



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

PRODUCT INFORMATION					
Company	Qilu Pharma Spain, S.L.				
Product trade name	Check	Strength	Packaging	Market	Name on the Marketing Authorization
	☐	4g/0.5g	10 vials/pack	IT	Piperacilina / Tazobactam Qilu 4g/0,5g polvere per soluzione per infusione
	☐	4g/0.5g	10 vials/pack	NO/DK	Piperacillin / Tazobactam Qilu 4g / 0,5g pulver til infusionsvæske, opløsning / pulver til infusionsvæske, oppløsning
	☐	4g/0.5g	50 vials/pack	ES	Piperacilina/Tazobactam Qilu 4g/0.5g polvo para solución para perfusión EFG
	☐	4g/0.5g	10 vials/pack	HR/SI	Piperacilin/tazobaktam Qilu 4g/0,5g prašak za otopinu za infuziju/ prašek za raztopino za infundiranje
	☐	4g/0.5g	10 vials/pack	FR	Piperacilline/Tazobactam Qilu 4g/0,5g poudre pour solution pour perfusion
	☐	4g/0.5g	10 vials/pack	UK	Piperacilina/Tazobactam Qilu 4g/0,5g powder for solution for infusion
	☐	4g/0.5g	10 vials/pack	BG	Пиперациллин/Тазобактам Килу прах за инфузионен разтвор - Piperacillin / Tazobactam Qilu powder for solution for infusion 4g/0,5g
	☐	4g/0.5g	10 vials/pack	FI/SE	Piperacillin/Tazobactam Qilu 4g/0,5g pulver till infusionsvätska, lösning infuusiokuiva-aine, liuosta varten
	☐	4g/0.5g	10 vials/pack	CZ/SK	Refocil 4g/0,5g prášek pro infuzní roztok / prášok na infúzny roztok
	☐	4g/0.5g	10 vials/pack	LV/LT /EE	Piperacillin/Tazobactam Qilu 4g/0,5g milteilai infuziniam tirpalui / pulveris infūziju šķīduma pagatavošanai / infusioonilahuse pulber piperacillinum/tazobactamum
Batch number					
Manuf. date					
Expiry date				Approved shelf life	24 months
Type of review	☐	Extensive review			
	☐	Routine review in accordance with RA_QAMPC_0126 (previously RA_QABR_0126, according to deviation INV/INCA/015886).			

MINIMUM DOCUMENTATION REQUIRED FOR THE REVIEW PROCESS
- Subsidiary record (the first batch for review). - Batch Production Record (BPR). - Environmental Monitoring Record. - Online environmental monitoring system. - Bioburden results.



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• Certificate of Analysis (CoA) of the API. • Certificates of Analysis (CoA) of the key excipient: Sodium bicarbonate. • Certificates of Analysis (CoA) of the packaging materials: Aluminum 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. ○ Packing list • Commission of the batch and decommission of the QC samples (except for IT and UK markets). • Change control reports, deviation/incidence reports and CAPAs affecting any step of the manufacturing and packaging process.
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MANUFACTURER AND PRODUCT FILE					
API MANUFACTURER					
Company: Shandong Anshun Pharmaceutical Co., Ltd					
Address: Circular Economy Demonstration Park, Laoling county, Dezhou City, Shandong Province, 253600, China.					
Activity: API manufacturer					
cGMP	Certificate	Certificate reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	According to the Chinese Regulation, no GMP certificate renewal is issued.
	EU	N/A	N/A	N/A	N/A
	FDA	FEI 3015326904	18-22/09/2023	N/A	N/A
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.	Inspection date	Auditor		Comments
	AUD-4991	09-10/09/2025	Rephine (Louis Lu and José Carlos Vergara Amat)		CVs are available. CAPA plan is received.
CEP Piperacillin monohydrate		R0-CEP 2020-383-Rev 00 (Process 2)			Renewal due: 08/07/2027
CEP Piperacillin monohydrate, Process II		R0-CEP 2022-445 - Rev 01			Renewal due: 03/03/2028
Current dossier sections of 3.2.S. provided – current version					
Comments		☐ N/A			



