

Research of the main rules regarding pharmaceutical development of drug substance and drug product

Varduhi M. Ghazoyan*, PhD, Abbas Al-Husseini, BS

Eurasia International University, Department of Pharmacy, Yerevan, Armenia

* ghazoyanvarduhi@gmail.com

On the example of «Furacillin 0.02 % 200 ml solution for external use» drug product the main rules regarding pharmaceutical development of drug substances and drug products were studied and discussed. Section 3.2.P.2 Pharmaceutical Development of CTD for this drug product which is developed as an antimicrobial medicine against gram-positive and gram-negative bacteria was provided by six main parts. There were provided sections 3.2.P.2.1-3.2.P.2.6 of CTD, as well as some reference sections where more detailed information may be found. Reference sections provided by ICH were extracted and provided.

Key-words: Regulation, pharmaceutical development, Common Technical Document, section 3.2.P.2, reference sections.