

Proposals to Variation Regulation (version 24.10.2007)

	Current redaction	Proposed redaction
Page 28 7. b.3.	7. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product	
	3. Liquid pharmaceutical forms (e.g. suspensions, emulsions) Conditions: 1,2,3,4,5 Type:IB	3. Liquid pharmaceutical forms (e.g. suspensions, emulsions) Conditions: 1,2,3,4,5 Type:IA
Page 29 10.	10. Minor change in the manufacturing process of the active substance Type: IB	10. Minor change in the manufacturing process of the active substance Type: IA
Page 31 13.b.	13. Change in test procedure for active substance or starting material, intermediate, or reagent used in the manufacturing process of the active substance	
	b. Other changes to a test procedure, including replacement or addition of a test procedure Conditions 2,3,4,5 Type IB	b. Other changes to a test procedure, including replacement or addition of a test procedure for active substance Conditions 2,3,4,5 Type IB for starting material, intermediate, reagent Conditions 2,3,4,5 Type IA
Page 34-35 20.c	20. Change in test procedure for an excipient	
.	c. Other changes to a test procedure, including replacement of an approved test procedure by a new test procedure. Conditions 2,3,4,5 Type IB	c. Other changes to a test procedure, including replacement of a non-critical approved test procedure by a new test procedure. Conditions 2,3,4,5 Type IA