

Manufacturing Formula for 10,000 litre of finished product from 1,000 litre of Concentrate: Actigrip Gola concentrate 1,000 l: 929.000 kg Purified water q.s. 10,000 l: 8,981.000 kg	
Manufacturing Formula for 6,000 litre of finished product from 600 litre of Concentrate: Actigrip Gola concentrate 600 l: 557.400 kg Purified water q.s. 6,000 l: 5,388.600 kg	

*La modifica della *batch formula* è richiesta con l'AIN/2013/532.

variazione B.II.b.5 z) - Tipo IB unforeseen - modifica della frequenza dell'IPC controllo della dissoluzione

IPCs FREQUENCY PRESENT DA	IPCs FREQUENCY PROPOSED A
Section II.B.2	Module 3.2.P.3.3
Continuous process IPCs	Continuous process IPCs
	Step 2 Control of dissolution: complete dissolution
	Step 3 Control of dissolution: complete dissolution
Step 2 After stirring visual control: no droplet detected	Step 4 Control of dissolution: absence of oil droplets
Batch process IPCs	Batch process IPCs
	Step 2 Control of dissolution: complete dissolution
Step 1 After stirring visual control: no droplet detected	---
	Step 5 Control of dissolution: complete dissolution

B.II.b.5.z) - Tipo IB unforeseen - modifica dell'IPC controllo del pH

DA	A
Section II.B.2	Module 3.2.P.3.3
Continuous process IPCs	Continuous process IPCs
Step 4 pH: 4.7 – 5.1	Step 11 pH: 5.5 ± 0.2
Batch process IPCs	Batch process IPCs
Step 4 pH: 4.7 – 5.1	Step 11 pH: 5.5 ± 0.2

B.II.b.5.z) - Tipo IB unforeseen - eliminazione di un metodo di analisi per l'IPC controllo continuo della diluizione (controllo dell'assorbanza)

DA	A
Section II.B.2	Module 3.2.P.3.3
Continuous process IPCs	Continuous process IPCs
Step 5 Continuous control of dilution May be performed by two ways: - control of the absorbance of the diluted product - continuous control of flow rates	Step 5 Continuous control of dilution May be performed by two ways: --- - continuous control of flow rate

B.II.b.5.c) - Tipo IA - eliminazione dell'IPC controllo dei filtri

