



KYMOS
GROUP

Document information	
Document code	C003-IG0004-m23e01
Document title	CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB

Approval panel	
Approval Type	Signature
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QA review / approval Gracia Piqueras <i>Deputy QP & QA</i>	

Last edition / Validity date	Description of changes
–	First edition

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

PRODUCT INFORMATION					
Company	Qilu Pharma Spain, S.L.				
Product trade name	Market	Name on the Marketing Authorization			
	☐ DE	Rimmyrah 10 mg/ml Injektionslösung			
	☐ DK/SE	Rimmyrah 10 mg/ml injektionsvæske, opløsning i fyldt injektionssprøjte/ injektionsväska, lösning			
	☐ ES	Rimmyrah 10 mg/ml solución inyectable			
	☐ ES/PT	Rimmyrah 10 mg/ml solución inyectable/ solução injetável			
	☐ FI/SE	Rimmyrah 10 mg/ml injektioneste, liuos/ injektionsväska, lösning			
	☐ FR	Rimmyrah 10 mg/ml solution injectable			
	☐ IT	Rimmyrah 10 mg/ml soluzione iniettabile			
	☐ LT/EE	Rimmyrah 10 mg/ml injekcinis tirpalas/ süstelahus			
	☐ LT/LV	Rimmyrah 10 mg/ml injekcinis tirpalas/ šķīdums injekcijām			
	☐ NO/SE	Rimmyrah 10 mg/ml injeksjonsvæske, oppløsning/ injektionsväska, lösning			
	☐ PL	Rimmyrah 10 mg/ml roztwór do wstrzykiwań			
	☐ UK	Rimmyrah 10 mg/ml solution for injection			
Batch number					
Manuf. date					
Expiry date		Approved shelf life	36 months		
Type of review	☐	Extensive review.			
	☐	Routine review, in accordance with RA_QAMPC_0326.			

MINIMUM DOCUMENTATION REQUIRED FOR THE REVIEW PROCESS	
- For Drug Substance (DS): - Fermentation process: - Batch Production Record (BPR). - Annexes to the BPR. - Environmental Monitoring, including microbe and particles monitoring. - Purification process: - Batch Production Record (BPR). - Annexes to the BPR. - Environmental Monitoring, including microbe and particles monitoring. - Certificates of Analysis (CoA) of key excipients: histidine hydrochloride, histidine, polysorbate 20 and trehalose. - Certificates of Analysis (CoA) of DS intermediates. - Certificates of Analysis (CoA) of DS. - Assessment report of DS. - Storage Temperature Record of DS. - Drug Product (DP) – bulk: - Batch Production Record (BPR), including Environmental Monitoring. - Analysis report: Bioburden. - Analysis report: Protein concentration. - Certificates of Analysis (CoA) of the packaging materials: glass vials, rubber stoppers and caps.	

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Customer	Product	Batch
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○ Assessment report of DP bulk. ○ Storage Temperature Record of DP. • Drug Product (DP) – packaging: ○ Batch Production Record (BPR). ○ Assessment report of DP packaging. ○ Storage Temperature Record of DP. • 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. ○ Storage Temperature Record on release day. • Commission of the batch and decommission of the QC samples (except from IT and UK). • 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					
MASTER AND WORKING CELL BANK					
Company: Qilu Pharmaceutical Co., Ltd.					
Address: No. 849, Dongjia Town, Licheng District, Jinan, 250105 Shandong Province, China					
Activity: MCB and WCB Manufacturing and Storage					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	N/A
	EU	ES/110HV/23	02/06/2023	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.	Audit date	Auditor	Comments
		AUD-4042	14-16/04/2025	Rephine.	None.
Dossier sections of 3.2.S. provided – current version.					
Comments					
DRUG SUBSTANCE MANUFACTURER					
Company: Qilu Pharmaceutical Co., Ltd. (Biological Industry Park)					
Address: 8888 Lvyou Road, High-Tech Zone, Jinan, Shandong, 250104, China					
Activity: DS Manufacturing and Storage / MCB and WCB Storage					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	N/A
	EU	ES/111HV/23	02/06/2023	3 years	Issued by AEMPS
	FDA	N/A	N/A	N/A	N/A
GMP audit		Audit ref.	Audit date	Auditor	Comments

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB					
Customer		Product		Batch	
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection			
(full audit report, updated CAPA plan, CV of the auditor available)		AUD-4042	14-16/04/2025	Rephine.	None.
Annual PQR for DS report updated and reviewed.		☐ Yes, detail breakdown per year: ☐ Pending to receive an update, explain:			
Dossier sections of 3.2.S. provided – current version.					
Comments					
FINISHED PRODUCT MANUFACTURER					
Company: Qilu Pharmaceutical Co., Ltd (Biological Industry Park) Address: 8888 Lvyou Road, High-Tech Zone, Jinan, Shandong, 250104, China. DUNS: 544532200. Activity: DP Manufacturing, Storage and Testing					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	None.
	EU	ES/111HV/23	02/06/2023	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.	Audit date	Auditor	Comments
		AUD-4042	14-16/04/2025	Rephine	None.
Periodic Aseptic Process Simulation Report (media fill) provided and reviewed.		☐ Updated report received. Report reference: Date of latest media fill: ☐ Pending to receive an update; requested.			
Annual PQR reports received and reviewed.		☐ Yes, see current <i>Review and Acceptance Form for PQRs C003-IG0004-m21</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 C003-IG0004-m22</i> approved on: ☐ Pending to receive an update, explain:			
Quality Technical Agreement in place			Rev.: 2.0, effective on 01/2025.		
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	

CHECKLIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS - RANIBIZUMAB		
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	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					

BATCH RECORDS REVIEW	
MASTER CELL BANK	☐ N/A
Master cell bank batch identification	
WORKING CELL BANK	☐ N/A
Working cell bank batch identification	
Batch manufacturing records edition	BPR-K-75-01-1.1
Vial identification (refer to Drug Substance BPR Primary Seed Expansion page 10/25)	
Certificate of Analysis (CoA) or equivalent document	Reference: Date of issuance:
Deviations and CAPA registered, and deviation reports provided. They are reviewed and accepted.	☐ No deviation or CAPA registered. ☐ Reference:

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Master batch record of the BMR approved.

