



INSTRUCTION MANUAL FOR TURNITIN SIMILARITY

1. Application for account-ID

Please send a message from your university address (name@ ... uni-heidelberg.de) to Dr. Martin Nissen (nissen@ub.uni-heidelberg.de), who is responsible for the Turnitin Similarity plagiarism detection system at Heidelberg University Library. You will receive an email from the provider to set up the account. All authorized examiners at the university are permitted to use it. Students and doctoral candidates are not permitted.

2. Accepting the terms of use

Click on the link "Set up my Account" given in the email.

Choose a username (e.g. your university email address) and a password. The password must consist of at least 8 characters and contain at least one letter and one number.

Read section B for users within the European Union and select "I agree to the terms and conditions". The terms of use conform to the European data protection guideline General Data Protection Regulation (GDPR) of May 25, 2018.

3. Uploading and checking a text

After clicking on "Launch", you can start uploading documents. To do this, it is advisable to create folders for the files to be checked. When creating a folder, you can select the option "Files uploaded to this folder will be used for similarity comparison" to store the documents in the internal document server (institutional repository). This enables you to compare texts to be checked against the texts stored on the internal document server at a later point in time.

Via "Upload" you can select documents to be checked either by "Drag and Drop" or by "Select Files". Make sure that all pages with personal data (e.g. name, email address, student number) have been removed beforehand.

A new window with a data mask opens. Fill in the fields "Title", "Author First Name" and "Author Last Name" with pseudonymised names that allow you to assign the document again later.

4. Accessing results

After a short while (usually within minutes), the results are ready to be accessed (Login via: <https://uni-heidelberg.turnitin.com/home/sign-in>). The result is displayed as a percentage in the column "similarity".

INTRODUCTION

In recent years, the Food and Drug Administration (FDA) has emphasized “Quality by Design” (QbD) as a current Good Manufacturing Practices (cGMP) initiative for the twenty-first century. Despite numerous presentations and publications by FDA officials and leading pharmaceutical researchers (1, 2, 3, 4, 5, 6, 7, 8, 9, 10), several pilot programs (11,12), and the adoption of QbD by the International Conference on Harmonization, misunderstanding about QbD is still prevalent throughout pharmaceutical, biotechnology, and medical device industries. This article points out the basic components of QbD and application of QbD concepts to develop formulations and optimize manufacturing processes for topical dermatologic products.

The basic premise of QbD is that a product cannot be tested or inspected into a quality product and quality attributes should be designed *via* the thorough understanding of raw materials, formulation, and manufacturing process into a drug product. Additionally, under quality by testing (QbT), the sample size for each stage of testing is generally insufficient to ensure acceptable quality attributes for an entire batch. Hence, under QbD, testing confirms acceptable quality attributes, without extensive sampling. Specifications from raw materials, active ingredients, in-process testing, and drug product are only part of the quality control strategy. The quality needs to be designed into a drug product based upon a systematic understanding of how critical material attributes (CMAs) of drug substance and excipients, and critical process parameters (CPPs) used during manufacturing affect critical quality attributes of the drug product. This type of understanding can be achieved using various QbD

Sources Overview

79% OVERALL SIMILARITY

0 Flags

79% Overall Similarity

link.springer.com INTERNET 4%

historicum.net INTERNET 3%

www. INTERNET

Mikas CROSSREF

www. INTERNET

*Unite CROSSREF

files. INTERNET

*Russi CROSSREF

de.wik INTERNET

*Shi La CROSSREF

*South CROSSREF

*US: B

link.springer.com INTERNET 4%

1 of 1

https://link.springer.com/article/10.1208/s12248-013-947-3

riticality analysis FMEA Failure mode effects analysis The opinions expressed in this review by the authors do not necessarily reflect the views or policies of the Food and Drug Administration (FDA). **INTRODUCTION** In recent years, the Food and Drug Administration (FDA) has emphasized “Quality by Design” (QbD) as a current Good Manufacturing Practices (cGMP) initiative for the twenty-first century. Despite numerous presentations and publications by FDA officials and leading pharmaceutical researchers (1, 2, 3, 4, 5, 6, 7, 8, 9, 10), several pilot

Please note: The percentage shown is only an indicator of the extent of the matches with searched internet sources. It does not provide any information about whether the submitted text is plagiarism or not! The software also displays correct quotations, common idioms, and random matches. Only you can judge by carefully reading the report whether the document to be checked actually contains plagiarism.

You will find further assistance from the provider on the following webpage:
<https://help.turnitin.com/integrity.htm>