



KYMOS
GROUP

Document information	
Document code	C003-IG0004-m24e01
Document title	CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - CEFAZOLIN

Approval panel	
Approval Type	Signature
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 - CEFAZOLIN

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

PRODUCT INFORMATION						
Company	Qilu Pharma Spain, S.L.					
Product trade name	Market	Strength	Name on the Marketing Authorization			
	☐ ES	1 g	Cefazolina Qilu 1 g polvo para solución inyectable y para perfusión EFG			
	☐ ES	2 g	Cefazolina Qilu 2 g polvo para solución inyectable y para perfusión EFG			
	☐ FR	1 g	CEFAZOLINE QILU 1 g, poudre pour solution injectable/pour perfusion			
	☐ FR	2 g	CEFAZOLINE QILU 2 g, poudre pour solution injectable/pour perfusion			
	☐ HR-SI	1 g	Cefazolin Qilu 1 g prašak za otopinu za injekciju/infuziju · prašek za raztopino za injiciranje/infundiranje			
Batch number						
Manuf. date						
Expiry date				Approved shelf life 36 months		
Type of review	☐ Extensive review.					
	☐ Only for Qilu Antibiotics Pharmaceutical Co., Ltd.: Routine review, in accordance with RA_QAMPC_0826.					

MINIMUM DOCUMENTATION REQUIRED FOR THE REVIEW PROCESS

- Batch Production Record (BPR).
- Environmental Monitoring Records (EM), including microbe and particles monitoring.
- Fumigation record for API canisters (only for Antibiotics)
- Integrity tests for filters.
- Certificate of Analysis (CoA) of the API.
- 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, stamped.
- Commission of the batch and decommission of the QC samples.
- Change control reports, deviation/incidence reports and CAPAs affecting any step of the manufacturing and packaging process.

MANUFACTURER AND PRODUCT FILE

API MANUFACTURER

Company: Qilu Antibiotics Pharmaceutical CO., Ltd.

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

Activity: API manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
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Qilu Pharma Spain, S.L.	Cefazolin Sodium for Injection	

	Local	N/A	N/A	N/A	N/A
	EU	INS-482709-101208378-18965677	18-22/09/2023	3 years	Issued by Austrian Authorities.
	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-5005	05-09/01/2026	Rephine	None.
CEP		R1-CEP 2006-016-Rev 04			
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, 250105 Shandong Province, China Activity: Finished product manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	N/A
	EU	ES/108HV/24	24/04/2024	3 years	Issued by AEMPS.
	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-5005	05-09/01/2026	Rephine	None.
Periodic Aseptic Process Simulation Report (media fill) provided and reviewed.			☐ Updated report received. Date of media fill: ☐ Pending to receive an update; requested.		
Annual PQR reports received and reviewed.			☐ Yes, see current <i>Review and Acceptance Form for PQRs</i> 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 <i>Review and Acceptance Form for stability report</i> 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.					
☐ Company: Qilu Pharmaceutical Co., Ltd. ☐ Address: No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong Province, CN-250101, China Activity: Finished product manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments



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

	Local	N/A	N/A	N/A	None.				
	EU	ES/009HV/25	08/07/2024	3 years	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-5001	09-11/12/2025	Rephine	None.				
Periodic Aseptic Process Simulation Report (media fill) provided and reviewed.		☐ Updated report received. Date of media fill: ☐ Pending to receive an update; requested.							
Annual PQR reports received and reviewed.		☐ Yes, see current <i>Review and Acceptance Form for PQRs</i> 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 <i>Review and Acceptance Form for stability report</i> approved on: ☐ Pending to receive an update, explain:							
Quality Technical Agreement in place		TA-QL-011 Rev.: 4.0, effective on 06/2025.							
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.				
☐ 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.								