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FINISHED PRODUCT MANUFACTURER					
Company: Shandong Anxin 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	According to the Chinese regulation, no GMP certificate renewal is issued.
	EU	ES/083HV/25	13/05/2025	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-3931	11-13/06/2025	Rephine (Felix Liu and José Carlos Vergara Amat)	CV is available. CAPA plan is received.
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, detail breakdown per year: ☐ Pending to receive an update, explain:		
On-Going Stabilities results updated and reviewed. All results are within the registered specifications (at least 1 batch/dose/year)			☐ Yes, detail breakdown per year: ☐ Pending to receive an update, explain:		
Quality Technical Agreement in place			TA-QL-013 Rev.: 4.0, effective on 05/2025.		
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	N/A	

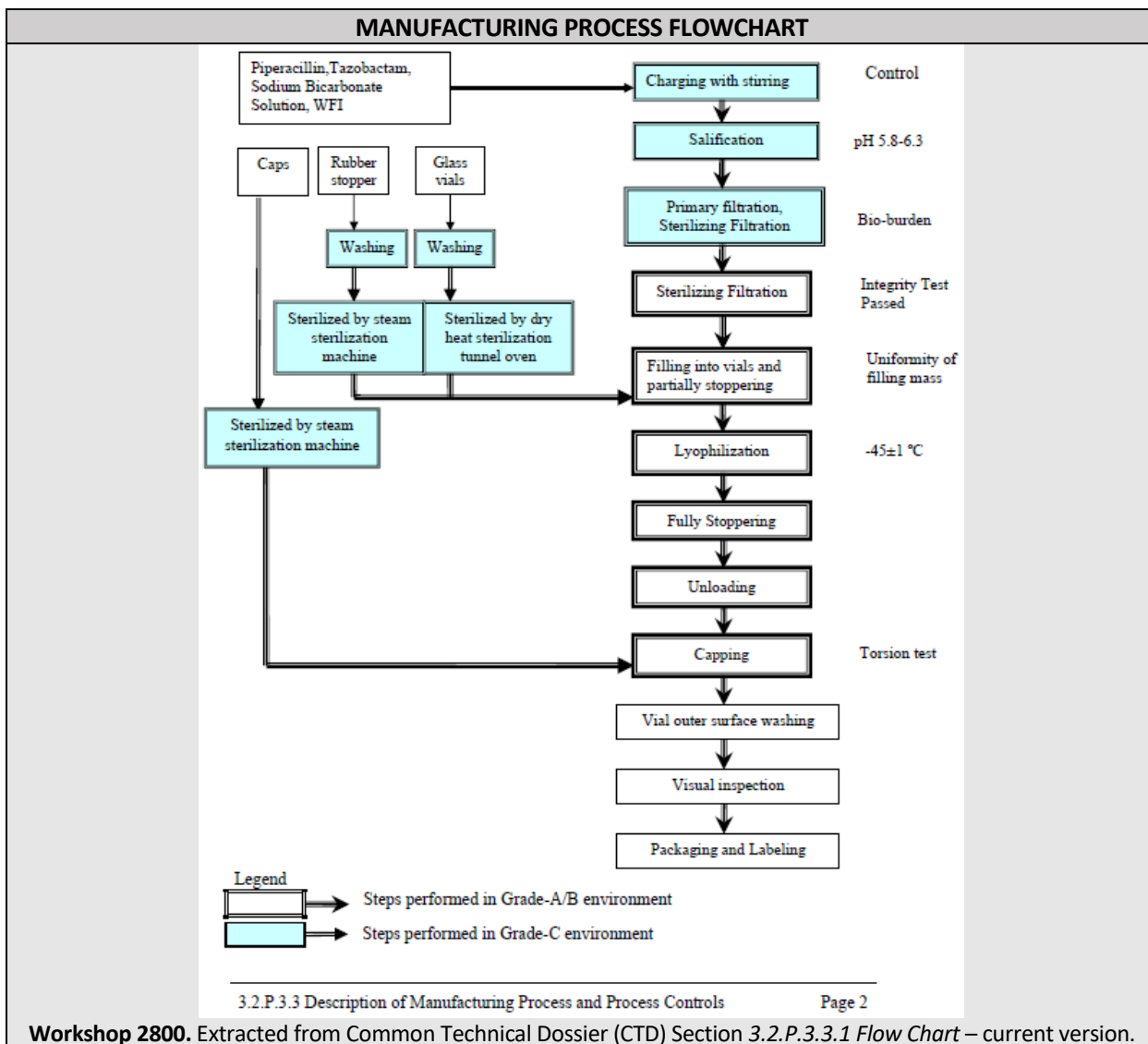


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	WDA	0087-MAD	29/11/2023	N/A	
	MIA	0367	30/09/2024	Laboratory auth. number 3451E	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	N/A	20/01/2025	Qilu Pharma Spain, S.L.	CV available, CAPA plan not applicable (no deviations).	N/A
☐ 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 plan available	Comments
	N/A	11/03/2025	Qilu Pharma Spain, S.L.	CV and CAPA plan available.	N/A
Comments		☐ N/A			



