



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

PRODUCT INFORMATION					
Company	Qilu Pharma Spain, S.L.				
Product trade name	Market	Name on the Marketing Authorization			
	☐ DE	Sugammadex Hikma 100 mg/ml Injektionslösung			
	☐ DK/NO	Sugammadex Qilu 100 mg/ml injektionsvæske, opløsning / injeksjonsvæske, oppløsning			
	☐ ES	Sugammadex Qilu 100 mg/ml solución inyectable EFG			
	☐ FI/SE	Sugammadex Qilu 100 mg/ml injektionsvätska, lösning / injektioneste, liuos			
	☐ FR	SUGAMMADEX QILU 100 mg/mL, solution injectable			
	☐ HR/SI	Sugamadeks Qilu 100 mg/ml otopina za injekciju / raztopina za injiciranje			
	☐ IT	Sugammadex Qilu 100 mg/mL soluzione iniettabile			
	☐ NL	Sugammadex Qilu 100 mg/ml oplossing voor injectie			
Batch number					
Manuf. date					
Expiry date			Approved shelf life 36 months		
Type of review	☐ Extensive review				
	☐ Routine review, according to RA_QABR_0226				

MINIMUM DOCUMENTATION REQUIRED FOR THE REVIEW PROCESS
• Batch Production Record (BPR). • Environmental Monitoring Records (EM), including microbe and particles monitoring. • Sampling records. • Certificate of Analysis (CoA) of the API. • Certificates of Analysis (CoA) of the key excipients: hydrochloric acid and/or sodium hydroxide, liquid nitrogen and water for injection. • Certificates of Analysis (CoA) of the packaging materials: caps, glass vials and rubber stoppers. • Certificate of Analysis (CoA) and Certificate of Conformity (CoC) of the batch. • Shipping: ○ Review of temperature signed by MAH. ○ Entry records of the goods in the logistics warehouse. ○ Entry records of the reference and retention samples and of the QC samples. • Commission of the batch and decommission of the QC samples (except from IT market). • Change control reports, deviation/incidence reports and CAPAs affecting any step of the manufacturing and packaging process.



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MANUFACTURER AND PRODUCT FILE						
API MANUFACTURER						
Company: BrightGene Fine Chemicals Co. Ltd.						
Address: No. 22 Binjiang South Road, Taixing Economic Development Zone, Taizhou, Jiangsu, 225400, China.						
Activity: API intermediate manufacturer (Sugammadex sodium Crude).						
☐ Final API manufacturer						
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments	
	Local	N/A	N/A	N/A	N/A	
	EU	DE_HE_01_GMP_2023_0223	25/08/2023	3 years	The scope does not include Sugammadex API. GMP compliance is assured through a GMP audit.	
	FDA	N/A	N/A	N/A	N/A	
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor	Comments	
		AUD-4113	08/05/2025	Rephine (Louis Lu)	None.	
Company: BrightGene Pharmaceutical Co. Ltd. ☐ N/A						
Address: No. 218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123, China.						
Activity: ☐ Final API manufacturer						
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments	
	Local	N/A	N/A	N/A	N/A	
	EU	DE_HE_01_GMP_2023_0223	25/08/2023	3 years	The scope does not include Sugammadex API. GMP compliance is assured through a GMP audit.	
	FDA	N/A	N/A	N/A	N/A	
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor	Comments	
		AUD-4087	07/05/2025	Rephine (Louis Lu)	None.	
Current dossier sections of 3.2.S. provided – current version.						
Comments						
FINISHED PRODUCT MANUFACTURER						
Company: Qilu Pharmaceutical (Hainan) Co., Ltd.						
Address: No. 273-A, Nanhai Ave. National High-Tech Zone Haikou, Hainan, 570314, China						