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

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							

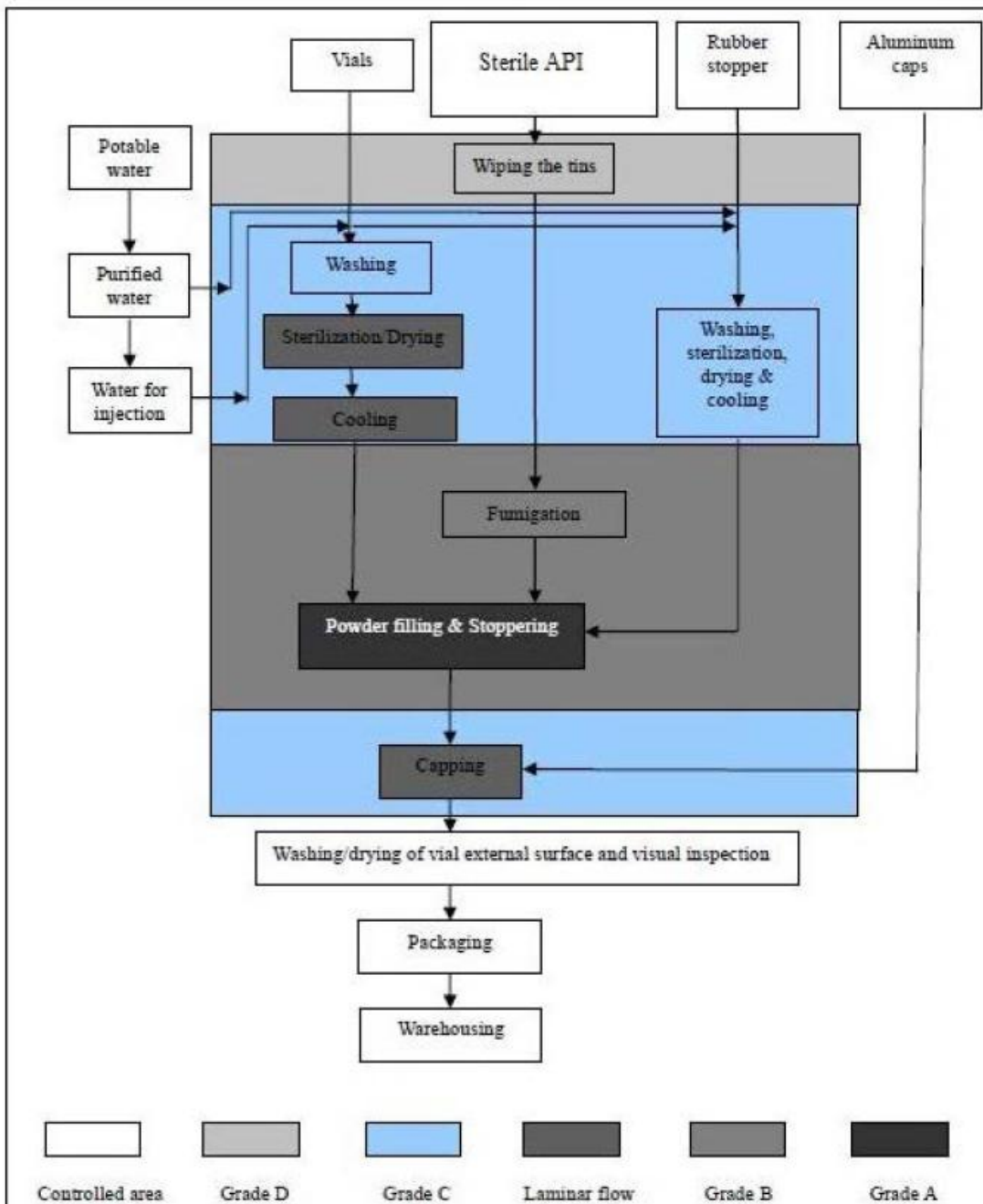


CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS - CEFAZOLIN

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

MANUFACTURING PROCESS FLOWCHART

➤ For Qilu Antibiotics Pharmaceutical Co., Ltd.