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BATCH RECORDS REVIEW							
API AND KEY EXCIPIENTS							
Finished product Manufacturer: Shandong Anxin Pharmaceutical Co., Ltd.							
Name	Batch number	CoA number	Specification CEP (IF any)	Specifications reference and version	Identified and traceable in BR	Compliance with CTD specif.	N/A
Piperacillin			2022-445-Rev01 (renewal date 03/03/2028)	AX-Q-210100003041/2.0	☐	☐	-
					☐	☐	☐
					☐	☐	☐
Tazobactam			-	AX-Q-211200001166/1.0	☐	☐	-
					☐	☐	☐
					☐	☐	☐
Comments	☐ N/A						
API Manufacturer: Shandong Anshun Pharmaceutical Co., Ltd							
Name	Batch number	CoA number		Specifications reference and version	Identified and traceable in BR	Compliance with CTD specif.	N/A
Piperacillin				Q-B0301/4.0	☐	☐	-
					☐	☐	☐
					☐	☐	☐
Tazobactam				Q-A0301/1.0	☐	☐	-
					☐	☐	☐
					☐	☐	☐
Comments	Tazobactam and Piperacillin testing have some non-routine tests that are tested at least three times a year.						
	☐ N/A						
Key excipients							
Excipient	Batch number	CoA number		Specifications reference	Identified and traceable in BR		N/A
Sodium bicarbonate					☐		-
					☐		☐
BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT							
Subsidiary record							
Subsidiary batch identification			Rubber stoppers				
			Preparation (capping)				
			Glass vials				
			Outer reparation (filling)				
☐ Revised on this batch ☐ Revised on batch:							



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Batch production records of the subsidiary	BPR	Code	Version
	Cleaning and sterilization record for rubber stoppers	AX-EP-2800-0002-BPR-01	
	BPR of cleaning and sterilization for outer preparation of workshop 2800 (capping)	AX-PO-8801-BPR-04	
	Cleaning and sterilization record for glass vial	AX-EP-2800-0004-BPR-01	
	BPR of cleaning and sterilization for outer preparation of workshop 2800 (filling)	AX-PO-8801-BPR-03	

Batch Manufacturing Record and Critical Controls review

Instructions for Routine review: Critical Process Parameters (CPP) and In-Process Controls (IPC) are indicated with **bold and underlined** format and classified in column PP(process parameters)/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.

Process step	Page	Material	Parameter /Process	Specification	CPP /IPC	Compliance		
						C	NC	N/A
Cleaning and sterilization for rubber stoppers	2/6	Rubber stoppers	Batch No. stoppers	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	4/6		<u>Sterilization</u>	<u>Temp.: ≥121°C</u> <u>Time: 30 min</u> Pressure: 1.2 bar (0.12 MPa)	CPP	☐	☐	-
	Att.			Sterilization report reviewed and compliant.	-	☐	☐	-
Outer preparation (capping)	6-7 /9	Aluminum caps	Sterilization	Temp: ≥121°C Time: 30 min Pressure: 115 KPa	CPP	☐	☐	☐
	7/9		Batch No. caps	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	Att.		Sterilization	Sterilization report reviewed and compliant.	-	☐	☐	☐
Cleaning and sterilization for glass	2/7	Glass vials	Batch No. vials	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-



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vials	6/7			Temp.: 330 °C. Belt speed: 337 mm/min	CPP	☐	☐	-								
	Att.		Sterilization	Sterilization report reviewed and compliant.	-	☐	☐	-								
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 (attached status labels if necessary). All are within validity period.					☐	☐	☐								
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.): ☐ N/A															
Comments	☐ N/A															
Bulk records																
Bulk batch identification																
☐ Revised on this batch																
☐ Revised on batch:																
Batch production records of Piperacillin /Tazobactam	BPR		Code		Version											
	Workshop 2800 (salification process)		AX-PO-9501-BPR-01													
Batch Manufacturing Record and Critical Controls review																
Instructions for Routine review: Critical Process Parameters (CPP) and In-Process Controls (IPC) are indicated with <u>bold and underlined</u> format and classified in column PP(parameter process)/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>																
Process step	Page	Parameter /Process	Specification	PP /CPP /IPC	Compliance											
Salification	1/21	Batch size of salification	Two-batch solution: About 510.1 kg (about 26000 vials) Single-batch solution: About 1000.6 kg (about 51000 vials)	-	☐	☐	☐									
		Shelf-life	Expiry date in accordance with approved shelf life: 24 months.	-	☐	☐	☐	-								
	2/21	Batch No. API	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	☐	-								



