What's New with Impurities in Pharmaceuticals?

Southern California Pharmaceutical Discussion G

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ICH Q3 Impurities

Q3A Drug Substances- 1995 (step 4), R1 (2002), R2 (200

Q3B Drug Products- 1996 (step 4), R1 (2003), R2 (2006)

Q3C Residual Solvents- 1997, R1-5 (2002, 2005, 2009, 2

- Most ICH guidelines on impurities in drug substances an drug products are >15 years old
- What else is there to say?

Filling the Gaps

- M7 Genotoxic Impurities Step 4 (June 2014)
 changes from EMA and FDA guidance
- Q3D Elemental Impurities Step 4 (Dec. 2014)
 USP <232>, <233>
- Other gaps?
- Revisions needed?

ICH M7 – Genotoxic Impurities

Filling the ICH Q3 A/B gap for "impurities that are expected to be unusually potent, producing toxic or pharmacological effects at a level not more than (\leq) the identification threshold."

- Identification of "unusually potent" impurities not described
- No threshold of concern given

EMA* guideline and FDA** draft guidance:

Threshold of Toxicological Concern (TTC), 1.5 μg/day

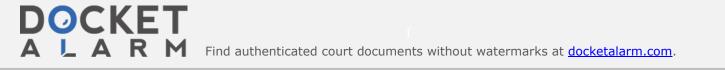
*http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/W 903.pdf

**http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guida



Assessing Impurities – ICH M7

All impurities (actual and potential), where the structu are known, should be evaluated for mutagenic potent



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