we will achieve the required quality, efficiency and reliability of the finished pharmaceutical product.