Development and Stability of Forced Degradation Studies Indicating Different Brands of Metformin Drugs

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Abstract: *In present study, Accouring to specification of Indian pharmacopeia the content official limit of not less than (98.5%) and not more than (101.0%) of the lable amount our hypothesis was that when all different brands of metformin were expose to the different degradation parameters. The Forced degradation studies show the chemical behavior of the molecule which in turn helps in the development of formulation and package. A forced degradation study is an essential step in the design of a regulatory compliant stability program for both drug substances and products, and formalized as a regulatory requirement in ICH Guideline Q1A in 1993. Forced degradation is a degradation of new drug substance and drug product at conditions more severe than accelerated conditions.*

Keywords: Drug Degradation, mineral oils, lipogels, Forced, Organic solvent etc.

REFERENCES

[1]. Ragine Maheswaran.FDA Perspectives: Scientific Considerations of Forced Degradation Studies in ANDA Submissions. Pharmaceutical Technology 2012; 36:73-80.

[2]. Bojana P, Markus D, Kappe CO. Microwave-assisted forced degradation using high-throughput microtiter platforms. Pharmaceut Biomed 2011; 56:867-873.

[3]. International conference on harmonization (ICH) of technical requirements for registration of pharmaceuticals for human use, Validation of analytical procedures: Text methodology, (Q2 (R1) Geneva, 2005) 6-13.

[4]. Draft guidance analytical procedures and method validation, US food and drug administration, Centre for drugs and biologics, Department of Health and Human Services. http://www.fda.gov/cder/guidance/2396 dft.htm#111, 2000.

[5]. Brummer H et.al. How to approach a forced degradation study. Life Sci.Tech. Bull.31, 2011, 1-4.

[6]. Kaushik D, Bansal G. Characterization of degradation products of idarubicin through LC-UV, MS and LC–MS-TOF studies. J Pharm Biomed Anal 2013; 85:123-31.

[7]. Jain D et.al. Forced degradation and impurity profiling: Recent trends in analytical perspectives. Journal Of Pharmaceutical and Biomedical Analysis 86, 2013, 11–35.

[8]. Forced Degradation Studies for Drug Substances and Drug Products. Q1 Scientific Stability Storage Specialists;2017. Available from: http://www.q1scientific.com/forced-degradation-studies-drug-products. [Last accessed on 2018 Feb](Table-2)

[9]. Singh S, Bakshi M. Guidance on conduct of stress tests to determine inherent stability of drugs. Phrama Tech 2000; 24:1:14

[10]. Boccardi G. Oxidative susceptibility testing: 220. In; pharmaceutical Stress testing-Predicting Drug Degradation; Baertschi SW, editors, Taylor and Francis, New York. 2005.