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Customer	Product	Batch	
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion		

		Batch No. Sodium bicarbonate	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	5-6 /21	Sterilizing filtration	3 rd and 4 th filters: CIP and SIP (≥ 121 °C for 30 min)	-	☐	☐	☐
	Att.		Sterilization report reviewed and compliant.	-	☐	☐	☐
	7/21		4th filter Integrity test before use: Acceptance criteria ≥ 50 psi If performed in different batch records, clarify:	CPP	☐	☐	-
	Att.		Integrity test strips reviewed and compliant.	-	☐	☐	-
	11-14 /21	Dissolution temperature	2 – 6 °C	PP	☐	☐	☐
	14/21	pH of ending point	5.8 – 6.3	IPC	☐	☐	-
	15/21	Density					
		Holding times	From preparation of the solution to end of reaction: Two-batch solution: ≤ 900 min Single-batch sol.: ≤ 480 min	PP	☐	☐	☐
			From completion of reaction to the beginning of pre-freezing: ≤ 15 h.	PP	☐	☐	☐
	18/21	Bioburden Test of solution	Sampling before the last stage of sterilizing filtration.	-	☐	☐	-
	Att. (separate)		Total sampling quantity (vials): ≤10cfu/100mL	IPC	☐	☐	-
	19/21	Sterilizing filtration	4th filter Integrity test after use: Acceptance criteria ≥ 50 psi If performed in different batch records, clarify:	CPP	☐	☐	-
	Att.		Integrity test strips reviewed and compliant	-	☐	☐	-
General aspects	All attachments (Filter integrity test, sterilization graphs) to the BPR are received and reviewed.				☐	☐	-



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	The raw data is recorded according to Good Documentation Practices.	☐	☐	-			
	Batch Records properly document line clearance.	☐	☐	-			
	Batch Records include the registry of equipment, calibration/qualification status and cleaning status (attached status labels if necessary). All are within validity period.	☐	☐	☐			
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):						
	☐ N/A						
Comments	☐ N/A						
Production records							
Batch identification							
☐	Revised on this batch						
☐	Revised on batch:						
Batch production records of Piperacillin/Tazobactam	BPR		Code	Version			
	Workshop 2800 (filling, loading, unloading and capping)		AX-PO-8803-BPR-01				
	Workshop 2800 (Lyophilization)		AX-PO-8804-BPR-01				
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 PP/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>							
Process step	Page	Parameter/Process	Specification	PP/ CPP /IPC	Compliance		
					C	NC	NA
Filling, loading, unloading and capping	1/31	Batch size of final drug product	24752 vials	-	☐	☐	☐
	9/31	Theoretical fill qty.	(Density x 18 mL) g	-	☐	☐	-
		<u>Uniformity of filling mass</u>	<u>Within weight ± 5%</u>	IPC	☐	☐	-
	10/31	Filling period	(dd/mm, hh:mm - hh:mm)				
	16/31	Total rejected vials (filling):					
	28/31	Total rejected quantity (unloading + capping):					
Lyophilization	6/8	<u>Pre-freezing temperature</u>	<u>-45 ± 1 °C</u>	IPC	☐	☐	-
		<u>Primary drying</u>	<u>65 ± 1 °C</u>	IPC	☐	☐	-
	7/8	<u>Secondary drying (end point)</u>	<u>Pressure increase < 2 Pa</u>	IPC	☐	☐	-