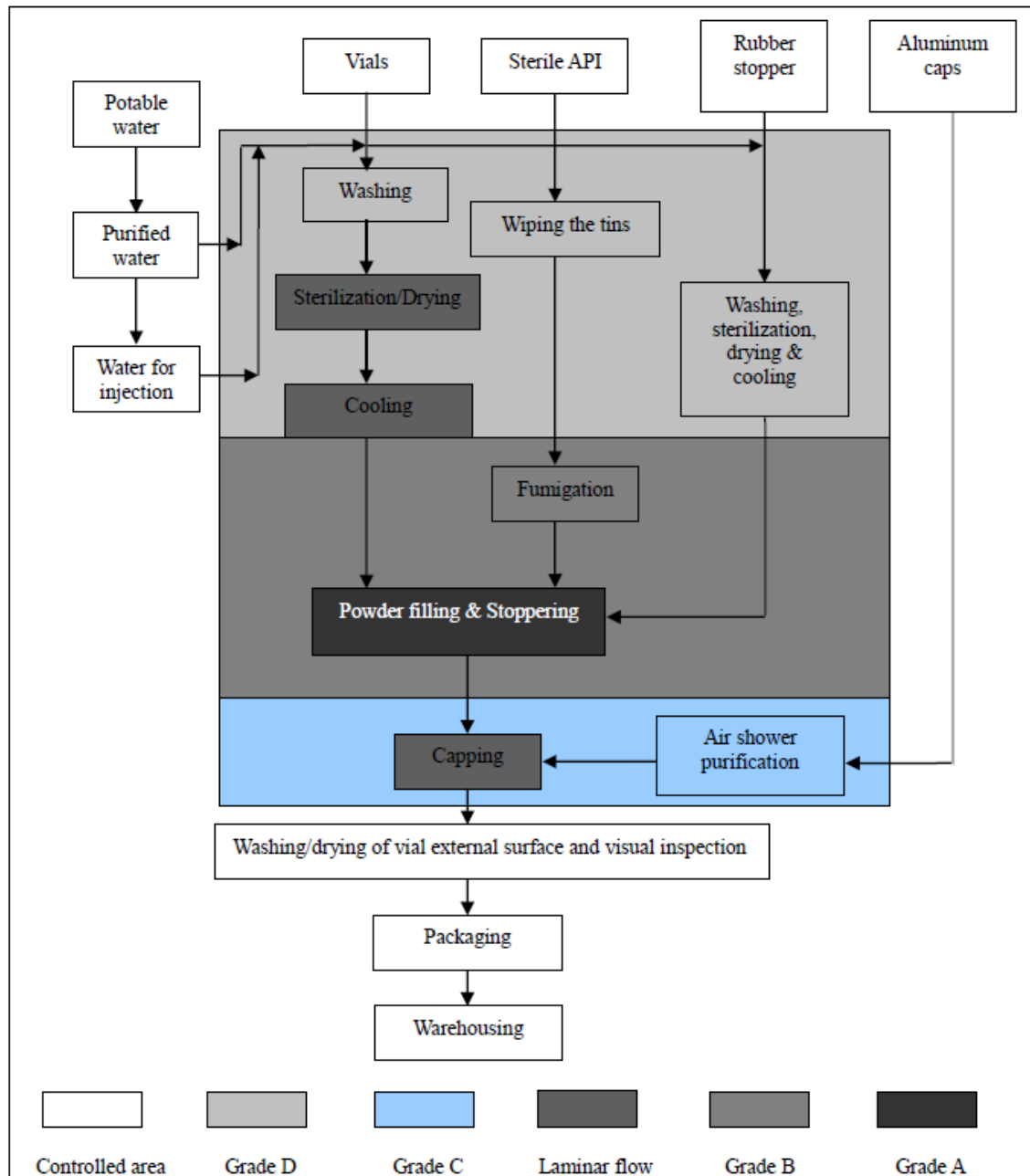




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Qilu Pharma Spain, S.L.	Cefazolin Sodium for Injection	

➤ **For Qilu Pharmaceutical Co., Ltd.**



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



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

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*: on anhydrous substance API specifications, extracted from CTD Section 3.2.S.4.1 – current version.																																																																																																													