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Activity: Finished product manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	None.
	EU	ES106HV/24/1	04/08/2022	31/01/2026	Issued by AEMPS.
	FDA	N/A	N/A	N/A	None.
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor	Comments
		AUD-5002	02-04/12/2025	Rephine (Louis Lu)	None.
Annual PQR reports received and reviewed.		☐ Yes, detail breakdown per year: ☐ Pending to receive an update, explain:			
On-Going Stabilities results updated and reviewed. All results are within the registered specifications (at least 1 batch/dose/year)		☐ Yes, detail breakdown per year: ☐ Pending to receive an update, explain:			
Quality Technical Agreement in place		TA-QL-014 Rev.: 5.0, effective on 10/2025.			
Current dossier sections of 3.2.P. provided – current version.					
Comments					
SUBCONTRACTORS					
☐ N/A	Company: Picking Pharma Address: Calle Marcelino Camacho n.º 15, San Fernando de Henares, 28830, Madrid Activity: Warehouse and sampling after importation into EU)				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	N/A	N/A	N/A	
	GDP	BPD/2408/335/MAD	27/03/2024	None.	
	WDA	0087-MAD	29/11/2023	None.	
	MIA	0367	30/09/2024	Laboratory auth. number 3451E	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	N/A	20/01/2025	Qilu Pharma Spain, S.L.	N/A, no observations.	None.



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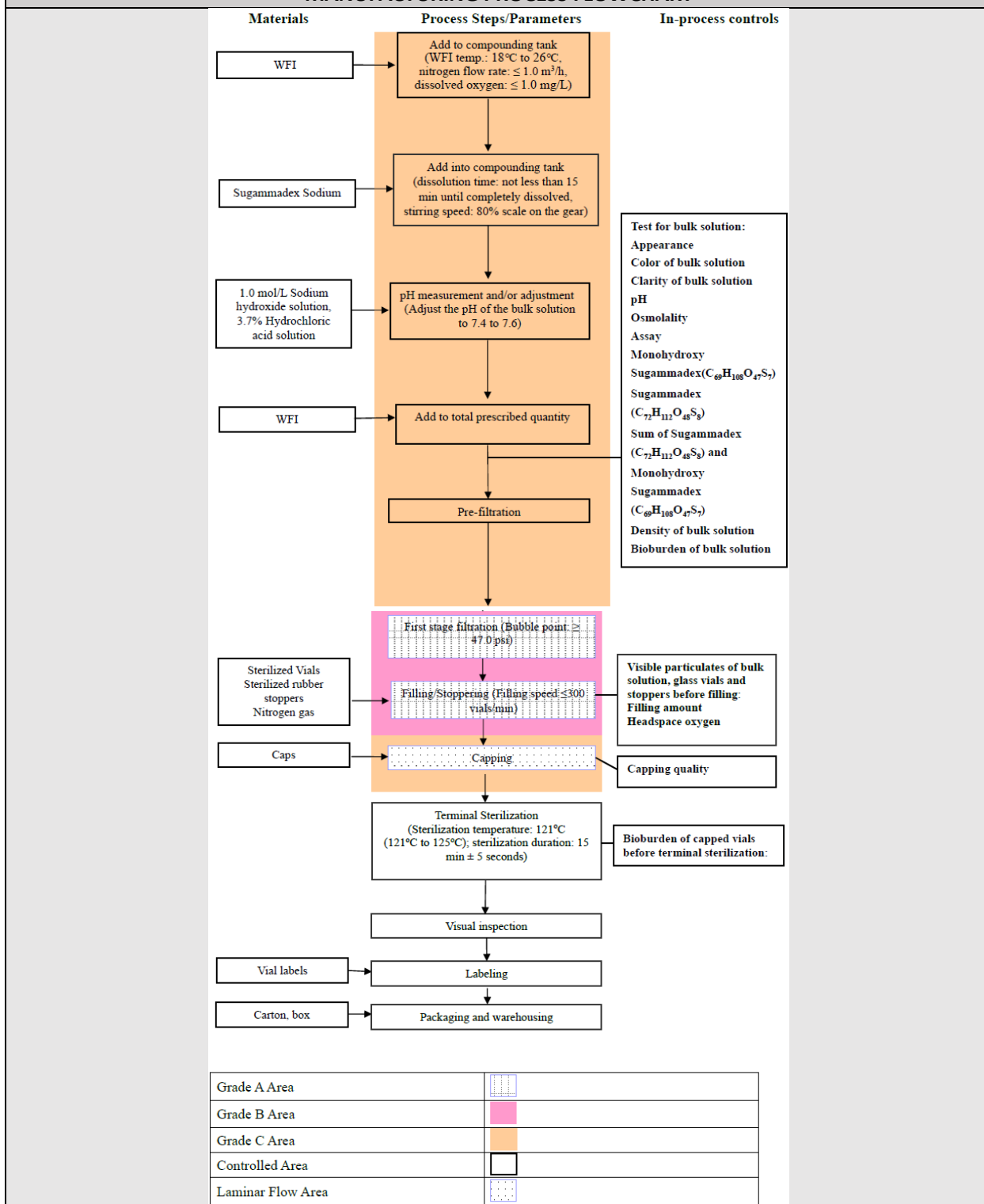
☐ N/A	Company: Airpharm Address: Calle Margarita Nelken Prologis Park 4-6. Pol. Ind. SUP. 14, 28830 San Fernando de Henares, Madrid, Spain. Activity: ☐ Warehouse and sampling after importation into EU. ☐ Storage of reference/retention samples.				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	N/A	N/A	N/A	
	GDP	BPD/2023/303/MAD	11/10/2023	Auth. number 0049-MAD.	
	WDA	07/946754.9/23	19/04/2023	None.	
	MIA	6785	22/12/2023	None.	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	N/A	11/03/2025	Qilu Pharma Spain, S.L.	Yes.	None.
Comments					



