

## **Publication**

An explorative analysis of process and formulation variables affecting comilling in a vibrational mill: the case of praziquantel

## JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

**ID** 4117151

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Year 2017

**Title** An explorative analysis of process and formulation variables affecting comilling in a vibrational mill: the case of praziquantel

Journal International journal of pharmaceutics

Volume 533 Number 2

Pages / Article-Number 402-412

Praziquantel, a BCS II class anthelmintic drug used for the treatment of schistosome infections, was coground in a vibrational mill with different polymers (linear and crosslinked povidone, copovidone and sodium starch glycolate). An explorative analysis of formulation variables (drug-polymer wt ratio and polymer type) and process parameters (type of grinding media, grinding time and frequency) was carried out with the help of an experimental screening design. The influence of the above mentioned factors on three PZQ characteristics (residual crystallinity, water solubility enhancement and drug recovery) was studied. The variation of carrier amount proved to be by far the most important variable affecting all the experimental responses. A lower impact and, in some cases, rather null effect, had the variation of the process variables. All coground systems were characterized by a high amorphous degree and a solubility significantly higher than the API. A very promising product was obtained by processing at 20Hz for 4h, using 3 spheres of 15mm as grinding media, i.e. a coground having a 50% API content, showing a 4.6-fold greater solubility at 20řC than pure praziquantel. This product maintained the same antischistosomal activity of pure API and was both physically and chemically stable for at least 6 months.

Publisher Elsevier ISSN/ISBN 0378-5173

edoc-URL http://edoc.unibas.ch/58034/

Full Text on edoc No;

**Digital Object Identifier DOI** 10.1016/j.ijpharm.2017.05.053 **PubMed ID** http://www.ncbi.nlm.nih.gov/pubmed/28552799

ISI-Number WOS:000414188500011

Document type (ISI) ArticleProceedings Paper