

Document information	
Document code	C003-IG0004-m25e01
Document title	CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - MEROPENEM

Approval panel	
Approval Type	Signature
Elaboration: Tabatha Brisa Montes <i>QA Batch Release Scientist</i>	
Elaboration: Belén Martín <i>QA Batch Release Scientist</i>	
QA review / approval Gracia Piqueras <i>Deputy QP & QA</i>	

Last edition / Validity date	Description of changes
–	First edition.



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

PRODUCT INFORMATION			
Company	Qilu Pharma Spain, S.L.		
Product trade name	Market	Strength	Name on the Marketing Authorization
	☐ BG	1 g	Меропенем Килу 1g прах за инжекционен/инфузионен разтвор. Meropenem Qilu 1g powder for solution for injection/infusion.
	☐ CZ-SK	500 mg	Meropenem Olikla 500 mg prášek pro injekční/infuzní roztok prášok na injekčný/infúzny roztok
	☐ CZ-SK	1 g	Meropenem Olikla 1000 mg prášek pro injekční/infuzní roztok prášok na injekčný/infúzny roztok
	☐ DE	500 mg	Meropenem Qilu 500 mg Pulver zur Herstellung einer Injektions-/Infusionslösung
	☐ DE	1 g	Meropenem Qilu 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
	☐ ES	500 mg	Meropenem Qilu 500 mg polvo para solución inyectable y para perfusión EFG
	☐ ES	1 g	Meropenem Qilu 1 g polvo para solución inyectable y para perfusión EFG
	☐ FR	1 g	MEROPENEM QILU 1 g, poudre pour solution injectable/pour perfusion
	☐ HR-SI	1 g	Meropenem Qilu 1000 mg prašak za otopinu za injekciju/infuziju / prašek za raztopino za injiciranje/infundiranje
	☐ IT	500 mg	Meropenem Qilu 500 mg polvere per soluzione iniettabile/infusione
	☐ IT	1 g	Meropenem Qilu 1 g polvere per soluzione iniettabile/infusione
	☐ LT-LV-EE	1 g	Meropenem Qilu 1 g milteliai injekciniam ar infuziniam tirpalui / pulveris injekciju/infūziju šķīduma pagatavošanai / süste-/infusioonilahuse pulber
	☐ SE-FI	500 mg	Meropenem Qilu 500 mg pulver till injektions-/infusionsvätska, lösning injektio-/infuusiokuiva-aine liuosta varten
	☐ SE-FI	1 g	Meropenem Qilu 1 g pulver till injektions-/infusionsvätska, lösning injektio-/infuusiokuiva-aine liuosta varten
	☐ UK	500 mg	Meropenem Qilu 500 mg powder for solution for injection / infusion
	☐ UK	1 g	Meropenem Qilu 1 g powder for solution for injection / infusion
Batch number			
Manuf. date			
Expiry date			Approved shelf life 36 months
Type of review	☐ Extensive review.		
	☐ Routine review, in accordance with RA_QAMPC_0826.		



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

MINIMUM DOCUMENTATION REQUIRED FOR THE REVIEW PROCESS

- For Sterile Sodium Carbonate:
 - Batch Production Record (BPR)
 - Certificates of Analysis (CoA) of the excipients: sodium carbonate and ethanol.
 - Certificates of Analysis (CoA) of the packaging materials: PE bags.
 - Bioburden test results.
 - Integrity test for material solution sterilizing-grade filter.
 - Integrity test for ethanol sterilizing-grade filter (extensive review)
- For Intermediate:
 - Batch Production Record (BPR).
 - Certificates of Analysis (CoA) of the API.
 - Certificates of Analysis (CoA) of the key excipient: Sterile Sodium Carbonate.
 - Environmental Monitoring Records (EM), including microbe and particles monitoring.
 - Certificate of Conformity (CoC) of the Intermediate.
 - Shipping: Packing list and Transportation record.
- For Meropenem for Injection:
 - Batch Production Record (BPR)/ Electronic Batch Record (EBR)
 - MES-Record
 - Certificates of Analysis (CoA) of the Intermediate: from Intermediate manufacturer and from FP manufacturer.
 - Certificates of Analysis (CoA) of the packaging materials: caps, glass vials and rubber stoppers.
 - VHP fumigation record of canisters.
 - Environmental Monitoring Records (EM), including microbe and particles monitoring.
 - Record of the visual inspection process.
 - Certificate of Analysis (CoA) and Certificate of Conformity (CoC) of the batch.
- Shipping:
 - Review of assessment 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 and UK markets).
- Change control reports, deviation/incidence reports and CAPAs affecting any step of the manufacturing and packaging processes.

MANUFACTURER AND PRODUCT FILE

API MANUFACTURER

Company: Shandong Anhong Pharmaceutical Co., Ltd.

Address: No. 29 Huayuan Street Linyi County, Dezhou, Shandong, 251500, China

Activity: API and intermediate manufacturer

	Certificate	Certif. reference	Inspection date	Validity	Comments
cGMP	Local	N/A	N/A	N/A	N/A
	EU	DE_BY_05_GMP_2023_0052	18/07/2023	3 years	Issued by German Authorities.



