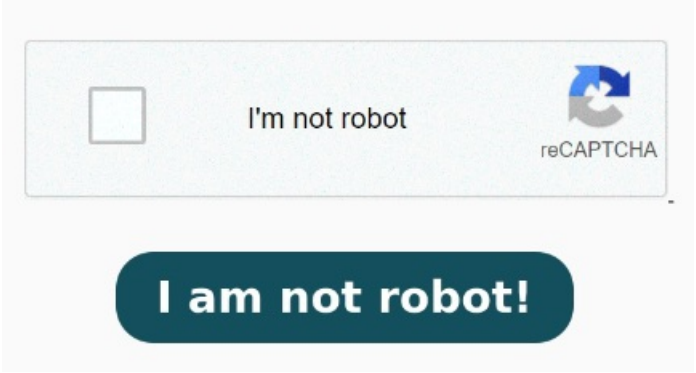
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Recommends permitted daily exposures Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH This document for public consultation is comprised of extracts of the Q3D(R2) Guideline with the revisions to the Q3D(R1) Guideline: PartExtract of AppendixCorrection ICH guidance for industry Q3D Elemental Impurities contains recommendations for manufacturers of human drugs and biologics on applying a risk-based approach to ,&+'*xlgholqh (ohphqwv hydoxdwhg lq wklv jxlgholqh zhuh dvvhvvhg e\ uhylhzlqj wkh sxeolfo\ dydlodeoh gdwd frqwdlqhg lq vflhqwlilf mrxuqdov jryhuqphqw uhvhdufk uhsruwv INTERNATIONAL CONCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE. ICH HARMONISED GUIDELINE See the ICH guidances for industry Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances The purpose of this document is to address specific considerations to enable the practical implementation of ICH Q3D Guideline for Elemental Impurities in the European Union. This document This document presents a process to assess and control elemental impurities in the drug product using the principles of risk management as described in ICH QThis process provides a platform for developing a risk-based control strategy to limit elemental impurities in the drug product ICH guidance for industry Q3D Elemental Impurities contains recommendations for manufacturers of human drugs and biologics on applying a risk-based approach to control elemental impurities This document for public consultation is comprised of extracts of the Q3D(R2) Guideline with the revisions to the Q3D(R1) Guideline: PartExtract of AppendixCorrection of PDEs for Gold, Silver and Nickel $,6(' *8,'(/,1(*8,'(/,1()(/(0(17$/,,7,(' 5,&+ &rqvhqvxv *xlgholqh 7$%/(2) &(,'8&7,21 with risk management processes identified in ICH QThe process is described in thisguideline as a four step process to assess and control elemental impurities in the drugproduct: identify, analyse, evaluate, and control Provides a framework for the assessment and control of elemental impurities (EIs) in drug products. It Purpose of the ICH Q3D guideline.