Journal of Innovations in Pharmaceutical and Biological Sciences (JIPBS)
ISSN: 2349-2759
Available online at www.jipbs.com

Mini Review

Stability by Design (SbD): A proposal of application of Quality by Design (QbD) concept to physical stability as a control strategy

Maher Abdulrazzaq Al-hakeem*, Lăcrămioara Popa, Cristina Dinu-Pîrvu, Mihaela Violeta Ghica, Răzvan Prisada

Department of Physical and Colloidal Chemistry, Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila", Bucharest 020956, Romania.

Received on: 11/03/2020, Revised on: 22/03/2020, Accepted on: 24/03/2020, Published on: 02/04/2020.

***Corresponding Author: Maher Abdulrazzaq Al-hakeem,** 6, TraianVuia, Bucharest, Romania. Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania.
Email id: abdul.maher@drd.umfcd.ro

Key words: Stability Control Strategy, Analytical Quality by Design, Stability Acceptable Design Region, Stability by Design and Quality by Design.

Vol. 7 (2): 01-05, Apr-Jun, 2020.

Abstract

The ability to begin with the end in mind is a vital aspect of the Quality by Design (QbD) concept. The application of the concept to the process of pharmaceutical manufacturing, the first most requirement lies in developing a rather quality product. Also, the QbD concepts can be utilized in designing and developing product stability by assessing the reportable value of the given product as an analytical procedure for stability. Thus, a Stability Target Profile (STP) ought to be developed as it forms the foundation for stability development about the Stability Control Strategy (SCS). Contrary to the routine approaches, the SbD has to be initiated with a thorough comprehension of STP as well as risk evaluation for all the method variables that are likely to affect the response. An in-depth understanding of QbD will, therefore, be useful in the identification of the vulnerabilities and risks that relate to drug production, storage, and usage which will help in making informed choices and in return support the implementation of a control strategy.

Abbreviations

Quality by Design (QbD), Stability by Design (SbD), Stability Control Strategy (SCS), Analytical Quality by Design (AQbD), Continuous Stability Monitoring (CSM), Analytical Target Profile (ATP), Critical Quality Attributes (CQA), Stability Acceptable Design Region (SADR), Method Operable Design Region. (MODR), Design of Experiments (DoE), International Conference of Harmonization (ICH), Drug Substance (DA), Food and Drug Administration (FDA).