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Quality Control and Quality Assurance in Pharmaceuticals

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Abstract: *The international methods for evaluating the presence of geotaxis impurities (residual solvents and different inorganic and organic impurities) in pharmaceuticals are briefly discussed in this study. Due to national and international requirements, it is now important to give not only the purity profile but also the impurity profile of a certain pharmaceutical product. These factors, as well as the importance of the quality, effectiveness, and safety of medicines, are examined. These include the origin, types, and regulation of impurities. One of the requirements for the delivery of any nation's healthcare system has been defined as the availability of important medicines of high quality. This is because consumers can be harmed or even killed by subpar medications. Even in very small doses, the presence of undesirable compounds in a certain medicine may affect both its efficacy and safety. A pharmaceutical is a dynamic product that, unlike products from other industries, can alter between manufacture and final consumption in terms of colour, consistency, weight, and even chemical identity.*

Keywords: Quality Control

REFERENCES

[1]. Woodcock J, The concept of pharmaceutical quality. American Pharmaceutical Review, 7(6), 2004, 10–15.
[2]. Q9: Quality Risk Management. ICH Harmonized Tripartite Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2006.
[3]. Q10: Pharmaceutical Quality System, ICH Tripartite Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2007.
[4]. Lionberger RA, Lee LS, Lee L, Raw A ,Yu LX, Quality by design: Concepts for ANDAs, The AAPS Journal, 10, 2008,268–276.
[5]. FDA Guidance for Industry and Review Staff: Target Product Profile – A Strategic Development Process Tool (Draft Guidance).
[6]. Q8 (R1): Pharmaceutical Development, Revision 1, ICH Harmonized Tripartite Guidelines, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2007.
[7]. Callis JB, Illman DL, Kowalski BR, Process analytical chemistry. Analytical Chemistry, 59, 1987, 624A–637A.
[8]. Yu LX, Pharmaceutical quality by design: Product and process development, understanding, and control. Pharmaceutical Research, 25, 2008, 781–791.
[9]. Munson J, Gujral B, Stanfield CF, A review of process analytical technology (PAT) in the
[10]. U.S. pharmaceutical industry. Current Pharmaceutical Analysis, 2, 2006, 405–414.
[11]. Leuenberger H, Puchkov M, Krausbauer E, Betz G, Manufacturing pharmaceutical granules, Is the granulation end-point a myth, Powder Technology, 189, 2009, 141–148.
[12]. Miller CE, Chemometrics and NIR: A match made in heaven, Am. Pharm. Rev. Food and Drug Administration CDER,Guidance for industry, Q8 pharmaceutical development;2:41–48, 2006.
[13]. Nasr M. Risk-based CMC review paradigm, Advisory committee for pharmaceutical science meeting, 2004.
[14]. Food and Drug Administration CDER. Guidance for industry: Immediate release solid oral dosage forms scale-up and post approval changes: Chemistry, manufacturing, and controls, in vitro dissolution testing, and in vivo bioequivalence documentation, 1995.

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[15]. Food and Drug Administration CDER. Guidance for industry: Modified release solid oral dosage forms scale-up and post approval changes: Chemistry, manufacturing, and controls, in vitro dissolution testing, and in vivo bioequivalence documentation, 1997.

[16]. Food and Drug Administration CDER. Guidance for industry: Non sterile semisolid dosage forms scale-up and post approval changes: chemistry, manufacturing, and controls, in vitro dissolution testing, and in vivo bioequivalence documentation, 1997.

[17]. Food and Drug Administration CDER. Guidance for industry: Changes to an approved NDA or ANDA, 2004.

[18]. Woodcock J, The concept of pharmaceutical quality. American Pharmaceutical Review, 2004, 1–3.

[19]. Food and Drug Administration, Office of Generic Drugs White Paper on Question-based Review:http://www.fda.gov/cder/ OGD/QbR.htm.

[20]. Food and Drug Administration, Guidance for industry, Q6A specifications for new drug substances and products: Chemical substances, 1999.

[21]. Nasr M, FDA's quality initiatives: An update, http://www.gmpcompliance.com/daten/download/ FDAs_Quality_Initiative.pdf, 2007.

[22]. Naresh Bhakar, Audit check list for quality assurance pharmaceuticals,2022.