



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-CEFUROXIME		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

PRODUCT INFORMATION			
Company	Qilu Pharma Spain, S.L.		
Product trade name	Market	Strength	Name on the Marketing Authorization
	☒ FI	1.5 g	Cefirion 1,5 g injektio-/infuusiokuiva-aine liuosta varten/pulver till injektions-/infusionsvätska, lösning
Batch number	6005KFNQL1		
Manuf. date	28/01/2026		
Expiry date	31/12/2028		Approved shelf life 36 months
Type of review	☐ Extensive review.		
	☒ 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. • Integrity tests for filters. • Certificate of Analysis (CoA) of the API. • Certificates of Analysis (CoA) of the key excipient: nitrogen. • 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
	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		Audit ref.	Inspection date	Auditor	Comments



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(full audit report, updated CAPA plan, CV of the auditor available)	AUD-5005	05-09/01/2026	Rephine	None.
CEP	R0-CEP 2020-383-Rev 00 (Process 2)		Renewal due: 08/07/2027	
Current dossier sections of 3.2.S. provided – current version.				

Comments	N/A
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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	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: APS-364-15, 28/02/2026. Reviewed and confirmed as compliant. ☐ Pending to receive an update; explain:
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Annual PQR reports received and reviewed.	☒ Yes, detail breakdown per year: PQR 2025 for 1.5 g dose approved in 03/2026. Reviewed and confirmed as compliant. The PQR confirms that, during the period reviewed, the manufacturing process remained in a validated state and under control, in compliance with specifications and GMP requirements. No adverse trends or quality issues were identified that would require CAPAs or additional actions at this time ☐ Pending to receive an update, explain:
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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: Data for 2025 batch (1.5 g) updated up to 3 months. Reviewed and confirmed as compliant Data for 2026 batches is not available yet. In accordance with the Quality Technical Agreement, the Manufacturer is responsible for performing stability studies and handling any Out of Specification
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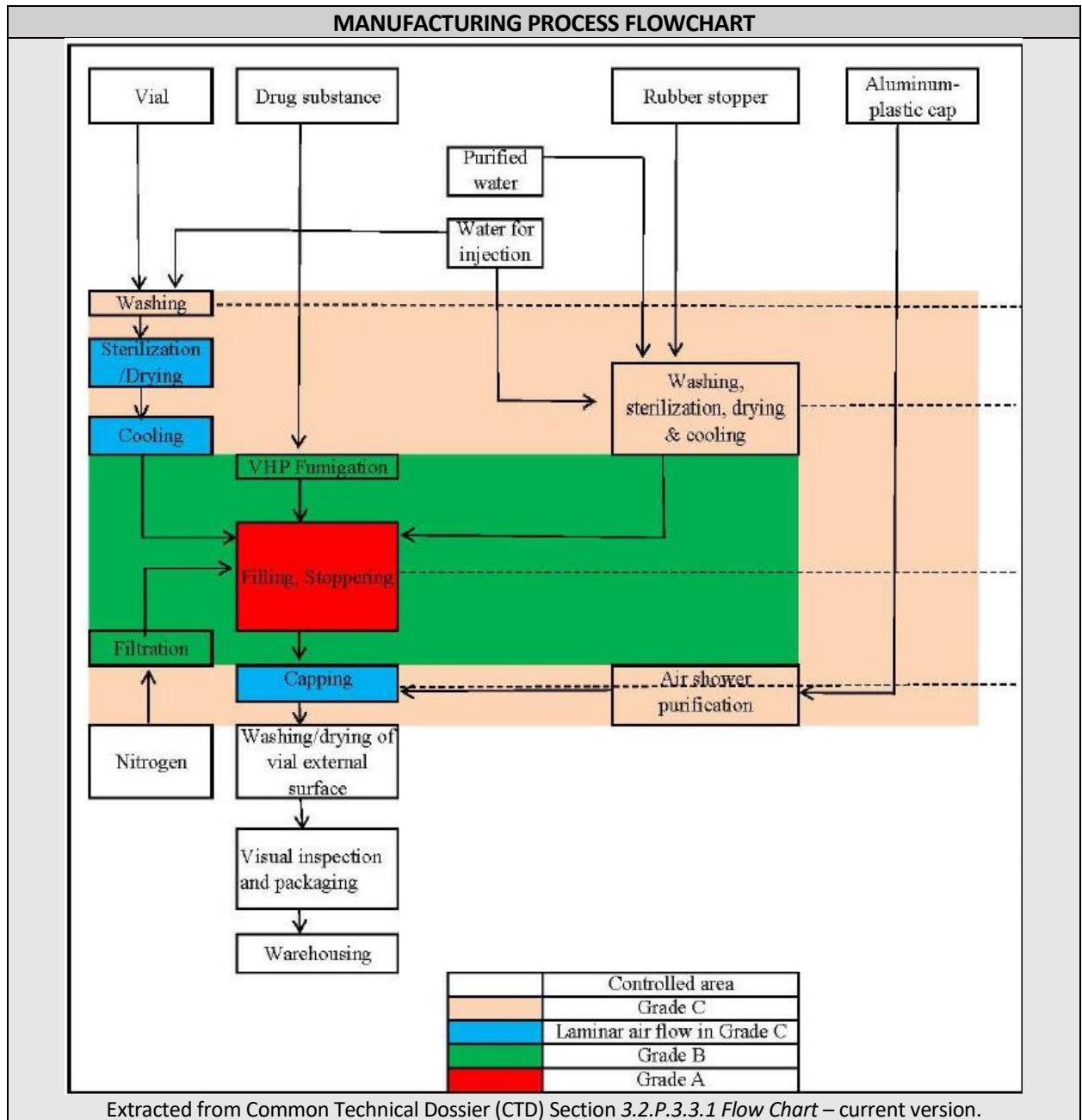
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		(OOS) investigations. Any OOS result identified during stability testing shall be promptly communicated to the MIA. ☐ Pending to receive an update, explain:			
Quality Technical Agreement in place		TA-QL-012 Rev.: 3.0, effective on 12/2025.			
Current dossier sections of 3.2.P. provided – current version.					
Comments		N/A			
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.				
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		N/A			