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	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
		N/A	11-12/04/2024	Dominique Pechon	None
CEP	RO-CEP-2020-020- Rev 02 (Process I)				
Current dossier sections of 3.2.S. provided – current version.					
Comments					

FINISHED PRODUCT MANUFACTURER

Company: Qilu Antibiotics Pharmaceutical Co., Ltd.

Address: No.849 Dongjia Town, Licheng District, Jinan, Shandong 250105, China

Activity: Finished product manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	None.
	EU	ES/108HV/24	24/04/2024	3 years	Issued by AEMPS.
	FDA	3009831352	22-30/05/2023	N/A	None.
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor	Comments
		AUD-5005	05-09/01/2026	Rephine	None.

Periodic Aseptic Process Simulation Report (media fill) provided and reviewed.

☐ Updated report received.

Ref. and date of media fill:

☐ Pending to receive an update; explain:

Annual PQR reports received and reviewed.

☐ Yes, see current *Review and Acceptance Form for PQRs* approved on:

☐ 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, see current *Review and Acceptance Form for stability report* approved on:

☐ Pending to receive an update, explain:

Quality Technical Agreement in place

TA-QL-012 Rev.: 3.0, effective on 12/2025.

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
--------------	-------------	-------------------	-----------------------	----------



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	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.
☐ 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					