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MANUFACTURING PROCESS FLOWCHART



Extracted from Common Technical Dossier (CTD) Section 3.2.P.3.3.1 Flow Chart – current version.



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Key excipients					
Excipient	Batch number	CoA number	Specifications reference	Identified and traceable in BR	N/A
Hydrochloric Acid, Dilute				☐	☐
				☐	☐
Sodium Hydroxide				☐	☐
				☐	☐
Liquid nitrogen				☐	-
				☐	☐
Water for Injection				☐	-
				☐	☐

BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT					
Bulk batch identification					
Batch manufacturing record edition. Master batch record available.	Section	Code	Ver.	Code	Ver.
	Batch Record code and version:	☐ BPR-JB3Z-01-		☐ BPR-JB6Z-01-	
	Title	BRP-JB3Z-01-00-		N/A	
	Formulation	BPR-JB3Z-01-01-		BPR-JB6Z-01-01-	
	List of Production Equipment	BPR-JB3Z-01-02-		BPR-JB6Z-01-02-	
	Washing and Sterilization of Vials (EU)	BPR-JB3Z-01-03-		BPR-JB6Z-01-03-	
	Washing, Sterilization and Drying of Rubber Stoppers	BPR-JB3Z-01-04-		BPR-JB6Z-01-04-	
	Compounding Process	BPR-JB3Z-01-05-		BPR-JB6Z-01-05-	
	Preparation Process	BPR-JB3Z-01-06-		BPR-JB6Z-01-06-	
	Filling Process	BPR-JB3Z-01-07-		BPR-JB6Z-01-07-	
	Capping Process	BPR-JB3Z-01-08-		BPR-JB6Z-01-08-	
	Sterilization	BPR-JB3Z-01-09-		BPR-JB6Z-01-09-	
	Visual Inspection	BPR-JB3Z-01-10-		BPR-JB6Z-01-10-	
	In-process Control Process	BPR-JB3Z-01-11-		BPR-JB6Z-01-11-	
	Packaging	BPR-P-JB3Z-		BPR-P-JB6Z-	
	Material Balance	BPR-JB3Z-01-12-		BPR-JB6Z-01-12-	
	Comments				



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Batch Manufacturing Record and Critical Controls review								
Instructions for Routine review: Critical Process Parameters and In-Process Controls are indicated with <u>bold, and underlined</u> format and classified in column CPP/IPC.								
Note: Page numbers are provided for guidance only and may vary slightly between BPR versions. Any discrepancies shall be documented in the comments and corrected at the next routine or otherwise required revision; they do not, by themselves, trigger a document revision.								
Step	Page		Parameter /Process	Specification	CPP /IPC	Compliance		
	JB3Z	JB6Z				C	NC	NA
Batch Record	N/A	N/A	Batch size	☐ 200 mg / 2 mL: 150 L (75 000 vials) ☐ 500 mg/ 5 mL: 200 L (40 000 vials)	-	☐	☐	-
			Shelf-life	Expiry date in accordance with approved shelf life: 36 months.	-	☐	☐	-
Washing and Sterilization of Vials	3/13	3/15	Batch No. vials	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	7/13	6/15	Sterilization	Set temp.: 335 °C. Set belt speed: 230 mm/min	-	☐	☐	☐
	10/13			Actual temp.: 325 °C – 345 °C. Actual belt speed: ≤ 230 mm/min.	-	☐	☐	☐
	12/13	14/15	Qualified quantity:					
Washing, Sterilization and Drying of Rubber Stoppers	4/9	4/9	Batch No. stoppers	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	6/9	6/9	Washing	Primary w. with purified water for 10 min. Fine washing with WFI for 20 min. Rinse by WFI for 5 min.	-	☐	☐	☐
			Sterilization	Temp.: 122 °C (range 121 °C – 125 °C). Time: 20 min.	-	☐	☐	☐
			Drying	Time: 20 min.	-	☐	☐	☐
8/9	8/9	Washed quantity:						
Compounding	3/21	3/21	Last filtration filter:	Temp.: 121.0 °C (range 121.0 °C – 134 °C). Time: 20 min – 30 min.	-	☐	☐	☐
	Att.	Att.	Sterilization	Sterilization report attached.	-	☐	☐	☐



