

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT (REVISION 2)

NAME: SACCHARIN SODIUM

	Harmonized attributes		
	EP*	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
Clarity of solution	+	+	+
Color of solution	+	+	+
Acidity or alkalinity	+	+	+
Water	+	+	+
Readily carbonizable substances	+	+	+
Limit of benzoate and salicylate	--	+	+
Assay	+	+	+

Legend

+ will adopt and implement; – will not stipulate

*EP will state "It may be anhydrous or contain a variable quantity of water."

Non-harmonized attributes

Characters/Description, Limit of toluenesulfonamide, Heavy metals, Packaging and storage, Labeling.

Local Requirements

EP	JP	USP
Second identification (melting point, reaction with resorcinol, reaction with ferric chloride, identification of sodium).		

Reagents and reference materials

Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.

Signatures:

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European Pharmacopoeia

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Japanese Pharmacopoeia

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for Kazuhiko Mori

United States Pharmacopoeia

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KEVIN MOORE