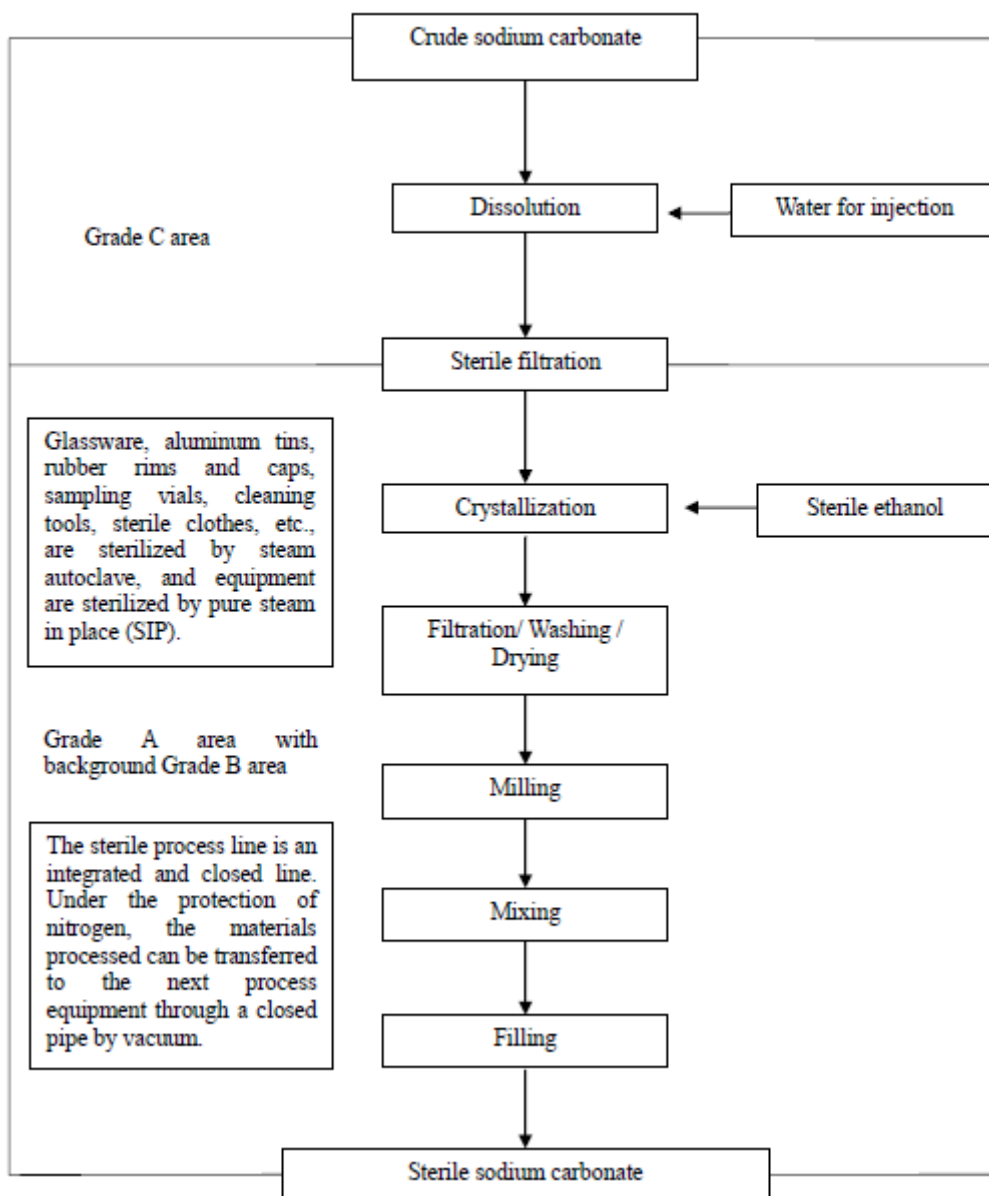


CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

MANUFACTURING PROCESS FLOWCHART

● **Production of sterile sodium carbonate**





CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

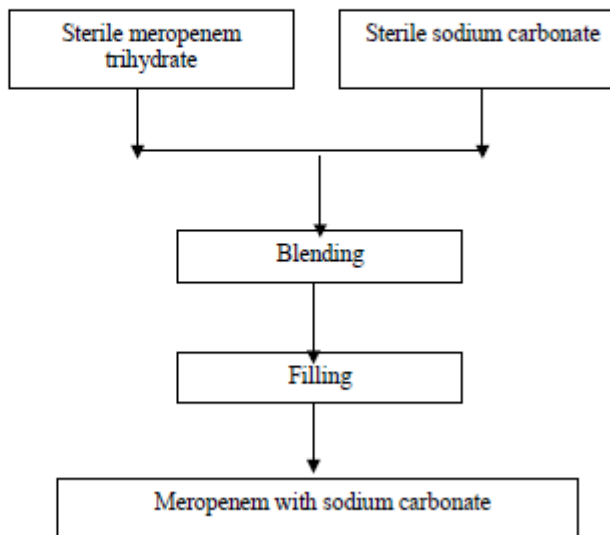
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

● **Production of drug product intermediate-Sterile Meropenem with sodium carbonate**

Glassware, aluminum tins, rubber rims and caps, sampling vials, cleaning tools, sterile clothes, etc., are sterilized by steam autoclave, and equipment are sterilized by pure steam in place (SIP).

Grade A area with background grade B area

The sterile process line is an integrated and closed line. Under the protection of nitrogen, the materials processed can be transferred to the next process equipment through a closed pipe by vacuum.

