

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).	<u>Heavy metals</u>	

Reagents and reference materials

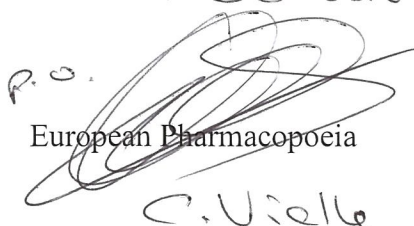
Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.


Date: 26 Oct 2016

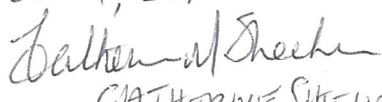
Oct 26, 2016

Signatures:

Oct. 26, 2016


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