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	4/21	4/21	Last filtration filter: Integrity test	Before sterilization. Bubble point ≥ 47.0 psi.	-	☐	☐	-
				After use. Bubble point ≥ 47.0 psi	-	☐	☐	-
	8/21	7/21	Batch No. API	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	9/21	8/21	Batch No. excipients	The recorded batch Nos. correspond to the batch No. in the provided CoAs.	-	☐	☐	-
	12/21	11/21	WFI	Temp.: $18^{\circ}\text{C} - 26^{\circ}\text{C}$.	-	☐	☐	☐
			Dissolved oxygen	≤ 1.0 mg/L.	-	☐	☐	☐
	13/21	12/21	API	Add API. Stir time ≥ 15 min.	-	☐	☐	☐
		13/21	Bulk solution	Record temp. once every 10 min.	-	☐	☐	☐
	13-14/21	13-14/21		pH: $7.4 - 7.6$ (adjust if necessary; stir time: 5 min after adding adjuster).	-	☐	☐	☐
	15/21	14/21		Add WFI. Stir time ≥ 5 min.	-	☐	☐	☐
	18/21	18/21	Holding times	From start of compounding to end of compounding. Time ≤ 8 h.	-	☐	☐	☐
				From end of compounding to start of filtration. Time ≤ 1 h.	-	☐	☐	☐
				From start of filtration to end of filtration. Time ≤ 11 h.	-	☐	☐	☐
	20/21	20/21	Actual qty. transferred to the next step:					
			Yield range	90.0 % - 100.0 %	-	☐	☐	☐
			Reconciliation	90.0 % - 100.0 %	-	☐	☐	☐
	Att.	Att.	Integrity test	Last filtration filter before use - test att.	-	☐	☐	-
				Last filtration filter after use - test attached.	-	☐	☐	-
Filling	7/28	7/31	The qty. of rubber stoppers received is consistent with the qualified qty.		-	☐	☐	☐
	8/28	8/31	<u>Visible particles</u>	<u>Visible particles of stoppers, vials and bulk solution before filling: Absent.</u>	IPC	☐	☐	-
	9-11/28	9-11/31	<u>Filling amount</u>	<u>2.14 g – 2.25 g.</u>	IPC	☐	☐	-
	Att.	Att.		<u>Weight records reviewed and compliant.</u>		☐	☐	-



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	9, 12-13/28	9, 12-13/31	Headspace oxygen	≤ 5.0 %.	IPC	☐	☐	-
	15/28	14/31	Filling speed	≤ 300 mm.	-	☐	☐	☐
	24-25/28	28/31	The actual qty. received for filling is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Actual qty. transferred to the next step:					
			Yield range	84.0 % - 98.0 %	-	☐	☐	☐
			Reconciliation	90.0 % – 100.0 %	-	☐	☐	☐
	27/28	30/31	Filling period	Day, start time - end time:				
			Holding time	From start of filtration to end of filling. Time ≤ 12 h.	-	☐	☐	-
	4/10	4/10	Batch No. caps	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	6/10	6/10	Capping machine	Speed of capping machine ≤ 300 vials/min.	-	☐	☐	☐
Capping	7/10	7/10	Capping quality	100 % qualified.	IPC	☐	☐	-
	8/10	8/10	The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Actual qty. transferred to the next step:					
			Yield range	97.0 % - 100.0 %	-	☐	☐	☐
			Reconciliation	98.0 % – 102.0 %	-	☐	☐	☐
Terminal sterilization	4/15	4/13	The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Bioburden	Sampling	-	☐	☐	☐
	5/15	5/13	Container closure integrity test	≤ 2.6 mbar	IPC	☐	☐	-
	Att.	Att.		Leak test records reviewed and compliant.		☐	☐	-
	9/15	8/13	Holding time	From end of filling to start of terminal sterilization. Time ≤ 1 h.	-	☐	☐	-
	10-11/15	9/13	Sterilization	Temp.: 121 °C (range 121 °C – 125 °C).	CPP	☐	☐	-
		9-10/13		Time: 15 min ± 5 s.				
			Sub-lot 1 sterilization period:					
			Sub-lot 2 sterilization period:					
			Sub-lot 3 sterilization period:					
	14/15	12/13	The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Qty. transferred to the next step:					