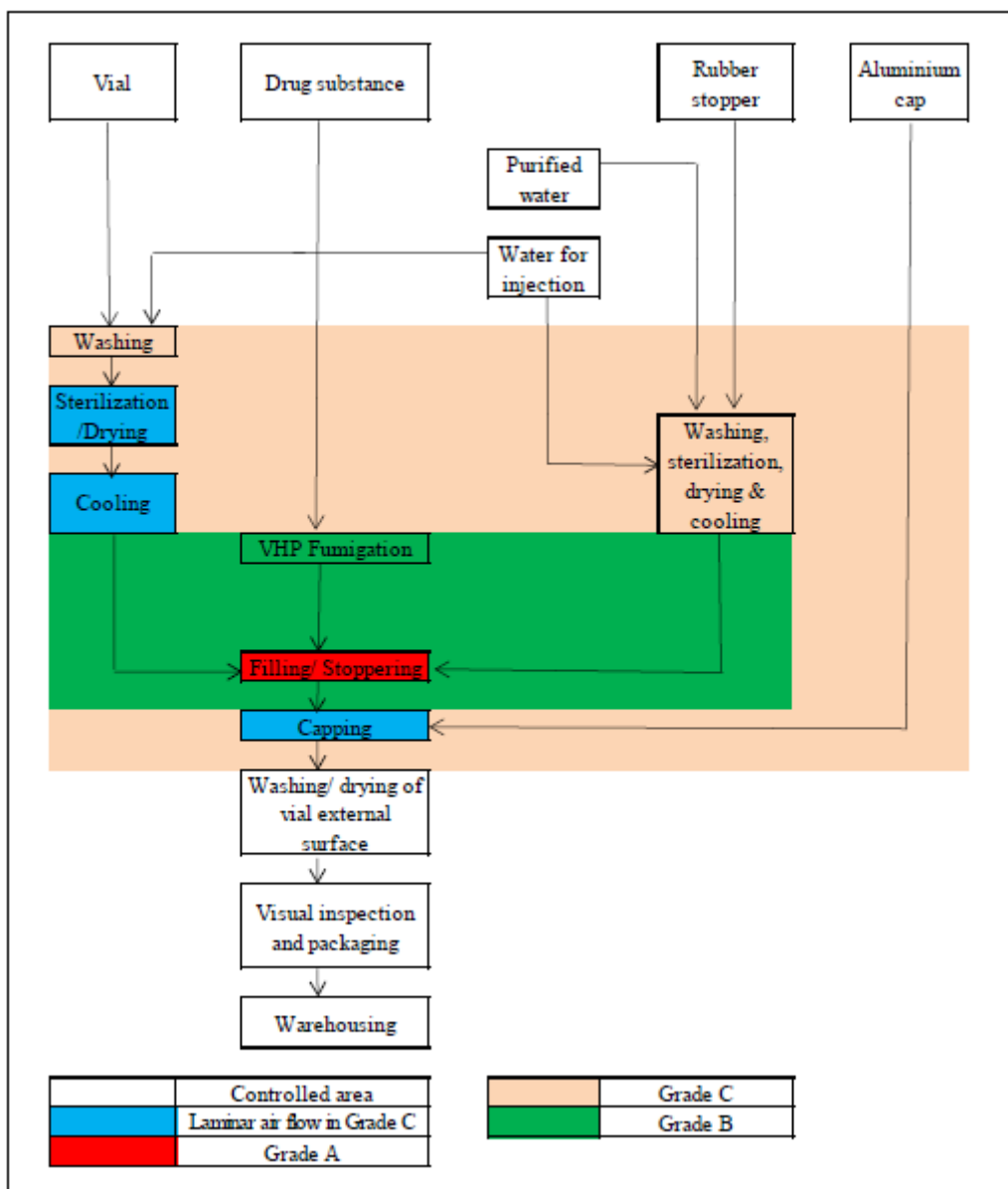




CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

● **Production of final drug product-Meropenem for Injection**



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



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

BATCH RECORDS REVIEW						
EXCIPIENT – STERILE SODIUM CARBONATE						
Manufacturer: Shandong Anhong Pharmaceutical Co., Ltd.						
Bulk batch identification						
Batch manufacturing record edition. Master batch record available.	Batch Record code	Version				
	☐ ROP8005					
	☐ ROP8014					
	☐ ROP8033					
	☐ ROP8035					
Comments						
Batch Manufacturing Record and Critical Controls review						
Instructions for Routine review: No CPPs nor IPCs are defined for this step.						
Step	Parameter /Process	Specification	Compliance			
			C	NC	NA	
Batch Records review	Manufacturing date					
	Filter sterilization: sodium carbonate	122 °C for 30 min	☐	☐	☐	
	Filter sterilization: Ethanol	122 °C for 30 min	☐	☐	☐	
	Qualified quantity					
Integrity tests	Sterile filtration sodium carbonate – third filter	Pre and post integrity test pass	☐	☐	-	
	Ethanol	Pre and post integrity test pass	☐	☐	-	
Bioburden results	Solution before sterile filtration	≤ 10 cfu/100ml	☐	☐	-	
General aspects	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. All are within validity period.		☐	☐	☐	
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):					
INTERMEDIATE – Sterile Meropenem with sodium carbonate						
Manufacturer: Qilu Shandong Anhong Pharmaceutical CO., Ltd						
Batch identification						
Batch manufacturing record edition. Master batch record available. Associated CC available, if applicable.	Batch Record code	Version				
	☐ ROP8019					
	Comments					
Name	Batch number	CoA number	Specifications reference	Identified and traceable in BR	Compliance with CTD spec.	N/A
Sterile Meropenem				☐	☐	-
				☐	☐	☐
				☐	☐	☐



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

				☐	☐	☐
Anhydrous Sodium Carbonate				☐	☐	-
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐

Batch Manufacturing Record and Critical Controls review

Instructions for Routine review: No CPPs nor IPCs are defined for this step.

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	Compliance		
				C	NC	NA
Batch Record review	1/14	Batch size	About 47 - 166 kg	☐	☐	☐
		Manuf. date				
	3/14	API CoA	The recorded batch No. corresponds to the batch No. in the provided CoA.	☐	☐	-
		Anh. Sodium Carbonate CoA	The recorded batch No. corresponds to the batch No. in the provided CoA.	☐	☐	-
		Anh. Sodium Carbonate	The weighed amount is equal to or less than the qualified amount.	☐	☐	-
	5/14	Composition	Ratio of sterile Meropenem trihydrate and sterile sodium carbonate 84.6 : 15.4	☐	☐	-
	7/14	Blending	Clockwise and counterclockwise each for 10 min at 5 rpm and 10 rpm separately.	☐	☐	☐
		Time	2 hours	☐	☐	☐
		Filling period	Day (DD/MM/YYYY), start time – end time (HH:MM):			
	12/14	Qualified amount				
		Yield	95 – 100 %	☐	☐	☐
General aspects	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. All are within validity period.			☐	☐	☐
	Manufacturing yield of all relevant manufacturing steps registered and within the acceptance criteria			☐	☐	-
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):					



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

SUPPORTING DOCUMENTATION REVISION - INTERMEDIATE								
Record	Review					Comply		
						C	NC	
Environmental monitoring records. <i>(Traceability through filling period).</i>	Monitoring of non-viable airborne particles is available and within the acceptance criteria.					☐	☐	
	Monitoring of microbes is available and within the acceptance criteria.			Settling microbe		☐	☐	
				Airborne microbe		☐	☐	
				Surface microbe		☐	☐	
				Personnel		☐	☐	
Shipping intermediate	Route		From: Qilu Shandong Anhong Pharmaceutical CO., Ltd To: Qilu Antibiotics Pharmaceutical Co., Ltd.					
	Packing list		Delivery number					
			Shipping date					
			Quantity (Coincident with BPR total quantity).					
	Datalogger		Data logger Code					
			Date and time shipping		From:			
					To:			
			Review of temperature		Max:			
					Min:			
Comments								

CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER - INTERMEDIATE	
Name of the product	
Batch number	
Quantity released (kg)	
Manufacturing date	
Retest date (24 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 - INTERMEDIATE	
CoA reference number	
Quality Spec. number	Product No. 210300002010
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:



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

Results: complies. Signed by:	Position/title and date:
----------------------------------	--------------------------

BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT

Manufacturer: Qilu Antibiotics Pharmaceutical Co., Ltd.

