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# Guidance for Industry

## Q3C — Tables and List

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

February 2012  
ICH

Revision 2

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## Q3C — Tables and List

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**U.S. Department of Health and Human Services  
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Center for Biologics Evaluation and Research (CBER)**

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**Revision 2**

*Contains Nonbinding Recommendations*

## Guidance for Industry<sup>1</sup>

### Q3C — Tables and List

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if that approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

#### I. INTRODUCTION

This is the companion document for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance for industry *Q3C Impurities: Residual Solvents* (1997), which makes recommendations as to what amounts of residual solvents are considered safe in pharmaceuticals.

This document may be updated if proposals for change are submitted to the International Conference on Harmonisation (ICH) Steering Committee. Proposals for change and the ICH Steering Committee final decision on any proposed changes will be announced through a notice in the *Federal Register* prior to the updating of this document. The guidance was revised in November 2003 to reflect updated recommendations for N-Methylpyrrolidone and Tetrahydrofuran and in February 2012 to reflect an updated recommendation for cumene.

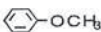



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
<sup>1</sup> This document was developed within the Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document was endorsed by the ICH Steering Committee at *Step 4* of the ICH process in July 1997. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan, and the United States. This guidance was published in the *Federal Register* on December 24, 1997 (62 FR 67377), and is applicable to drug and biological products.

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**II. LIST OF SOLVENTS INCLUDED IN THE Q3C GUIDANCE**

Solvent	Other Names	Structure	Class
Acetic acid	Ethanoic acid	CH <sub>3</sub> COOH	Class 3
Acetone	2-Propanone Propan-2-one	CH <sub>3</sub> COCH <sub>3</sub>	Class 3
Acetonitrile		CH <sub>3</sub> CN	Class 2
Anisole	Methoxybenzene		Class 3
Benzene	Benzol		Class 1
1-Butanol	n-Butyl alcohol Butan-1-ol	CH <sub>3</sub> (CH <sub>2</sub> ) <sub>3</sub> OH	Class 3
2-Butanol	<i>sec</i> -Butyl alcohol Butan-2-ol	CH <sub>3</sub> CH <sub>2</sub> CH(OH)CH <sub>3</sub>	Class 3
Butyl acetate	Acetic acid butyl ester	CH <sub>3</sub> COO(CH <sub>2</sub> ) <sub>3</sub> CH <sub>3</sub>	Class 3
<i>tert</i> -Butylmethyl ether	2-Methoxy-2-methyl-propane	(CH <sub>3</sub> ) <sub>3</sub> COCH <sub>3</sub>	Class 3
Carbon tetrachloride	Tetrachloromethane	CCl <sub>4</sub>	Class 1
Chlorobenzene			Class 2
Chloroform	Trichloromethane	CHCl <sub>3</sub>	Class 2
Cumene	Isopropylbenzene (1-Methyl)ethylbenzene	C <sub>6</sub> H <sub>5</sub> -CH(CH <sub>3</sub> ) <sub>2</sub>	Class 2
Cyclohexane	Hexamethylene		Class 2
1,2-Dichloroethane	<i>sym</i> -Dichloroethane Ethylene dichloride Ethylene chloride	CH <sub>2</sub> ClCH <sub>2</sub> Cl	Class 1
1,1-Dichloroethene	1,1-Dichloroethylene Vinylidene chloride	H <sub>2</sub> C=CCl <sub>2</sub>	Class 1
1,2-Dichloroethene	1,2-Dichloroethylene Acetylene dichloride	ClHC=CHCl	Class 2

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Dichloromethane	Methylene chloride	$\text{CH}_2\text{Cl}_2$	Class 2
1,2-Dimethoxyethane	Ethyleneglycol dimethyl ether Monoglyme Dimethyl Cellosolve	$\text{H}_3\text{COCH}_2\text{CH}_2\text{OCH}_3$	Class 2
N,N-Dimethylacetamide	DMA	$\text{CH}_3\text{CON}(\text{CH}_3)_2$	Class 2
N,N-Dimethylformamide	DMF	$\text{HCON}(\text{CH}_3)_2$	Class 2
Dimethyl sulfoxide	Methylsulfinylmethane Methyl sulfoxide DMSO	$(\text{CH}_3)_2\text{SO}$	Class 3
1,4-Dioxane	p-Dioxane [1,4]Dioxane		Class 2
Ethanol	Ethyl alcohol	$\text{CH}_3\text{CH}_2\text{OH}$	Class 3
2-Ethoxyethanol	Cellosolve	$\text{CH}_3\text{CH}_2\text{OCH}_2\text{CH}_2\text{OH}$	Class 2
Ethyl acetate	Acetic acid ethyl ester	$\text{CH}_3\text{COOCH}_2\text{CH}_3$	Class 3
Ethyleneglycol	1,2-Dihydroxyethane 1,2-Ethanediol	$\text{HOCH}_2\text{CH}_2\text{OH}$	Class 2
Ethyl ether	Diethyl ether Ethoxyethane 1,1'-Oxybisethane	$\text{CH}_3\text{CH}_2\text{OCH}_2\text{CH}_3$	Class 3
Ethyl formate	Formic acid ethyl ester	$\text{HCOOCH}_2\text{CH}_3$	Class 3
Formamide	Methanamide	$\text{HCONH}_2$	Class 2
Formic acid		$\text{HCOOH}$	Class 3
Heptane	n-Heptane	$\text{CH}_3(\text{CH}_2)_5\text{CH}_3$	Class 3
Hexane	n-Hexane	$\text{CH}_3(\text{CH}_2)_4\text{CH}_3$	Class 2
Isobutyl acetate	Acetic acid isobutyl ester	$\text{CH}_3\text{COOCH}_2\text{CH}(\text{CH}_3)_2$	Class 3
Isopropyl acetate	Acetic acid isopropyl ester	$\text{CH}_3\text{COOCH}(\text{CH}_3)_2$	Class 3
Methanol	Methyl alcohol	$\text{CH}_3\text{OH}$	Class 2
2-Methoxyethanol	Methyl Cellosolve	$\text{CH}_3\text{OCH}_2\text{CH}_2\text{OH}$	Class 2
Methyl acetate	Acetic acid methyl ester	$\text{CH}_3\text{COOCH}_3$	Class 3
3-Methyl-1-butanol	Isoamyl alcohol Isopentyl alcohol 3-Methylbutan-1-ol	$(\text{CH}_3)_2\text{CHCH}_2\text{CH}_2\text{OH}$	Class 3

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