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	Att.	Lyophilization raw data	Lyophilization curve reviewed and compliant.	-	☐	☐	-							
General aspects	All attachments (reports ticket) to the BPR are received and reviewed				☐	☐	-							
	The raw data is recorded according to Good Documentation Practices.				☐	☐	-							
	Batch Records properly document line clearance.				☐	☐	-							
	Batch Records include the registry of equipment, calibration/qualification status and cleaning status (attached status labels if necessary). All are within validity period.				☐	☐	☐							
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):													
Comments	☐ N/A													
Packaging records														
Batch identification														
Batch production records of Piperacillin/Tazobactam	BPR		Code		Version									
	BPR of packaging		AX-PO-8724-BPR-09											
	BPR of packaging		AX-PO-8724-BPR-05											
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 PP/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>														
Process step	Page	Parameter /Process	Specification	PP/ CPP /IPC	Compliance									
					C	NC	NA							
Packaging	5/26	Rejected quantity (vial washing):												
	7/26	Total rejected quantity (packaging and visual inspection):												
	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.	-	☐	☐	-							
			The artwork of the used label corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-							
	Att.	Leaflet contents	Copy endorsed in the BPR.	-	☐	☐	-							
			Name of the product, strength and dosage form follow the CTD and MA.	-	☐	☐	-							



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			The artwork of the used label corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-		
	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. (<i>SN N/A for IT and UK markets</i>)	-	☐	☐	-		
			The artwork of the used label corresponds to the currently approved artwork (<i>see below table</i>).	-	☐	☐	-		
		Market	Dose	Label	Carton	Leaflet			
	☐	IT	4g/0.5g	34050031304A	34050031301B	34050031311C			
	☐	NO/DK	4g/0.5g	34050032004A	34050032101B	34050032011A			
	☐	ES	4g/0.5g	34050030004A	34050030201A	34050030311B			
	☐	HR/SI	4g/0.5g	34050029404B	34050029401C	34050029411C			
	☐	FR	4g/0.5g	1161704-01AA	1161704-02AA	1161704-03AB			
	☐	UK	4g/0.5g	34050036504A	34050036501B	34050036511A			
	☐	BG	4g/0.5g	34050031704A	34050031801B	34050031711C			
	☐	FI/SE	4g/0.5g	34050029204A	34050029201C	34050030511C			
	☐	CZ/SK	4g/0.5g	34050038504A	34050038501A	34050038511A			
	☐	LV/LT/EE	4g/0.5g	34050031904A	34050031901A	34050031911A			
	21/26	Sampling	Qty. of QC samples:						
			130 vials as test samples to customer. 260 vials as retention samples to customer.			-	☐	☐	-
			For ES market: 150 vials as test samples to customer. 300 vials as retention samples to customer.			-	☐	☐	-
		23/26	Torsion test	Total IPC sampling for torsion test:					
	Torsion test > 3kgf.cm			IPC	☐	☐	-		
Att.		Torsion test strip reviewed and compliant.			-	☐	☐	-	
Packaging	2/4	Vial reconciliation	The recorded vials quantities match the following quantities:				☐	☐	-



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		Rejected salification (page 18/21) Rejected filling (page 16/31) Rej. unloading and capping (page 28/31) Rejected packaging (page 5/26 + 7/26) Sampling qty (page 21/26 + 23/26)				
		Warehoused qty.:				
	Yield range	90.0 % - 103.0 %	-	☐	☐	☐
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 (attached status labels if necessary). All are within validity period.			☐	☐	☐
	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):					
	☐ N/A					
Comments	☐ N/A					

SUPPORTING DOCUMENTATION REVISION

Record	Review	Compliance		
		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	☐	☐
	Personnel	☐	☐	

CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER

Name of the product	
Strength	
Dosage form	
Batch number	
Quantity released (vials)	
Manufacturing date	
Expiry 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:



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER			
CoA reference number			
Quality specification number		AX-Q-TA0307/1.0	
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			
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	☐ Shandong Anxin (China) > Picking Pharma (Spain) > Samples: Kymos and Airpharm. ☐ Shandong Anxin (China) > Airpharm (Spain) > QC samples: Kymos.	
	Dataloggers	Shipment	Shipment: Batch:
		Samples to Kymos	☐ Same dataloggers as shipment. ☐ Different from shipment. Dataloggers ref.:
		Samples to Airpharm	☐ Performed under transport responsibility of Qilu Pharma Spain. ☐ N/A
Deviations available, if any	☐ No deviation and/or OOS registered. ☐ Reference: Deviation reports are provided, reviewed and accepted.		
Temperature evaluation report	"Review of temperature data during transportation of finished product from Qilu Pharma Spain" available and approved by the MAH. ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. Based on Freeze-Thaw studies, the excursions do not have an impact on the quality of the batch stability.		
Comments	☐ N/A		
PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES			