Batch identification			
Batch manufacturing record edition. Master batch record available.	Strength	Batch Record code	Version
	500 mg	☐ BR: PREPARATION_INJ_373_EP /	
	1 g	☐ MES report: ROP37117	
	Comments		

Intermediate by DP manufacturer: Qilu Antibiotics Pharmaceutical Co., Ltd.

Name	Batch number	CoA number	Specifications reference	Identified and traceable in BR	Compliance with CTD specs.	N/A
Meropenem Sodium Carbonate				☐	☐	-
				☐	☐	☐
				☐	☐	☐

Intermediate by Intermediate Manufacturer: Qilu Shandong Anhong Pharmaceutical CO., Ltd

Name	Batch number	CoA number	Specifications reference	Identified and traceable in BR	Compliance with CTD specs.	N/A
Meropenem Sodium Carbonate				☐	☐	-
				☐	☐	☐
				☐	☐	☐

Batch Manufacturing Record and Critical Controls review

Instructions for Routine review: Critical Process Parameters and In-Process Controls are indicated with **bold and underlined** format and classified in column CPP/IPC. For routine reviews, parameters designated as "NA" are excluded from the assessment.

Step	Sub-section	Parameter /Process	Specification	CPP /IPC	Compliance		
					C	NC	NA
Batch Record	BPR registry	Workshop	Unit 373 of Workshop No. 370	-	☐	☐	☐
		Batch size	☐ 500 mg/vial: 10 kg (around 14 000 vials) to 70 kg (around 103 000 vials) ☐ 1 g/vial: 20 kg (around 14 000 vials) to 140 kg (around 103 000 vials)	-	☐	☐	☐
		Manuf. date					
		Expiry date					
		Shelf-life	Expiry date in accordance with approved shelf life: 36 months	-	☐	☐	-
Washing of Vials	Vial conveying (2/2)	Vials Batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	Washing (3/5)	<u>Visible particles of washed vials</u>	<u>Fiber or particles (≤ 2 mm) should be not more than 2</u>	IPC	☐	☐	-	
			<u>Visible particles and color particles should be absent</u>	IPC	☐	☐	-	
		<u>Sterilization temperature</u>	<u>Set at 330 °C</u> (actual temperature range is 320 °C to 340 °C)	IPC	☐	☐	-	
		<u>Running speed of conveyer</u>	☐ 20 mL vial (500 mg/vial): <u>set at 256 mm/min</u> ☐ 30 mL vial (1 g/vial): <u>set at 215 mm/min</u>	IPC	☐	☐	-	
		Att. (MES record)	Sterilization	Sterilization record reviewed and compliant.	-	☐	☐	-
Filling	Repertoire	API batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-	
	Att.	API CoA	CoA for API from manufacturer provided.	-	☐	☐	☐	
	Prep. before filling	Sterilized batch No. of the components:						
		Rubber stoppers sterilization batch No. and units:						
		Components and Rubber stoppers sterilization	Within expiry date: They must be used within 48 hours after sterilization.	-	☐	☐	☐	
	Filling (1/5)	API preparation	API canisters are wiped with dust-free cloth dipped in disinfectant and appearance and quantity are checked.	-	☐	☐	☐	
	Filling (2/5)	<u>Maximum filling speed</u>	☐ 500 mg/vial: <u>300 vials/min</u> ☐ 1 g/vial: <u>200 vials/min</u>	IPC	☐	☐	-	
		Filling period	Day (DD/MM/YYYY), start time – end time (HH:MM):					
		Filling time	Total time ≤ 16 h	-	☐	☐	☐	
	Filling (3/5)	<u>Labeled amount</u>	<u>93.0 to 107.0%</u>	IPC / CPP	☐	☐	-	
		<u>Uniformity of mass</u>	<u>Within ± 5.0 %.</u>	IPC / CPP	☐	☐	-	
	Att. (MES record)	Filling mass	Print strips reviewed and compliant.	-	☐	☐	-	
	Att. (MES record)	Qualified quantity:						
Att. (MES record)	Interventions records	Whether intervention during the filling process has been recorded and is compliant.	-	☐	☐	☐		



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

Capping	Feeding before capping	Caps batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-	
	Capping (2/6)	Capping tightness	Qualified rate: 100 %.	IPC	☐	☐	-	
	Capping (6/6)	Unqualified amount:						
Washing/ Drying of Vial External Surface and Visual Inspection	Vial External Surface-Checking	Capping tightness (before starting the process)	Qualified rate: 100 %.	IPC	☐	☐	-	
	VI (3/6) VI (4/6)	Visual inspection	The vials are 100 % visually inspected.	-	☐	☐	-	
	VI (6/6)	Rejected amount	Rejected amount complies with rejected rate	-	☐	☐	☐	
			Quantity of rejected vials:					
Package	Package (2/10)	Labeling quality	Batch No. and expiry date are correct	-	☐	☐	☐	
			Meets requirements.	-	☐	☐	☐	
	Att. (MES record)	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.	-	☐	☐	-	
			Antifalsified measures and devices (unique SN, Data Matrix) comply with regulation. <i>(UK and IT: SN and Data Matrix N/A)</i>	-	☐	☐	☐	
			Copy endorsed in the BPR.	-	☐	☐	-	
	Att. (MES record)	Leaflet contents	Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-	
			Copy endorsed in the BPR.	-	☐	☐	-	
	Att. (MES record)	Carton contents	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. <i>(UK and IT: SN and Data Matrix N/A)</i>	-	☐	☐	-	
			The label, leaflet and carton artworks correspond to the currently approved artworks (according to below table).	-	☐	☐	-	
		Market	Strength	Vials/ carton	Label	Leaflet	Carton	