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-CEFUROXIME

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1





CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-CEFUROXIME

Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

BATCH RECORDS REVIEW

API AND CRITICAL EXCIPIENTS

DP and API Manufacturer: Qilu Antibiotics Pharmaceutical CO., Ltd.

Name	Batch number	CoA number	Specifications reference	Identified and traceable in BR (page 11/71)	Compliance with CTD specif.	N/A
Sterile Cefuroxime Sodium	5128LK81P	No. 5	N/A	☒	☒	-
				☐	☐	☒
				☐	☐	☒

No.	Test Items		Acceptance Criteria	Analytical Procedure
1	Appearance		White or almost white powder	Visual
2	Identification	Infrared absorption	Complies	Ph. Eur. monograph 0992
		Sodium	Complies	Ph. Eur. monograph 0992
3	Appearance of solution (10%)	Clarity	≤ II	Ph. Eur. monograph 0992
		Absorbance (450nm)	≤ 0.25	Ph. Eur. monograph 0992
4	Visible particles		Free from particles of foreign matter	Ph. Eur. 2.9.20
	Sub-visible particles	≥ 10 µm	≤ 3000 pieces/g	Ph. Eur. 2.9.19, method 1
		≥ 25 µm	≤ 300 pieces/g	
5	pH (1%)		5.5 ~ 8.5	Ph. Eur. monograph 0992
6	Specific optical rotation (20°C, 2%)*		+59° ~ +66°	Ph. Eur. monograph 0992
7	Water (K.F.)		≤ 3.5%	Ph. Eur. monograph 0992
8	Assay, as sodium salt*		96.0% ~ 102.0%	Ph. Eur. 2.2.29 / In-house
9	Related Substances	EP Imp. A	≤ 1.0%	Ph. Eur. 2.2.29 / In-house
		EP Imp. E	≤ 1.0%	
		EP Imp. C	≤ 1.0%	
		EP Imp. B	≤ 1.0%	
		EP Imp. H	≤ 1.0%	
		RRT0.77 (M467)	≤ 0.10%	
		RRT1.23 (M381)	≤ 0.10%	
		Max unspecified impurity	≤ 0.05%	
		Total impurities	≤ 3.0%	
10	Bacterial Endotoxins		< 0.10 IU/mg	Ph. Eur. monograph 0992
11	Sterility		Sterile	Ph. Eur. 2.6.1, membrane filtration
12	Residual Solvents	Ethanol	≤ 0.5%	Ph. Eur. 2.2.28 / In-house
		Acetone	≤ 0.5%	
13	Sodium lactate		≤ 0.5%	Ph. Eur. 2.2.29 / In-house

*: on anhydrous basis.

API specifications, extracted from CTD Section 3.2.S.4.1 – current version.



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Key excipients					
Excipient	Batch number	CoA number	Specifications reference	Identified and traceable in BR	N/A
Nitrogen	260122002	000050, 057	SE9407-1.0	☐ See comments ⁽¹⁾	-
				☐	☒

BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT							
Bulk batch identification		6005KFNQL1					
Batch manufacturing record edition. Master batch record and associated change controls (when applicable) available.		Strength	Batch Record code and version.				
		1.5g	ROP36413.02				
		Strength	Market	Packaging Repertoire Sheet code and version			
		1.5g	FI	ROP36481.01			
		Comments	N/A				
Batch Manufacturing Record and Critical Controls review							
Instructions for Routine review: Critical Process Parameters and In-Process Controls are indicated with <i><u>bold, italic and underlined</u></i> 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		
					C	NC	NA
Batch Record	1/71	Workshop	Unit 364 of Workshop No. 360	-	☒	☐	-
		Batch size	100 kg (around 61 000 vials)	-	☐	☐	☒
		Manuf. date	28/01/2026				
		Expiry date	12/2028				
		Shelf-life	Expiry date in accordance with approved shelf life: 36 months	-	☒	☐	-
Washing and Sterilization of Vials See comments ⁽²⁾	5/71	Vials batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☒	☐	-
	8/71	<i><u>Visible particles of washed vials</u></i>	<i><u>Fibers or particles shorter than 2 mm ≤ 2.</u></i> <i><u>Visible and color particles: absent.</u></i>	IPC	☒	☐	-
	9/71	<i><u>Sterilization</u></i>	<i><u>Temp.: 330 °C (range 320 – 340 °C).</u></i> <i><u>Belt speed for 50 mL-vials: 215 mm/min</u></i>	CPP	☒	☐	-
	Att.	Sterilization	Sterilization record reviewed and compliant.	-	☒	☐	-
Aseptic filling, nitrogen	11/71	API batch No.	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☒	☐	-
	Att.	API CoA	CoA for API from manufacturer attached.	-	☐	☐	☒