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

BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT										
☐ Manufacturer: Qilu Antibiotics Pharmaceutical Co., Ltd.										
Bulk batch identification										
Batch manufacturing record edition. Master batch record available.	Strength	Batch Record code and version								
	1 g	☐ ROP3653.08								
	2 g	☐ ROP3654.06								
	Strength	Market	Packaging Repertoire Sheet code				Version			
	1 g	ES	☐ ROP36456.							
	2 g	ES	☐ ROP36324.							
	1 g	FR	☐ ROP36342.							
	2 g	FR	☐ ROP36343.							
	1 g	HR/SI	☐ ROP36330.							
	Comments									
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. <i>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.</i>										
Step	Page		Parameter /Process	Specification	CPP /IPC	Compliance				
	ROP 3653.08	ROP 3654.06				C	NC	NA		
Batch Record	1/76	1/75	Workshop	Unit 363 of Workshop No. 360	-	☐	☐	☐		
			Batch size	☐ 1 g/vial: 70 kg (around 66 000 vials) or 130 kg (around 120 000 vials) ☐ 2 g/vial: 140 kg (around 66 000 vials)	-	☐	☐	☐		
			Manuf. date							
			Expiry date							
			Shelf-life	Expiry date in accordance with approved shelf life: 36 months	-	☐	☐	-		
Washing and Sterilization of Vials	5/76	5/75	Vials batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-		
	8/76	8/75	<u>Visible particles of washed vials</u>	<u>Fibers or particles shorter than 2 mm ≤ 2.</u> <u>Visible and color particles: absent.</u>	IPC	☐	☐	-		
	9/76	9/75	<u>Sterilization</u>	☐ 10 mL-vials: <u>Temp.:310 °C</u> (range 300–320°C) <u>Belt speed set at 171 mm/min</u>	CPP	☐	☐	-		



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

				☐ 20 mL-vials: Temp.:320°C (range 300–320 °C) Belt speed set at 211 mm/min				
	Att.	Att.	Sterilization	Sterilization record reviewed and compliant.	-	☐	☐	-
Aseptic filling and stoppering	11/76	11/75	API batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	Att.	Att.	API CoA	CoA for API from manufacturer attached.	-	☐	☐	☐
	12/76	12/75	T and <u>RH during filling</u>	Filling room and laminar flow T: 18 – 26 °C. Filling room RH: 15 – 65 %. Laminar flow RH: 20 – 50 %.	IPC	☐	☐	-
	14/76	14/75	Components sterilized batch No.:					
			Rubber stoppers disposed batch No. and units:					
			Components and Rubber stoppers sterilizations are within expiry date.		-	☐	☐	-
	15/76	15/75	API preparation	API canisters are wiped with dust-free cloth dipped in disinfectant and appearance and quantity are checked.	-	☐	☐	☐
	17/76	17/75	Filling period	Day (DD/MM/YYYY) and time (HH:MM – HH:MM):				
			<u>Stated amount</u>	Sampling amount: 10 vials (refer to RA_QABR_0225). 95.0 % - 105.0 %	CPP	☐	☐	-
			<u>Uniformity of mass</u>	Sampling amount: 10 vials (refer to RA_QABR_0225). Within ± 5.0 %.	CPP	☐	☐	-
	Att.	Att.	Filling mass	Print strips reviewed and compliant.	-	☐	☐	-
	Att.	Att.	Qualified quantity:					
Att. (separate doc.)	Att. (separate doc.)	Integrity test (periodic)	Filling filter before use.	-	☐	☐	-	
			Date (DD/MM/YYYY):					
			Filling filter after use.	-	☐	☐	-	
			Date (DD/MM/YYYY):					
Capping	23/76	23/75	Caps batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	24/76	24/75	<u>Capping tightness</u>	<u>Qualified rate: 100 %.</u>	IPC	☐	☐	-
			Unqualified vials:					



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Qilu Pharma Spain, S.L.			Cefazolin Sodium for Injection					