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	☐	BG	1 g	10	34160033204A	34160033211C	34160033201A														
	☐	CZ-SK	500 mg	10	34160073604A	34160073511A	34160073501A														
	☐	CZ-SK	1 g	10	34160073504A	34160073511A	34160073801A														
	☐	DE	500 mg	10	34160031604A	34160031611B	34160031601B														
	☐	DE	1 g	10	34160031504A	34160031511B	34160031501B														
	☐	ES	500 mg	10	34160032004A	34160032011B	34160032101A														
	☐	ES	1 g	10	34160032201A	34160032211C	34160032204A														
	☐	FR	1 g	10	34160033004A	34160033011C	34160033001A														
	☐	HR-SI	1 g	1	34160032604A	34160032611B	34160032601A														
	10			34160032701A																	
	☐	IT	500 mg	10	34160032404A	34160032411B	34160032401A														
	☐	IT	1 g	10	34160032504A	34160032411B	34160032501A														
	☐	LT-LV-EE	1 g	10	34160032804A	34160032811B	34160032901A														
	☐	SE-FI	500 mg	1	34160035404A	34160035411D	34160035501A														
	☐			10	34160035804A		34160035401A														
	☐	SE-FI	1 g	1	34160035604A	34160035411D	34160035701A														
	☐			10	34160035904A		34160035601A														
	☐	UK	500 mg	10	34160034904B	34160034911C	34160035001B														
	☐	UK	1 g	10	34160035104B	34160035111C	34160035201B														
	Package (9/10)	Sampling	140 vials for EU testing. 230 vials as EU retention samples				-	☐	☐	-											
Package (10/10)	Warehousing amount: Must match: <table border="1"> <tr> <td>Actual output</td> <td>Sample retention</td> <td>Amount for QC analysis (total)</td> <td>IPC</td> <td>Other samplings</td> <td>Warehousing amount</td> </tr> <tr> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>=</td> </tr> </table>									Actual output	Sample retention	Amount for QC analysis (total)	IPC	Other samplings	Warehousing amount	-	-	-	-	-	=
Actual output	Sample retention	Amount for QC analysis (total)	IPC	Other samplings	Warehousing amount																
-	-	-	-	-	=																
Att. (MES record)	Bollini label (only IT market)	Copy endorsed in the BPR.				-	☐	☐	☐												
Packag. material check.		Bollini label reconciliation is compliant.				-	☐	☐	☐												
Washing, Sterilization and Drying of Rubber Stoppers	Prepared (1/2)	Stoppers batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.				-	☐	☐	-											
	Washing and steril. (2/2)	The Treated batch No. and qty. of washed and sterilized rubber stoppers is consistent with the stoppers used for filling.				-	☐	☐	-												
		Visible particles of rinsing water	Fibers or particles shorter than 2 mm ≤ 2.				IPC	☐	☐	-											
			Visible and color particles: absent.				IPC	☐	☐	-											
		Sterilization	Temp.: 122 °C (range 121 – 128 °C).				CPP	☐	☐	-											
	Time: not less than 20 min.				CPP	☐	☐	-													
Att. (MES record)	Sterilization	Sterilization record reviewed and compliant.				-	☐	☐	-												



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM			
Customer	Product	Batch	
Qilu Pharma Spain, S.L.	Meropenem for Injection		

Record of Washing and Sterilization for components	Steril. for comp.	Sterilization	B-D test: It is considered as qualified if the whole indication card shows a brown color.	-	☐	☐	☐
			The sterilization batch No. is consistent with the batch used for filling.	-	☐	☐	-
			Temp.: 122.0 °C (range 122 – 125 °C). Time: 30 min.	-	☐	☐	☐
	Att. (MES record)		Sterilization record reviewed and compliant. (Pressured holding and B-D test report).	-	☐	☐	☐
In-Process Control	Visible particles	<u>Visible particles</u>	<u>Should be absent, and during rotating, no smog particles pole should be detected.</u>	IPC	☐	☐	-
	pH test	pH test	pH: 7.3 - 8.3	-	☐	☐	☐
	Check of fill mass	<u>Labeled amount</u>	<u>93.0 to 107.0%</u>	IPC	☐	☐	-
		<u>Uniformity of mass</u>	<u>Within ± 5.0 % of 10 vials</u>	IPC	☐	☐	-
		<u>Individual fill mass</u>	<u>10 vials</u> <u>Theoretical fill mass x (1-5.0%) to theoretical fill mass x (1+5.0%)</u>	IPC	☐	☐	-
	Att. (MES record)	Filling mass	Print strips reviewed and compliant.	-	☐	☐	-
	Capping tightness	<u>Appearance</u>	<u>White to light yellow crystalline powder</u>	IPC	☐	☐	-
		<u>Capping tightness</u>	<u>Qualified rate: 100 %.</u>	IPC	☐	☐	-
	Dissolut. /Clarity	<u>Dissolution clarity and particulate matter</u>	<u>The solution should be essentially free from particles of foreign matter that can be observed on visual inspection.</u> <u>Compared with purified water, the reconstituted solution should be clear</u>	IPC	☐	☐	-
		<u>Visible particles</u>	<u>Should be absent, and during rotating, no smog particles pole should be detected.</u>	IPC	☐	☐	-
	Check material info.	Check materials information	Whether the product name, strength, batch No., and the expiry date on the packaging materials are correct.	-	☐	☐	☐