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charging and stoppering	14/71	API preparation	API canisters are transferred from the fumigation room to the filling room.	-	☐	☐	☒
		Components sterilized batch No.: M26012741-07					
		Rubber stoppers disposed batch No. and units: J26012643-2, J26012744-2. Units: not recorded. See comments ⁽²⁾ .					
		Components and Rubber stoppers sterilizations are within expiry date.		-	☒	☐	-
	15/71	API preparation	API canisters are wiped with dust-free cloth dipped in disinfectant.	-	☐	☐	☒
	17/71	<u>Filling speed</u>	For 50-mL vials: 50 – 134 vials/min.	CPP	☒	☐	-
		Filling period	Day (DD/MM/YYYY) and time (HH:MM – HH:MM): 28/01/2026, 19:50 – 29/01/2026 04:06				
		Maximum filling time	For 50-mL vials ≤ 16 h	-	☐	☐	☒
		<u>Labeled amount</u>	Sampling amount: 24 vials. Total 36 vials (12 + 12 + 12 = 36). 95.0 % - 105.0 %	IPC	☒	☐	-
		<u>Uniformity of mass</u>	Sampling amount: 24 vials. Total 36 vials (12 + 12 + 12 = 36). For 1.5 g: Within ± 4.5 % .	IPC	☒	☐	-
		<u>Residual oxygen</u>	≤ 3.0 %	IPC	☒	☐	-
		Att. Filling mass	Print strips reviewed and compliant.	-	☒	☐	-
		Att.	Qualified quantity: 58527 vials				
	Att. (separate doc.)	Integrity test (periodic)	Filling filter before use. Date (DD/MM/YYYY): 24/01/2026	-	☒	☐	-
			Filling filter after use. Date (DD/MM/YYYY): 01/02/2026	-	☒	☐	-
Capping	23/71	Caps batch No.	The recorded batch Nos. corresponds to the batch Nos. in the provided CoAs. See comments ⁽³⁾ .	-	☒	☐	-
	24/71	<u>Capping tightness</u>	Qualified rate: 100 %.	IPC	☒	☐	-
	Unqualified vials: 10 vials						
Washing/ drying of vials external surface and visual inspection	30/71	Capping tightness	Qualified rate: 100 %.	-	☒	☐	-
	31-33 /71	Visual inspection	The vials are 100 % visually inspected.	-	☒	☐	-
Packaging	36/71	Labeling quality	Meets requirements.	-	☐	☐	☒
	Att.		Copy endorsed in the BPR.	-	☒	☐	-



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		Label contents	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.	-	☒	☐	-
			The artwork of the label used corresponds to the currently approved artwork (according to the table below).	-	☒	☐	-
	Att.	Leaflet contents	Copy endorsed in the BPR.	-	☒	☐	-
			Name of the product, strength and dosage form follow the CTD and MA.	-	☒	☐	-
			The artwork of the leaflet used corresponds to the currently approved artwork (according to the table below).	-	☒	☐	-
	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.	-	☒	☐	-
			The artwork of the carton used corresponds to the currently approved artwork (according to the table below).	-	☒	☐	-
		Market	Strength	Label	Leaflet	Carton	
		FI	1.5 g	34160074204A	34160074211A	34160074201A	
	41/71	Sampling	130 vials as test samples for customer.	-	☒	☐	-
			260 vials as retention samples for customer.				
		Wasted amount (Db): 287 vials					
		Actual output: 58230 vials					
		Must match:					
	Visual inspection qualified qty. (att.)		Wasted amount (Db)		Capping unqualified vials (page 24/71)		Actual output
58527 vials		- 287 vials		- 10 vials		= 58230 vials	
Warehousing amount: 57950 vials							
Must match:							