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

	Route	Doc. reference	Received on	Units to be received	Units received	N/A	
Packing list	Shandong Anxin to Picking Pharma			CoC released qty.	☐ C ☐ NC	☐	
	Picking Pharma to Airpharm			☐ 260 vials ☐ 300 vials (ES market)	☐ C ☐ NC	☐	
	Picking Pharma to Kymos			☐ 130 vials ☐ 150 vials (ES market)	☐ C ☐ NC	☐	
	Shandong Anxin to Airpharm			CoC released qty. Including: ☐ 260 vials ☐ 300 vials (ES market)	☐ C ☐ NC	☐	
	Airpharm to Kymos			☐ 130 vials ☐ 150 vials (ES market)	☐ C ☐ NC	☐	
	Incoming inspection of goods into warehouse			Reception number: ☐ C ☐ NC, justify:			
Reference and retention samples location			Airpharm				
Comments			☐ N/A				
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	Name on the Marketing Authorization
	☐ IT	Piperacilina / Tazobactam Qilu 4g/0,5g polvere per soluzione per infusione
	☐ NO/DK	Piperacillin / Tazobactam Qilu 4g / 0,5g pulver til infusionsvæske, opløsning / pulver til infusionsvæske, opløsning
	☐ ES	Piperacilina/Tazobactam Qilu 4g/0.5g polvo para solución para perfusión EFG



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

	☐	HR/SI	Piperacilin/tazobaktam Qilu 4g/0,5g prašak za otopinu za infuziju/ prašek za raztopino za infundiranje
	☐	FR	Piperacilline/Tazobactam Qilu 4g/0,5g poudre pour solution pour perfusion
	☐	UK	Piperacillina/Tazobactam Qilu 4g/0,5g powder for solution for infusion
	☐	BG	Пиперациллин/Тазобактам Килу прах за инфузионен разтвор - Piperacillin / Tazobactam Qilu powder for solution for infusion 4g/0,5g
	☐	FI/SE	Piperacillin/Tazobactam Qilu 4g/0,5g pulver till infusionsvätska, lösning infuusiokuiva-aine, liuosta varten
	☐	CZ/SK	Refocil 4g/0,5g prášek pro infuzní roztok / prášok na infúzny roztok
	☐	LV/LT/EE	Piperacillin/Tazobactam Qilu 4g/0,5g milteilai infuziniam tirpalui / pulveris infūziju šķiduma pagatavošanai / infusioonilahuse pulber piperacillinum/tazobactamum
Destination country/ies		Market	Country
	☐	IT	Italy
	☐	NO/DK	Norway / Denmark
	☐	ES	Spain
	☐	HR/SI	Croatia / Slovenia
	☐	FR	France
	☐	UK	United Kingdom
	☐	BG	Bulgaria
	☐	FI/SE	Finland / Sweden
	☐	CZ/SK	Chzeck / Slovakia
☐	LV/LT/EE	Latvia / Lithuania / Estonia	
Marketing Authorization Number		Market	MA number
	☐	IT	DE/H/7113/002/DC-MCA/2021/105 (AIC: 050562091)
	☐	NO/DK	NO: 21-14089 / DK: 66246
	☐	ES	88989
	☐	HR/SI	HR: HR-H-878898010-03 / SI: H/24/03077/002
	☐	FR	34009 550 949 4 4
	☐	UK	PL 44570/0031
	☐	BG	62834
	☐	FI/SE	FI: 39496 / SE: 62145
	☐	CZ/SK	CZ: 15/304/22-C / SK: 15/0268/24-S
☐	LV/LT/EE	LV: 23-0080 / LT: LT/1/23/5185/003 / EE: 1110223	
Strength/Potency	☐	4g/0.5g	
Dosage form		Powder for solution for infusion	
Type and size of packaging	☐	10 vials/pack	☐ 50 vials/pack (ES market)
Batch number			



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

Quantity Released (packs)	Released by Qilu	QC testing in Kymos	Ref./Ret. samples in Airpharm	Other	Quantity Released
	-	☐ 130 vials ☐ 150 vials (ES market)	- ☐ 260 vials ☐ 300 vials (ES market)	-	=
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 Anxin Pharmaceutical Co., Ltd.		
		Address	No. 849, Dongjia Town, Licheng District, Jinan 250105, Shandong Province, China		
		Auth. No	Lu20160009		
		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		
Certification statement dully 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



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – PIPERACILLIN/TAZOBACTAM (WORKSHOP 2800)		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Piperacillin and Tazobactam powder for solution for infusion	

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☐ N/A

APPROVAL	
Performed by	Reviewed by