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX			
Customer	Product		Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection		

	Att.	Att.	Sterilization records	Sterilization primary data for sub-lots 1, 2 and 3 reviewed and compliant.	-	☐	☐	-
Visual Inspection	3/27	3/27	The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
	3-4, 7-22/27	3-4, 7-22/27	Visual inspection	100% visually inspected.	-	☐	☐	-
	26/27	26/27	The qty. visually inspected is consistent with the qualified qty. from the previous step ($\pm 1.0\%$).		-	☐	☐	-
			The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Actual qty. transferred to the next step:					
In-Process Controls	7/13	7/13	<u>Bulk solution: Appearance</u>	<u>Clear and colorless to slightly yellow solution.</u>	IPC	☐	☐	-
			<u>Bulk solution: Clarity</u>	<u>Clear.</u>	IPC	☐	☐	-
			<u>Bulk solution: pH</u>	<u>7.2 - 7.8.</u>	IPC	☐	☐	-
			<u>Bulk solution: Color</u>	<u>The solution shall be colorless, or not more intensely colored than Ph. Eur. Reference solution Y₁.</u>	IPC	☐	☐	-
			<u>Bulk solution: Osmolarity</u>	<u>300 mOsmol/kg - 500 mOsmol/kg.</u>	IPC	☐	☐	-
	8/13	8/13	<u>Bulk solution: Assay</u>	<u>Monohydroxy Sugammadex $\leq 1.0\%$ of the labeled amount.</u>	IPC	☐	☐	-
				<u>Sugammadex: 95.0 % - 105.0 % of the labeled amount.</u>	IPC	☐	☐	-
			<u>Bulk solution: bioburden</u>	<u>Prior to pre-filtration ≤ 25 cfu/5 mL.</u>	IPC	☐	☐	-
				<u>Before terminal sterilization ≤ 10 cfu/100 mL.</u>	IPC	☐	☐	-
	9/13	9/13	<u>Visible particles</u>	<u>Visible particles of stoppers, vials and bulk solution before filling: Absent.</u>	IPC	☐	☐	-
	12/13	12/13	<u>Capping quality</u>	<u>100 % qualified.</u>	IPC	☐	☐	-
Packaging	Variable.	Variable.	The qty. received is consistent with the qualified qty. from the previous step.		-	☐	☐	-
			Sampling	110 vials as test samples for customer.	-	☐	☐	-



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX					
Customer		Product		Batch	
Qilu Pharma Spain, S.L.		Sugammadex Solution of Injection			

				200 vials as retention samples.					
			Warehoused qty.:						
			Yield range	99.0 % - 100.0 %	-	☐	☐	☐	
			Reconciliation	100.0 %	-	☐	☐	☐	
	Variable.	Variable.	Label contents		Copy endorsed in the BPR.	-	☐	☐	-
					Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-
					Variable data (batch number and expiry date) is correct.	-	☐	☐	-
					The artwork of the used label corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-
	Variable.	Variable.	Carton contents		Copy endorsed in the BPR.	-	☐	☐	-
					Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-
					Variable data (batch number and expiry date) are correct.	-	☐	☐	-
					Antifalsified measures and devices (unique SN, Data Matrix and tamper evident) comply with regulation.	-	☐	☐	-
					The artwork of the used carton corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-
	Variable.	Variable.	Leaflet contents ☐ N/A		Copy endorsed in the BPR.	-	☐	☐	-
					Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-
					The artwork of the used leaflet corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-
		Market	Dose	Label	Carton	Leaflet			
	☐	DE	200mg/2mL	34120056004A	34120056001B	34120056011A			
	☐	DE	500mg/5mL	34120056104A	34120056101A	34120056011A			
	☐	DK/NO	200mg/2mL	34120061504A	34120061501A	34120061711A			
	☐	ES	200mg/2mL	34120055804A	34120055801B	34120055811A			
	☐	ES	500mg/5mL	34120055904A	34120055901B	34120055811A			