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		Actual output 58230 vials	-	QC sample retention 120 vials	-	Amount for QC analysis 60 vials	-	IPC 100 vials	-	Other samplings 0 vials	=	Warehousing amount 57950 vials
Washing, Sterilization and Drying of Rubber Stoppers	46/71	Stoppers batch No.	The recorded batch Nos. corresponds to the batch Nos. in the provided CoAs.					-	☒	☐	-	
	48/71	<u>Sterilization</u>	<u>Temp.: 122 °C (range 121 – 128 °C).</u> <u>Time: 20 min.</u>					CPP	☒	☐	-	
	49/71	<u>Visible particles of rinsing water</u>	<u>Fibers or particles shorter than 2 mm ≤ 2.</u> <u>Visible and color particles: absent.</u>					IPC	☒	☐	-	
		The Treated batch No. and qty. of washed and sterilized rubber stoppers is consistent with the stoppers used for filling. See comments (2)					-	☒	☐	-		
	Att.	Sterilization	Sterilization record reviewed and compliant.					-	☒	☐	-	
Washing and Sterilization of Filling Machine Components	50, 56-58 /71	Sterilization	Autoclave validated load pattern: Temp.: 122 °C (range 122 – 125 °C). Time: 20 min.					-	☐	☐	☒	
	56/71	Sterilization batch No. is consistent with the one used for filling. See comments (2)					-	☒	☐	☐		
	Att.	Sterilization	Sterilization record reviewed and compliant.					-	☐	☐	☒	
In-Process Controls	65/71	<u>Visible particles</u>	<u>Cleaned vials and stoppers before filling: Absent.</u>					IPC	☒	☐	-	
		<u>Labeled amount</u>	<u>95.0 % – 105.0 %</u>					IPC	☒	☐	-	
		<u>Uniformity of mass</u>	<u>For 1.5 g: Within ± 4.5 %.</u>					IPC	☒	☐	-	
	Att.	Filling mass	Print strips reviewed and compliant.					-	☒	☐	-	
	66/71	<u>Appearance</u>	<u>White or almost white powder.</u>					IPC	☒	☐	-	
		<u>Dissolution /clarity</u>	<u>The solid dissolves completely, leaving no undissolved matter, and compared with purified water, the reconstituted solution should be clear.</u>					IPC	☒	☐	-	
		<u>Visible particles</u>	<u>The visible particles should be absent, and during rotating, no smog particles pole should be detected.</u>					IPC	☒	☐	-	
		Capping tightness	Qualified rate: 100 %.					-	☒	☐	-	
	67/71	<u>Leak test</u>	<u>For 50 mL-vial: Microleakage (5 µm) ≤ 2.1 mbar within 20 s.</u>					IPC	☒	☐	-	



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			<i>Large leakage ≤ 843.2 mbar within 1 s.</i>					
Batch evaluation	70-71 /71	Deviation/Remark (type and ref. number): No deviations or change controls recorded.						
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			☒	☐	-		
Comments	⁽¹⁾ The batch number of the nitrogen used for the manufacture of this batch is not recorded in the BPR; however, the CoA for this batch is attached to the BPR, ensuring traceability. Qilu has issued a new version of the Batch Record (ROP36413-1.0, effective date 20/03/2026) with a designated space to record it. Evidence has been provided. ⁽²⁾ The following steps were performed jointly for several batches: • Washing and Sterilization of Vials and Washing – refer to batch 6004KFNQL1. • Sterilization and Drying of Rubber Stoppers: ○ Disposed batch No. J26012643-2 – refer to batch 6003KFNQL1. ○ Disposed batch No. 26012744-2 – refer to batch 6004KFNQL1. • Washing and Sterilization of Filling Machine Components: ○ Sterilized batch No. M26012741-07 – refer to batch 6004KFNQL1. The batch records include annotations referencing this situation, ensuring traceability. ⁽³⁾ For caps batch No and received amount, refer to batch 6004KFNQL1.							
SUPPORTING DOCUMENTATION REVISION								
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	Fumigation record for the API canisters is available and traceable.			☒	☐			
CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER								
Name of the product	Cefuroxime sodium for injection							
Strength	1.5g							
Dosage form	Powder for Injection							
Batch number	6005KFNQL1							
Quantity released (vials)	57950 vials							



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Manufacturing date		28/01/2026		
Expiry date (36 months)		12/2028		
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: Wang Li, Qualified Person, 14/02/2026		
CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER				
CoA reference number		N/A		
Quality Spec. number		SEFEQ-4.0		
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: QC responsible, 13/02/2026		
CERTIFICATE OF ANALYSIS (COA) ISSUED BY KYMOS				
CoA reference number		CA_0058290_V01		
Deviations and OOS reference available, if any		☐ No deviation and/or OOS registered. ☒ Reference: INV/INCA/016147, INV/INCA/016160, INV/INCA/016161, INV/INCA/016162 and INV/INCA/016197.		
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.		
	Dataloggers	Shipment	Shipment: EML25B105668, EML25B105670, EML25B105669, EML25B105665, EML25B105672, EML25B105664, EML25B105666, EML25B105671 and EML25B105667. Batch: EML25B105665, EML25B105672 and EML25B105664.	
		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.	