Washing/ drying of vials and visual inspection	31/76	31/75	Washing and drying	Capped vials are cleaned and dried by automatic cleaning and drying machine.	-	☐	☐	☐
	31-33 /76	31-33 /75	Visual inspection	The vials are 100 % visually inspected.	-	☐	☐	-
Packaging	36/76	36/75	Labeling quality	Meets requirements.	-	☐	☐	☐
	Att.	Att.	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.	-	☐	☐	-
	Att.	Att.	Leaflet contents	Copy endorsed in the BPR.	-	☐	☐	-
				Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-
	Att.	Att.	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.	-	☐	☐	-
	Att.	Att.	Artwork verification	The label, leaflet and carton artworks correspond to the currently approved artworks (according to below table).	-	☐	☐	-
	Market		Strength	Label	Leaflet	Carton		
	☐	ES	1 g	34040065704B	34040065711D	34040065901C		
	☐	ES	2 g	34040066004B	34040066201C	34040066011D		
	☐	FR	1 g	34160073904A	34160073911A	34160073901A		
	☐	FR	2 g	34160074004A	34160074011A	34160074001A		
	☐	HR/SI	1 g	34040139604A	34040139611C	34040139601A		
	45/76	44/75	Sampling	100 vials as test samples for customer. 200 vials as retention samples for customer.	-	☐	☐	-
	Wasted amount (Db):							



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

			Actual output:						
			Visual inspection qualif. qty. (att.)	Wasted amount (Db)	Capping unqualif. vials (page 24)	Actual output			
			-	-	-	=			
			Warehousing amount:						
			Must match:						
			Actual output	QC sample retention	Amount for QC analysis	IPC	Other samplings	Warehousing amount	
			-	-	-	-	=		
Washing, Sterilization and Drying of Rubber Stoppers	50/76	49/75	Stoppers batch No.	The recorded batch Nos. corresponds to the batch Nos. in the provided CoAs.		-	☐	☐	-
	52/76	51/75	Sterilization	Temp.: 122 °C (range 121 – 128 °C). Time: 20 min.		CPP	☐	☐	-
	53/76	52/75	Visible particles of rinsing water	Fibers or particles shorter than 2 mm ≤ 2. Visible and color particles: absent.		IPC	☐	☐	-
			The Treated batch No. and qty. of washed and sterilized rubber stoppers is consistent with the stoppers used for filling.		-	☐	☐	☐	
	Att.	Att.	Sterilization	Sterilization record reviewed and compliant.		-	☐	☐	-
Washing and Sterilization of Filling Machine Components	54/76	53/75	Sterilization	Autoclave validated load pattern: Temp.: 122 °C (range 122 – 125 °C). Time: 20 min.		-	☐	☐	☐
	61/76	60/75	Sterilization batch No. is consistent with the one used for filling.			-	☐	☐	☐
	Att.	Att.	Sterilization	Sterilization record reviewed and compliant.		-	☐	☐	☐
In-Process Control	70/76	69/75	Visible particles	Supplied vials and stoppers before filling: Absent.		IPC	☐	☐	-
			Stated amount	95.0 % – 105.0 %		IPC	☐	☐	-
			Uniformity of mass	Within ± 5.0 %.		IPC	☐	☐	-
	Att.	Att.	Filling mass	Print strips reviewed and compliant.		-	☐	☐	-
	71/76	70/75	Visible particles	After filling: Should not exist.		IPC	☐	☐	-
			Capping tightness	Qualified rate: 100 %.		IPC	☐	☐	-
	72/76	71/75	Leak test	☐ 10 mL-vial:		IPC	☐	☐	-