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	Perform leak test	Leak test	☐ 500 mg/vial: <u>Microleakage (5 µm) ≤ 1.8 mbar within 20 s.</u> <u>Large leakage ≤ 785.3 mbar within 1 s.</u> ☐ 1 g/vial: <u>Microleakage (5 µm) ≤ 2.0 mbar within 20 s.</u> <u>Large leakage ≤ 797.4 mbar within 1 s</u>	IPC	☐	☐	-		
Batch evaluation	Review content	Deviation/Remark:							
General aspects	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. All are within validity period.				☐	☐	☐		
	Manufacturing yield of all relevant manufacturing steps registered and within the acceptance criteria				☐	☐	-		
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):								
Comments									
SUPPORTING DOCUMENTATION – FINAL PRODUCT									
Record	Review			Comply					
				C	NC				
Environmental monitoring records. (Traceability through filling period).	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		☐	☐				
Fumigation record	Personnel			☐	☐				
	Fumigation record of the API canisters is available and traceable.			☐	☐				
CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER – FINAL PRODUCT									
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:						



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

CoC signed by QP or QA Manager	Name, position/title and date:		
CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER – FINAL PRODUCT			
CoA reference number			
Quality Spec. number	SEFJK-5.0		
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. Signed by:	Position/title and date:		
CERTIFICATE OF ANALYSIS (COA) ISSUED BY KYMOS			
CoA reference number			
CoA reference number Pharmaprogress			
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 Antibiotics (China) > Picking Pharma (Spain) > Samples: Kymos and Airpharm > Pharmaprogress (IT) ☐ Qilu Antibiotics (China) > Airpharm (Spain) > QC samples: Kymos > Pharmaprogress (IT)	
	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
		Samples to Pharmaprogress	Shipment:
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 (ref. Nos. FTSR-FJK-01 and FTSR-FMK-01), the	



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	excursions do not have an impact on the quality of the batch stability.
Temperature evaluation for Pharmaprogess shipment	Temperature review samples shipped to Pharmaprogess. T _{max} : T _{min} :
Comments	

PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES

Packing list	Route	Doc. reference	Received on	Units to be received	Units received	N/A
	Qilu Antibiotics to Picking Farma			FP CoC released qty.	☐ C ☐ NC	☐
	Picking Farma to Kymos			☐ 140 vials ☐ Other:	☐ C ☐ NC	☐
	Picking Farma to Airpharm			☐ 230 vials ☐ Other:	☐ C ☐ NC	☐
	Qilu Antibiotics to Airpharm			CoC released qty.	☐ C ☐ NC	☐
	Airpharm to Kymos			☐ 130 vials ☐ Other:	☐ C ☐ NC	☐
	Kymos to Pharmaprogess			☐ 15 vials ☐ Other:	☐ 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			
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	Strength	Name on the Marketing Authorization
	☐ BG	1 g	Меропенем Килу 1g прах за инжекционен/инфузионен разтвор. Meropenem Qilu 1g powder for solution for injection/infusion.



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

	☐	CZ-SK	500 mg	Meropenem Olikla 500 mg prášek pro injekční/infuzní roztok prášek na injekční/infúzný roztok
	☐	CZ-SK	1 g	Meropenem Olikla 1000 mg prášek pro injekční/infuzní roztok prášek na injekční/infúzný roztok
	☐	DE	500 mg	Meropenem Qilu 500 mg Pulver zur Herstellung einer Injektions-/Infusionslösung
	☐	DE	1 g	Meropenem Qilu 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
	☐	ES	500 mg	Meropenem Qilu 500 mg polvo para solución inyectable y para perfusión EFG
	☐	ES	1 g	Meropenem Qilu 1 g polvo para solución inyectable y para perfusión EFG
	☐	FR	1 g	MEROPENEM QILU 1 g, poudre pour solution injectable/pour perfusion
	☐	HR-SI	1 g	Meropenem Qilu 1000 mg prašak za otopinu za injekciju/infuziju / prašek za raztopino za injiciranje/infundiranje
	☐	IT	500 mg	Meropenem Qilu 500 mg polvere per soluzione iniettabile/infusione
	☐	IT	1 g	Meropenem Qilu 1 g polvere per soluzione iniettabile/infusione
	☐	LT-LV-EE	1 g	Meropenem Qilu 1 g milteliai injekciniam ar infuziniam tirpalui / pulveris injekciju/infūziju šķīduma pagatavošanai / süste-/infusioonilahuse pulber
	☐	SE-FI	500 mg	Meropenem Qilu 500 mg pulver till injektions-/infusionsvätska, lösning injektio-/infuusiokuiva-aine liuosta varten
	☐	SE-FI	1 g	Meropenem Qilu 1 g pulver till injektions-/infusionsvätska, lösning injektio-/infuusiokuiva-aine liuosta varten
	☐	UK	500 mg	Meropenem Qilu 500 mg powder for solution for injection / infusion
	☐	UK	1 g	Meropenem Qilu 1 g powder for solution for injection / infusion
Destination country/ies	☐	Bulgaria (BG)		
	☐	Czech Republic (CZ) and Slovakia (SK)		
	☐	Germany (DE)		
	☐	Spain (ES)		
	☐	France (FR)		
	☐	Croatia (HR) and Slovenia (SI)		
	☐	Italy (IT)		
	☐	Lithuania (LT), Latvia (LV) and Estonia (EE)		