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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.
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Comments	N/A
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PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES

Packing list	Route	Doc. reference	Received on	Units to be received	Units received	NA
	Qilu Antibiotics to Picking Pharma	JLZ260212-J	08/04/2026	CoC released qty.	☒ C ☐ NC	☐
	Picking Pharma to Airpharm	M0118555	09/04/2026	260 vials	☒ C ☐ NC	☐
	Picking Pharma to Kymos	M0118556	09/04/2026	130 vials	☒ C ☐ NC	☐
	Qilu Antibiotics to Airpharm			CoC released qty.	☐ C ☐ NC	☒
	Airpharm to Kymos			130 vials	☐ C ☐ NC	☒

Incoming inspection of goods into warehouse	Reception number: 19127 ☒ Compliant. ☐ Not compliant, justify:
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Reference and retention samples location	Airpharm
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Comments	N/A
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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	NA
	☒	☐	☐

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
	☒ FI	1.5 g	Cefirion 1,5 g injektio-/infuusiokuiva-aine liuosta varten/pulver till injektions-/infusionsvätska, lösning
Destination country/ies	☒ Finland (FI)		
	Market	Strength	MA number



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-CEFUROXIME		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

Marketing Authorization Number	☒ FI	1.5 g	44542		
Strength/Potency	☒	1.5 g			
Dosage form	Powder for solution for injection or infusion				
Type and size of packaging	☒	10 vials/carton			
Batch number	6005KFNQL1				
Quantity Released	Released by Qilu	QC testing in Kymos	Ref./Ret. samples in Airpharm	Other	Quantity Released (packs)
	57950 vials	- 130 vials	- 260 vials	- 0 vials	= 57560 vials (5756 packs)
Manufacture date (DD/MM/YYYY)	28/01/2026				
Expiry date (DD/MM/YYYY)	31/12/2028				
CoA number	CA_0058290_V01				
Comments/Remarks (deviations, customer's requirements, etc.)	Deviations: INV/INCA/016147, INV/INCA/016160, INV/INCA/016161, INV/INCA/016162 and INV/INCA/016197.				
Transport Deviations (if any and not reportable in CoC)	N/A				
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 2	Name	Qilu Pharma Spain, S.L.		
		Address	Paseo de la Castellana, 40, 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		
Certification statement duly completed					
Batch Release Certificate sent to QP in LIMS System.					

COMMENTS				
MANUFACTURING DEVIATIONS				
☒	No deviations recorded.			
☐	Deviations/OOS:			
Code	Impact Assessment /Classification	Short Description	Status	Related CAPA
-	-	-	-	-



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-CEFUROXIME		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

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

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/OOS:

Code	Impact Assessment /Classification	Short Description	Status
INV/INCA/016147	Minor	<u>Description:</u> On 28/04/2026, during assay testing, an error in the injection time of the Standard D was identified. <u>Root cause:</u> The issue was detected during Standard D verification due to missing peaks caused by an incorrect injection time, resulting from an oversight during sequence review. The issue was detected and corrected immediately, with no impact on reported results, data integrity, or product quality. <u>Impact:</u> The batches included in the impacted sequence are 6001KFNQL1, 6002KFNQL1, 6003KFNQL1, 6004KFNQL1, 6005KFNQL1 and 6006KFNQL1. <u>Resolution:</u> The issue was identified in real time, allowing the sequence to be modified, and the standard was re-injected without any impact on product quality. <u>CAPA:</u> N/A, isolated human error.	Closed
INV/INCA/016160	Minor	<u>Description:</u> During technical review of assay testing between 21-22/04/2026, the system suitability requirement for resolution between Impurity A and Cefuroxime was identified to not meet the established acceptance criterion. <u>Root cause:</u> Incorrect initial chromatographic integration review, due to failure to identify a co-eluting peak, led to misinterpretation of resolution compliance. <u>Impact:</u> The batches included in the impacted sequence are 6001KFNQL1, 6002KFNQL1, 6003KFNQL1, 6004KFNQL1, 6005KFNQL1 and 6006KFNQL1.	Closed