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

				<u>Microleakage (5 µm) ≤ 2.3 mbar within 20 s.</u> <u>Large leakage ≤ 743.2 mbar within 1 s.</u> ☐ 20 mL-vial: <u>Microleakage (5 µm) ≤ 2.6 mbar within 20 s.</u> <u>Large leakage ≤ 782.0 mbar within 1 s</u>								
Batch evaluation	75-76 /76	74-75 /75	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						☐	☐	-			
Supporting documentation	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.	Surface microbe			☐	☐	-				
			Settling microbe			☐	☐	-				
			Airborne microbe			☐	☐	-				
			Personnel			☐	☐	-				
	VHP fumigation report	Fumigation record of the API canisters is available and traceable.					☐	☐	-			
Comments												
☐		Manufacturer: Qilu Pharmaceutical Co., Ltd.										
Bulk batch identification												
Packaging batch identification (if different)												
Batch manufacturing record edition. Master batch record available.	Section		Batch Record code		Version							
	BPR		BPR-B08-0054-0-									
	Repertoire Sheet		BPR-B08-0054-0-01-									
	Washing of vials		BPR-B08-0054-0-03-									
	Filling		BPR-B08-0054-0-04-									
	Capping		BPR-B08-0054-0-05-									
	Visual Inspection		BPR-B08-0054-0-06-									
	Packaging		BPR-B08-0054-1-01-									
	Outer preparation		BPR-B08-0054-0-07-									
	Inner preparation		BPR-B08-0054-0-08-									
	In Process Control		BPR-B08-0054-0-09-									



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

		Material Balance	BPR-B08-0054-0-10-				
		Comments					
Batch Manufacturing Record and Critical Controls review							
Critical Process Parameters and In-Process Controls are indicated with <u>bold and underlined</u> format and classified in column CPP/IPC.							
<i>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.</i>							
Step	Page	Parameter /Process	Specification	CPP /IPC	Compliance		
					C	NC	NA
Batch Record	1/4	Workshop	Workshop No. 21	-	☐	☐	-
		Batch size	☐ 1 g/vial: 70 kg (around 66 000 vials) or 130 kg (around 120 000 vials) ☐ 2 g/vial: 140 kg (around 66 000 vials)	-	☐	☐	-
		Manuf. date					
		Expiry date					
		Shelf-life	Expiry date in accordance with approved shelf life: 36 months.	-	☐	☐	-
Washing and Sterilization of Vials	2/13	Vials batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	9/13	<u>Visible particles of washed vials</u>	<u>Fibers or particles shorter than 2 mm ≤ 2.</u> <u>Visible and color particles: absent.</u>	IPC	☐	☐	-
	11/13	<u>Sterilization</u>	<u>Temp.: 320 °C</u> (actual temp. ≥ 315 °C) ☐ 10 mL-vials: <u>Belt speed ≤ 203 mm/min</u> ☐ 20 mL-vials: <u>Belt speed ≤ 183 mm/min</u>	CPP	☐	☐	-
	Att.	Sterilization	Sterilization record reviewed and compliant.	-	☐	☐	-
Aseptic filling and stoppering	2/19	API batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	Att.	API CoA	CoA for API from DP manufacturer attached.	-	☐	☐	☐
	3/19	API preparation	API canisters are wiped with dust-free cloth dipped in disinfectant and appearance and quantity are checked.	-	☐	☐	-



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

	5/19	T and <u>RH during filling</u>	Filling room and laminar flow T: 18 – 26 °C. Laminar flow RH: 20 – 50 %.	IPC	☐	☐	-
	Att.		Filling room RH: 20 – 65 %.	IPC	☐	☐	-
	7/19	Filling period	Day (DD/MM/YYYY) and time (HH:MM – HH:MM):				
	Att.	Integrity test (periodic)	Filling filter before use.	-	☐	☐	-
			Date (DD/MM/YYYY):	-	☐	☐	-
	9-12 /19	<u>Stated amount</u>	Sampling amount: 20 vials (refer to RA_QABR_0225). 95.0 % - 105.0 %	CPP	☐	☐	-
		<u>Uniformity of mass</u>	Sampling amount: 20 vials (refer to RA_QABR_0225). Within ± 5.0 %.	CPP	☐	☐	-
	Att.	Filling mass	Print strips reviewed and compliant.	-	☐	☐	-
Capping	3/8	Caps batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
		Caps air shower	Air shower purification for 20 min.	-	☐	☐	-
	4/8	<u>Capping tightness</u>	Qualified rate: 100 %.	IPC	☐	☐	-
Washing/ drying of vials and visual inspection	3/9	Washing and drying	Capped vials are cleaned and dried by automatic cleaning and drying machine.	-	☐	☐	-
	4-6/9	Visual inspection	The vials are 100 % visually inspected.	-	☐	☐	-
Packaging	3/15	Labeling quality	Meets requirements.	-	☐	☐	-
	Att.	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.	-	☐	☐	-
	Att.	Leaflet contents	Copy endorsed in the BPR.	-	☐	☐	-
			Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-
	Att.	Carton contents	Copy endorsed in the BPR.	-	☐	☐	-
			Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-