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

	☐	FI/SE	200mg/2mL	34120061204A	34120061201B	34120061411A		
	☐	FI/SE	500mg/5mL	34120061304A	34120061301A	34120061411A		
	☐	FR	200mg/2mL	34120056204A	34120056201B	34120056211A		
	☐	FR	500mg/5mL	34120056304A	34120056301B	34120056211A		
	☐	HR/SI	200mg/2mL	34120068004A	34120068001A	34120068011A		
	☐	HR/SI	500mg/5mL	34120068104A	34120068101A	34120068011A		
	☐	IT	200mg/2mL	34120056504A	34120056801B	34120056811A		
	☐	IT	500mg/5mL	34120056904A	34120056901B	34120056811A		
	☐	NL	200mg/2mL	34120056604B	34120056601B	34120056611A		
		Varia- ble.	Varia- ble.	Label correctness	The product information on label is checked for correctness.	-	☐	☐
Material Balance	2/2	2/2	Yield range	77.0 % - 98.0 %	-	☐	☐	☐
			Reconciliation	90.0 % - 100.0 %	-	☐	☐	☐
MANUFACTURING PROCESS DEVIATIONS, CAPA AND CHANGE CONTROLS								
Type			Ref. No.			N/A		
						☐		
						☐		
						☐		
						☐		
GENERAL ASPECTS						Comply		
						C NC		
The raw data is recorded according to Good Documentation Practices.						☐		
Batch Records properly document line clearance.						☐		
Batch Records include the registry of equipment, calibration/qualification status and cleaning status (attached status labels if necessary). All are within validity period.						☐		
Comments								
SUPPORTING DOCUMENTATION REVISION								
Record	Review					Comply		
						C NC		
Environmental monitoring records.	Monitoring of non-viable airborne particles is available and within the acceptance criteria.					☐		
	Monitoring of microbes is available and within the acceptance criteria.	Airborne microbe				☐		
		Settling microbe				☐		
		Surface microbe				☐		
	Personnel					☐		
Sampling record	☐	200 mg/2 mL:	110 vials as test samples for customer. 200 vials as retention samples.			☐		
	☐	500 mg/5 mL:	100 vials as test samples for customer. 180 vials as retention samples.			☐		
CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER								



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

Name of the product	
Strength	
Dosage form	
Batch number	
Quantity released (vials)	
Manufacturing date	
Expiry date (36 months)	
Certification statement	
Deviations registered and available, if any	☐ No deviation, change control, OOS and/or CAPA registered. ☐ Reference:
CoC signed by QP or QA Manager	Name, position/title and date:
CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER	
CoA reference number	
Analytical parameters, specifications and analytical methods according to CTD and Marketing authorization	
Deviations and OOS reference available, if any	☐ No deviation and/or OOS registered. ☐ Reference:
Results: Complies.	



