

Initial Submission ZOMOD 3.5

Reg No. 1C 15115/63 (NG)

Approval date 22 Jun 2020

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
1C 15082/63	<b>Transfer</b>	22 Jun 2020		
15124/62 (N)	<b>Non-AVG MaV-3</b> : Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	1 Dec 2019	1. Water content limit: water: micro Determination Ph. Eur. <2.5.32> : Not more than 5.0% w/w 2. Specific optical rotation limit : Between -50.0 องศา to -56.0 องศา	
15136/62 (NG)	<b>MAV 7</b> : Change of batch size of sterile drug product	21 NOV 2019	ขนาดรุ่นการผลิต	
15124/62 (N)	<b>MiV-PA8</b> Change of the specification of drug substance			
1C 15019/62 (NG)	<b>Transfer</b>	11 Mar 2019		