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS-CEFUROXIME		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

		The initial results are considered invalid, therefore, there is no impact on product quality, safety or efficacy. <u>Resolution:</u> The test was repeated on 27-28/04/2026, meeting all system criteria. <u>CAPA:</u> N/A, isolated human error.	
INV/INCA/016161	Minor	<u>Description:</u> On 27-28/04/2026, during assay testing, it was identified that the pattern corresponding to Standard Solution A was used exclusively for repeatability assessment, while Standard Solutions B and C were used for sample quantification. <u>Root cause:</u> The most probable cause is incorrect preparation or affectation during preparation of Standard A that was only identified retrospectively through comparison with subsequently prepared standards. <u>Impact:</u> The batches included in the impacted sequence are 6001KFNQL1, 6002KFNQL1, 6003KFNQL1, 6004KFNQL1, 6005KFNQL1 and 6006KFNQL1. No impact on product quality, safety or efficacy. The incidence is focused on tracing the specific use of the injected standards throughout all involved sequences. <u>Resolution:</u> Retrospective evaluation showed a consistent deviation of Standard A versus standards B and C, indicating a likely preparation issue with Standard A. Despite this, the system suitability approach was maintained and results were considered valid, except for samples linked to high RSD (batches 6001KFNQL1 and 6005KFNQL1, refer to INV/INCA/016162). <u>CAPA:</u> N/A, the purpose of this incident is to define and clarify the use of the standards for Assay test quantification.	Closed
INV/INCA/016162	Minor	<u>Description:</u> On 27-28/04/2026, during the processing of assay testing, higher %RSD values were observed for batches 6001KFNQL1 and 6005KFNQL1. <u>Root cause:</u> Variability between replicate results, most likely due to inconsistent sample preparation, as instrumental performance and reference standards were confirmed suitable based on compliant results from other samples in the same sequence. <u>Impact:</u> The only impacted batches are 6001KFNQL1 and 6005KFNQL1. The results are invalidated. Therefore, no impact on quality or safety. <u>Resolution:</u> The test was repeated for the affected samples on 30/04/2026, meeting all acceptance criteria. <u>CAPA:</u> N/A, isolated human error.	Closed



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS-CEFUROXIME		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Cefuroxime powder for solution for injection or infusion	6005KFNQL1

INV/INCA/016197	Minor	<u>Description:</u> On 27/04/2026, during review of Water (KF) raw data, it was observed that the sample corresponding to batch 6005KFNQL1 did not meet the system suitability criteria. <u>Root cause:</u> The most likely cause is sample loss or incomplete transfer during addition of the sample to the KF vessel. <u>Impact:</u> The only impacted batch was 6005KFNQL1. The result was invalidated. Therefore, no impact on quality, safety or efficacy <u>Resolution:</u> The test was repeated on 06/05/2026, meeting all acceptance criteria. <u>CAPA:</u> N/A, isolated human error.	Closed
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TRANSPORT DEVIATIONS

☒ No deviations recorded.

☐ Deviations:

Code	Impact Assessment /Classification	Short Description	Status
-	-	-	-
-	-	-	-
-	-	-	-

ADDITIONAL COMMENTS

N/A

APPROVAL

Performed by	Reviewed by