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

Items		Acceptance criteria		Analytical method
		Release	Shelf-life	
Appearance		Clear and colorless to slightly yellow solution		Visual
Identification		(1) The retention time of the Sugammadex Sodium and Monohydroxy Sugammadex Sodium peaks in the chromatogram of the <i>Sample solution</i> shall correspond to that of the Sugammadex Sodium and Monohydroxy Sugammadex Sodium in <i>Standard solution</i> respectively, as obtained in the <i>Assay</i> .		Ph. Eur. 2.2.29
		(2) UV absorption spectrum of Sugammadex Sodium in <i>Sample solution</i> shall correspond to that of Sugammadex Sodium in <i>Standard solution</i> , as obtained in the <i>Assay</i> .		Ph. Eur. 2.2.29
pH		7.0 to 8.0		Ph. Eur. 2.2.3
Visible Particulates		Shall not exist		Ph. Eur. 2.9.20
Particulate Matter		≥ 10 µm: not exceed 6000 per vial ≥ 25 µm: not exceed 600 per vial		Ph. Eur. 2.9.19
Clarity of Solution		Clear		Ph. Eur. 2.2.1
Color of Solution		The solution shall be colorless, or not more intensely colored than Ph. Eur. reference solution Y ₁		Ph. Eur. 2.2.2
Osmolality		300 mOsmol/kg to 500 mOsmol/kg		Ph. Eur. 2.2.35
Sodium Content		7.40 mg/mL to 11.11 mg/mL		Ph. Eur. 2.2.23
Extractable Volume	200 mg/2 mL	Not less than the labeled amount (2.0 mL)		Ph. Eur. 2.9.17
	500 mg/5 mL	Not less than the labeled amount (5.0 mL)		
Related Substances	SGT-R4	≤ 0.2%	≤ 0.6%	Ph. Eur. 2.2.29
	SGT-R5	≤ 0.2%	≤ 0.6%	
	SGT-R6	≤ 0.2%		
	SGT-R7	≤ 0.5%		
	SGT-R23	≤ 0.17%		
	SGT-R24	≤ 0.17%		
	SGT-R26	≤ 0.2%		
	Acrylic acid	≤ 0.1%		
	Any Individual Unspecified Impurity	≤ 0.17%		
Total Impurities (Except Monohydroxy Sugammadex and Known Process Impurity)	≤ 2.5%		≤ 3.5%	
Assay		Monohydroxy Sugammadex (C ₆₉ H ₁₀₈ O ₄₇ S ₇) shall be not more than 1.0% of the labeled amount		Ph. Eur. 2.6.1
		Sugammadex (C ₇₂ H ₁₁₂ O ₄₈ S ₈) shall be not less than 95.0% and not more than 105.0% of labeled amount		
Sterility		Sterile		Ph. Eur. 2.6.1
Bacterial Endotoxins		< 0.30 EU/mg, calculated based on the sum of Sugammadex and Monohydroxy Sugammadex		Ph. Eur. 2.6.14

Final product specifications, extracted from CTD Section 3.2.P.5.1 – current version.

CERTIFICATE OF ANALYSIS (COA) ISSUED BY KYMOS		
CoA reference number		
Deviations and OOS reference available, if any	☐ No deviation and/or OOS registered. ☐ Reference:	
Results: Complies.		
TRANSPORT AND STORAGE CONDITIONS		
Transport route and Data logger ID	Route	☐ Qilu Pharmaceutical Hainan (China) > Picking Pharma (Spain) > Samples: Kymos and Airpharm. ☐ Qilu Pharmaceutical Hainan (China) > Airpharm (Spain) > QC samples: Kymos.



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

	Dataloggers	Shipment	Shipment: Batch:
		Samples to Kymos	☐ Same dataloggers as shipment. ☐ Different from shipment. Dataloggers ref.:
		Samples to Airpharm	☐ Performed under transport responsibility of Qilu Pharma Spain. ☐ N/A
Deviations available, if any		☐ No deviation and/or OOS registered. ☐ Reference: Deviation reports are provided, reviewed and accepted.	
Temperature evaluation report		"Review of temperature data during transportation of finished product from Qilu Pharma Spain" available and approved by the MAH. ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. Based on Freeze-Thaw studies, the excursions do not have an impact on the quality of the batch stability.	
Comments			

PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES

	Route	Doc. reference	Received on	Units to be received	Units received	N/A
Packing list	Qilu Hainan to Picking Pharma			CoC released qty.	☐ C ☐ NC	☐
	Picking Pharma to Airpharm			200 mg: 200 vials 500 mg: 180 vials	☐ C ☐ NC	☐
	Picking Pharma to Kymos			200 mg: 110 vials 500 mg: 100 vials	☐ C ☐ NC	☐
	Qilu Hainan to Airpharm			CoC released qty.	☐ C ☐ NC	☐
	Airpharm to Kymos			200 mg: 110 vials 500 mg: 100 vials	☐ C ☐ NC	☐
	Incoming inspection of goods into warehouse	Reception number: ☐ Compliant. ☐ Not compliant, justify:				
Reference and retention samples location	Airpharm					
Comments						

COMMISSIONING AND DECOMMISSIONING OF THE BATCH, QC, REFERENCE AND RETENTION SAMPLES

Commissioning and decommissioning records are provided, reviewed, and correspond with released units, QC, and reference and retention samples.	C	NC	N/A
	☐	☐	☐
If N/A, justify:			
VISUAL INSPECTION OF FINISHED PRODUCT			