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

			Variable data (batch number and expiry date) are correct.		-	☐	☐	-										
			Antifalsified measures and devices (unique SN, Data Matrix and tamper evident) comply with regulation.		-	☐	☐	-										
	Att.	Artwork verification	The label, leaflet and carton artworks correspond to the currently approved artworks (according to below table).		-	☐	☐	-										
		Market	Strength	Label	Leaflet	Carton												
		☐ ES	1 g	34040065704B	34040065711D	34040065901C												
		☐ ES	2 g	34040066004B	34040066201C	34040066011D												
		☐ FR	1 g	34160073904A	34160073911A	34160073901A												
		☐ FR	2 g	34160074004A	34160074011A	34160074001A												
		☐ HR/SI	1 g	34040139604A	34040139611C	34040139601A												
	12/15		Sampling	100 vials as test samples for customer. 200 vials as retention samples for customer.		-	☐	☐	-									
	Warehousing amount: Must match: <table border="1"> <tr> <td>Actual output</td> <td>Amount for QC analysis</td> <td>QC sample retention</td> <td>Vials for API identification</td> <td>Warehousing amount</td> </tr> <tr> <td>-</td> <td>-</td> <td>100 vials</td> <td>-</td> <td>=</td> </tr> </table>								Actual output	Amount for QC analysis	QC sample retention	Vials for API identification	Warehousing amount	-	-	100 vials	-	=
Actual output	Amount for QC analysis	QC sample retention	Vials for API identification	Warehousing amount														
-	-	100 vials	-	=														
Outer preparation Including: Preparation of Rubber Stoppers	4/18	Stoppers batch No.	The recorded batch Nos. corresponds to the batch Nos. in the provided CoAs.		-	☐	☐	-										
	7/18	Visible particles of rinsing water	Fibers or particles shorter than 2 mm ≤ 2. Visible and color particles: absent.		IPC	☐	☐	-										
	8/18	Sterilization	Temp.: 122 °C (range 121 – 128 °C). Time: 20 min.		CPP	☐	☐	-										
	15/18	API preparation	The recorded API batch No. is consistent with the API used for filling.		-	☐	☐	-										
	16/18		API canisters are sprayed with spore killer.		-	☐	☐	-										
	17/18		API canisters are fumigated.		-	☐	☐	-										
	Att.	Sterilization	Stoppers sterilization record reviewed, traceable and compliant.		-	☐	☐	-										
In-Process Control	1/9	Visible particles of stoppers rinsing water	Fibers or particles shorter than 2 mm ≤ 2. Visible and color particles: absent.		IPC	☐	☐	-										
	2/9	Visible particles	Supplied vials and stoppers before filling: Absent.		IPC	☐	☐	-										



