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HMPC Guideline on assessment of clinical S E -

page 2/13 emea 2006 guideline on the assessment of clinical safety and efficacy in the preparation of community herbal monographs for well-established and
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003644.pdf

Monograph - Wikipedia, the free encyclopedia -

A monograph is a specialist work of writing on a single subject or an aspect of a subject, usually by a single author. Contents 1 In academia 2 In library science 3
<http://en.wikipedia.org/wiki/Monograph>

Documentation in GMP (Good Manufacturing -

Why Documentation is necessary in pharmaceutical industry Name of pharmacopoeia or any other recognized book of standards in which monograph appears or
<http://www.authorstream.com/Presentation/rhytm8910-1339055-documentation-gmp/>

FDA-CHPA Joint Presentation - ASQ -

CHPA Guidelines on Stability Testing of OTC Monograph Drug Products all with appropriate documentation. Why Follow this Alternative Approach?
<http://asq.org/fdc/2005/06/chpa-guidelines-on-stability-testing-of-otc-monograph-drug-products.ppt>

General Opinion on Monographs - FIP - -

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https://www.fip.org/monographs_general_opinion

Biowaiver Q&A - FIP - International Pharmaceutical -

International Pharmaceutical Comments and new data to published Biowaiver Monographs can be posted when applicant submits documentation for variation

<http://www.fip.org/monographs>

Chapter 4 Final 0910 - European Commission -

EudraLex The Rules Governing Chapter 4: Documentation Legal basis for publishing the detailed guidelines: - The reference, if any, to a pharmacopoeial monograph;

http://ec.europa.eu/health/files/eudralex/vol-4/chapter4_01-2011_en.pdf

The International Pharmacopoeia Overview -

The International Pharmacopoeia Overview. Caroline Mendy Technical Officer - Quality Assurance and Safety: Medicines. Quality of Active Pharmaceutical Ingredients

<http://www.slideserve.com/Jimmy/the-international-pharmacopoeia-overview>

British Pharmacopoeia - Official Site -

The British Pharmacopoeia 2015, the official source of British pharmaceutical standards. Produced by the British Pharmacopoeia Commission Secretariat of the Medicines

<http://www.pharmacopoeia.co.uk/>

OEL Fastrac - Affygility Solutions -

OEL Fastrac Catalog. Handling highly potent compounds? OEL Fastrac by Affygility Solutions is a convenient and affordable way for pharmaceutical, biotechnology

<https://affygility.com/oel/>

United States Pharmacopeia - Official Site -

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<http://www.usp.org/>

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