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

Marketing Authorization Number	☐	Sweden (SE) and Finland (FI)			
	☐	United Kingdom (UK)			
	Market	Strength	Vials/carton	MA number	
	☐	BG	1 g	1 vial/carton 10 vials/carton	62562
	☐	CZ-SK	500 mg	10 vials/carton	CZ: 15/333/23-C SK: 15/0128/25-S
	☐	CZ-SK	1 g	10 vials/carton	CZ: 15/334/23-C SK: 15/0129/25-S
	☐	DE	500 mg	10 vials/carton	7003411.00.00
	☐	DE	1 g	10 vials/carton	7003412.00.00
	☐	ES	500 mg	10 vials/carton	88779
	☐	ES	1 g	10 vials/carton	88778
	☐	FR	1 g	1 vials/carton	34009 302 648 1 2
	☐	FR	1 g	10 vials/carton	34009 302 648 2 9
	☐	HR-SI	1 g	1 vial/carton	HR: HR-H-871429230-01 SI: 1010-64/2021-14
	☐	HR-SI	1 g	10 vials/carton	HR: HR-H-871429230-02 SI: 1010-64/2021-14
	☐	IT	500 mg	1 vial/carton	AIC No. 050412016
	☐	IT	500 mg	10 vials/carton	AIC No. 050412028
	☐	IT	1 g	1 vials/carton	AIC No. 050412030
	☐	IT	1 g	10 vials/carton	AIC No. 050412042
	☐	LT-LV-EE	1 g	10 vials/carton	LT: LT/1/23/5127/001 LV: 22-0228 EE: ML-4/1091222
	☐	SE-FI	500 mg	1 vial/carton 10 vials/carton	SE: 62435 FI: 39812
	☐	SE-FI	1 g	1 vial/carton 10 vials/carton	SE: 62436 FI: 39814
	☐	UK	500 mg	10 vials/carton	PL 44570/0028
	☐	UK	1 g	10 vials/carton	PL 44570/0029
	Strength/Potency	☐	1 g		
		☐	500 mg		
	Dosage form	Powder for injection			
	Type and size of packaging	☐	1 vials/carton		
		☐	10 vials/carton		
Batch number					
Quantity Released	Released by Qilu	QC testing in Kymos	Ref./Ret. samples in Airpharm	Other	Quantity Released (packs)
		- 140 vials	- 230 vials	-	=



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-MEROPENEM

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

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	Shandong Anhong Pharmaceutical Co., Ltd
		Address	No. 29 Huayuan Street Linyi Country, Dezhou, Shandong, 251500, China
		Auth. No	Lu20200444
		Activity	Manufacturing Intermediate Finished Product
	Site 2	Name	Qilu Antibiotics Pharmaceutical Co., Ltd.
		Address	No. 849 Dongjia Town, Licheng District, Jinan City, Shandong Providence, 250105, China.
		Auth. No	Lu20160006
		Activity	Manufacturing Finished Product, Packaging
	Site 3	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 4	Name	Kymos, S.L.
		Address	Ronda de Can Fatjó, 7B (Parc Tecnològic 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 (deviations/OOS):				
Code	Impact Assessment /Classification	Short Description	Status	Related CAPA
CHANGE CONTROLS				
☐ No change control recorded.				
☐ Change controls:				



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-MEROPENEM		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Meropenem for Injection	

Code	Regulatory Impact	Short Description	Status
	☐ Yes / ☐ No		
	☐ Yes / ☐ No		
	☐ Yes / ☐ No		

BATCH TESTING PROCESS DEVIATIONS/OOS☐ No deviations/OOS recorded.☐ Deviations (deviations/OOS):

Code	Impact Assessment /Classification	Short Description	Status

TRANSPORT DEVIATIONS☐ No deviations recorded.☐ Deviations (deviations):

Code	Impact Assessment /Classification	Short Description	Status

ADDITIONAL COMMENTS

--

APPROVAL

Performed by	Reviewed by