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

	3/9	<u>Stated amount</u>	<u>95.0 % – 105.0 %</u>	IPC	☐	☐	-	
		<u>Uniformity of mass</u>	<u>Within ± 5.0 %.</u>	IPC	☐	☐	-	
	Att.	Filling mass	Print strips reviewed and compliant.	-	☐	☐	-	
	4-5/9	<u>Visible particles</u>	<u>After filling: Should not exist.</u>	IPC	☐	☐	-	
	6/9	<u>Capping tightness</u>	<u>Qualified rate: 100 %.</u>	IPC	☐	☐	-	
	7/9	<u>Leak test</u>	<u>Decreased vacuum degree ≤ 2 mba within 1.3 s.</u> <u>Qualified rate: 100 %.</u>	IPC	☐	☐	-	
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.):							
Supporting documentation	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.	Surface microbe		☐	☐	-	
			Settling microbe		☐	☐	-	
			Airborne microbe		☐	☐	-	
			Personnel		☐	☐	-	
Comments								
CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER								
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								



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

CoA reference number	
Quality Spec. number	SEFEQ-4.0 (Antibiotics) QS-100100014039-5.0 (Pharmaceuticals)
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	
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.	
		☐ Qilu Antibiotics (China) > Airpharm (Spain) > QC samples: Kymos.	
		☐ Qilu Pharmaceutical (China) > Picking Pharma (Spain) > Samples: Kymos and Airpharm.	
		☐ Qilu Pharmaceutical (China) > Airpharm (Spain) > QC samples: Kymos.	
	Dataloggers	Shipment	Shipment: Batch:
Samples to Kymos		☐	Same dataloggers as shipment.
		☐	Different from shipment. Dataloggers ref.:
Dataloggers	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

Packing list	Route	Doc. reference	Received on	Units to be received	Units received	N/A
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CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - CEFAZOLIN		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefazolin Sodium for Injection	

	Qilu Antibiotics /Pharmaceuticals to Picking Pharma			CoC released qty.	☐ C ☐ NC	☐
	Picking Pharma to Airpharm			200 vials	☐ C ☐ NC	☐
	Picking Pharma to Kymos			100 vials	☐ C ☐ NC	☐
	Qilu Antibiotics /Pharmaceuticals to Airpharm			CoC released qty.	☐ C ☐ NC	☐
	Airpharm to Kymos			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						
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
	☐ ES	1 g	Cefazolina Qilu 1 g polvo para solución inyectable y para perfusión EFG
	☐ ES	2 g	Cefazolina Qilu 2 g polvo para solución inyectable y para perfusión EFG
	☐ FR	1 g	CEFAZOLINE QILU 1 g, poudre pour solution injectable/pour perfusion
	☐ FR	2 g	CEFAZOLINE QILU 2 g, poudre pour solution injectable/pour perfusion
	☐ HR-SI	1 g	Cefazolin Qilu 1 g prašak za otopinu za injekciju/infuziju · prašek za raztopino za injiciranje/infundiranje
Destination country/ies	☐	Spain (ES)	
	☐	France (FR)	
	☐	Croatia (HR), Slovenia (SI)	
	Market	Strength	MA number



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

Marketing Authorization Number	☐	ES	1 g	83507
	☐	ES	2 g	83506
	☐	FR	1 g (10 v/c)	34009 301 545 9 5
	☐	FR	2 g (10 v/c)	34009 301 546 1 8
	☐	HR-SI	1 g	HR: HR-H-572695905, SI: H/24/03078/002
Strength/Potency	☐	1 g		
	☐	2 g		
Dosage form	Powder for injection			
Type and size of packaging	☐	10 vials/carton		
	☐	100 vials/carton		
Batch number				
Quantity Released (packs)	Released by	QC testing in	Ref./Ret. samples	Other
	Qilu	Kymos	in Airpharm	
		- 100 vials	- 200 vials	-
Quantity Released	=			
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 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 1	Name	Qilu Pharmaceutical Co., Ltd.
			Address	No. 317 Xinluo Road, High-Tech Zone, Jinan, Shandong Providence, CN-250101, China
			Auth. No	Lu20160001
			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 (Parc Tecnològic del Vallès), 08290 Cerdanyola del Vallès, Barcelona, Spain
			Auth. No	6317E
			Activity	Quality Control, Batch Release

**CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - CEFAZOLIN**

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

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:

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

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APPROVAL

Performed by	Reviewed by
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CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS - CEFAZOLIN		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefazolin Sodium for Injection	

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