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

Verification artworks and variable data are in accordance with the approved artworks and according to the manufacturing batch records.		C	NC
		☐	☐
BATCH RELEASE CERTIFICATE (LIMS Batch Release Certificate)			
Product Trade Name	Market	Name on the Marketing Authorization	
	☐ DE	Sugammadex Hikma 100 mg/ml Injektionslösung	
	☐ DK/NO	Sugammadex Qilu 100 mg/ml injektionsvæske, opløsning / injeksjonsvæske, oppløsning	
	☐ ES	Sugammadex Qilu 100 mg/ml solución inyectable EFG	
	☐ FI/SE	Sugammadex Qilu 100 mg/ml injektionsvätska, lösning / injektioneste, liuos	
	☐ FR	SUGAMMADEX QILU 100 mg/mL, solution injectable	
	☐ HR/SI	Sugamadeks Qilu 100 mg/ml otopina za injekciju / raztopina za injiciranje	
	☐ IT	Sugammadex Qilu 100 mg/mL soluzione iniettabile	
Destination country/ies	☐ NL	Sugammadex Qilu 100 mg/ml oplossing voor injectie	
	☐ Germany (DE)	☐	France (FR)
	☐ Denmark (DK), Norway (NO)	☐	Croatia (HR), Slovenia (SI)
	☐ Spain (ES)	☐	Italy (IT)
Marketing Authorization Number	☐	Finland (FI), Sweden (SE)	☐ Netherlands (NL)
	Market	MA number	
	☐ DE	7005751.00.00	
	☐ DK/NO	DK: 66554, NO: 21-14218	
	☐ ES	88425	
	☐ FI/SE	FI: 39794, SE: 62391	
	☐ FR (200 mg/2 mL)	34009 550 919 1 2	
	☐ FR (500 mg/5 mL)	34009 550 919 2 9	
	☐ HR/SI	HR: HR-H-574668052, SI: H/24/03014/001	
	☐ IT (200 mg/2 mL)	AIC No. 050311012 MA No. DE/H/7182/001/DC	
	☐ IT (500 mg/5 mL)	AIC No. 050311024 MA No. DE/H/7182/001/DC	
Strength/Potency	☐ NL	RVG 128753	
	☐	200 mg/2 mL	
	☐	500 mg/5 mL	
Dosage form	Small volume parenteral solution		
Type and size of packaging	10 vials/carton		
Batch number			
Quantity Released (packs)	Released by Qilu	QC testing in Kymos	Ref./Ret. samples in Airpharm
			Other
			Quantity Released



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

		110 vials	200 vials		
		- or	- or	-	=
		100 vials	180 vials		
Manufacture date (DD/MM/YYYY)					
Expiry date (DD/MM/YYYY)					
CoA number					
Comments/Remarks (deviations, customer's requirements, etc.)					
Transport Deviations (if any and not reportable in CoC)					
Sites	Site 1	Name	Qilu Pharmaceutical (Hainan) Co., Ltd.		
		Address	No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China (CHN)		
		Auth. No	Qiong20150030		
		Activity	Manufacturing Finished Product, Packaging		
	Site 2	Name	Qilu Pharma Spain, S.L.		
		Address	Paseo de la Castellana, 40, planta 8, 28046, Madrid, Spain.		
		Auth. No	6664E		
		Activity	Marketing Authorization Holder		
	Site 3	Name	Kymos, S.L.		
		Address	Ronda de Can Fatjó, 7B (Parque Tecnológico del Vallès), 08290 Cerdanyola del Vallès, Barcelona, Spain		
		Auth. No	6317E		
		Activity	Quality Control, Batch Release		
Certification statement duly completed					
Batch Release Certificate sent to QP in LIMS System.					

COMMENTS				
MANUFACTURING DEVIATIONS				
☐	No deviations recorded.			
☐	Deviations:			
Code	Impact Assessment /Classification	Short Description	Status	Related CAPA
CHANGE CONTROLS				
☐	No change control recorded.			
☐	Change controls:			
Code	Regulatory Impact	Short Description	Status	



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - SUGAMMADEX		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Sugammadex Solution of Injection	

	☐ Yes / ☐ No		
	☐ Yes / ☐ No		
	☐ Yes / ☐ No		

BATCH TESTING PROCESS DEVIATIONS/OOS

☐ No deviations/OOS recorded.

☐ Deviations/deviations:

Code	Impact Assessment /Classification	Short Description	Status

TRANSPORT DEVIATIONS

☐ No deviations recorded.

☐ Deviations:

Code	Impact Assessment /Classification	Short Description	Status

ADDITIONAL COMMENTS

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APPROVAL

Performed by	Reviewed by