DRUG SUBSTANCE

Drug Substance batch identification

DS was revised during the revision of:

☐

This batch.

☐

A previous batch, specify:

Flow chart for the manufacturing process of Drug Substance:

Fermentation process (upstream):

Thaw a vial of QL1205 WCB
↓
Primary seed expansion
500 mL shake flask (N-3)
↓
Secondary seed expansion
42 L fermenter (N-2)
↓
Tertiary seed expansion
450 L fermenter (N-1)
↓
Fermentation and Induced Expression
3000 L fermenter (N)
↓
Harvest and Protein Extraction

Purification process (downstream):

Cation Exchange Chromatography 1 (CEX1)
↓
Affinity Chromatography (AFC)
↓
Anion Exchange Chromatography (AEX)
↓
Cation Exchange Chromatography 2 (CEX2)
↓
Size exclusion chromatography (SEC)
↓
Formulation and filtration
↓
Drug Substance

Fermentation Process (Upstream)

Batch manufacturing record edition. Master batch record available.	Section	Code	Version
	Cover page	BPR-D02-0001-0	Version
	Fermentation material preparation	BPR-D02-0002-0	Version
	Primary Seed Expansion	BPR-D02-0003-0	Version
	Secondary Seed Expansion	BPR-D02-0004-0	Version
	Tertiary Seed Expansion	BPR-D02-0005-0	Version
	Feed tank preparation	BPR-D02-0006-0	Version
	Fermentation	BPR-D02-0007-0	Version
	Harvest and Protein Extract	BPR-D02-0008-0	Version
	Comments		

Batch Manufacturing Record and Critical Controls review

Instructions for Extensive review: This section highlights the most relevant parameters, KPPs, CPPs and IPCs for guidance; full compliance with all parameters registered in the CTD must be verified during the extensive 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. The parameters containing "□" in the NA column are designated solely for extensive review.

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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 (guidance)	Parameter /Process		Specification	CPP /IPC	Compliance		
						C	NC	NA
Fermentation material preparation	All section	Materials and equipment		Within their expiry/retest date and qualified.	-	☐	☐	☐
		Medium/solution preparation		The solutions comply with the Material Ratio registered in the CTD.	-	☐	☐	☐
Primary seed expansion (N-3)	All section	Raw materials and reagents		Within their expiry date.	-	☐	☐	☐
	12/25	WCB thawing time		≤ 60 min	-	☐	☐	-
	Annex 07-07	WCB thawing temp.		Room temperature (10 - 25 °C)	-	☐	☐	-
	13/25	WCB inoculum size		0.2% (200 µL)	-	☐	☐	☐
		WCB inoculation time (DD/MM HH:MM):						
	14/25	Shaker temperature		Set-point: 37 °C NOR/AOR: 37 ± 2 °C	-	☐	☐	☐
		Shaker speed		Set-point: 200 rpm NOR/AOR: 200 ± 10 rpm	-	☐	☐	☐
	17/25	Cell density (OD₆₀₀)		NOR: 1.0 to 3.0 AU AOR: 0.6 to 3.0 AU	IPC	☐	☐	-
	19/25	AMP solution preparation		Complies with the Material Ratio registered in the CTD.	-	☐	☐	☐
	CoA DS interm.	Culture purity	Gram staining	Show typical morphology of E. coli, absence of non-host cell.	IPC	☐	☐	-
Secondary seed expansion (N-2)	8/28+ Annex 03-02	Inlet and exhaust filters		Integrity test: Pass.	-	☐	☐	☐
	19/28	Aeration rate		Set-point: 20 L/min NOR/AOR: 20 ± 2 L/min	-	☐	☐	☐
	19/28+ Annex 03-05	Fermentor temperature		Set-point: 37.0 °C NOR/AOR: 37.0 ± 2 °C	-	☐	☐	☐
		Dissolved oxygen		Set-point: 45.0 NOR/AOR ≥ 20%	-	☐	☐	☐
	22/28	Cell density (OD₆₀₀)		NOR/AOR: 1.0 to 3.0 AU	IPC	☐	☐	-
	CoA DS interm.	Culture purity	Gram staining	Show typical morphology of E. coli, absence of non-host cell.	IPC	☐	☐	-
Tertiary seed expansion (N-1)	8/28+ Annex 03-02	Inlet and exhaust filters		Integrity test: Pass.	-	☐	☐	☐
	19/28	Aeration rate		Set-point: 220 L/min	-	☐	☐	☐

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB							
Customer		Product			Batch		
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection					

				NOR/AOR: 220 ± 20 L/min				
	19/28+ Annex 04-05	Fermentor temperature		Set-point: 37.0 °C NOR/AOR: 37.0 °C ± 2 °C	-	☐	☐	☐
		Dissolved oxygen		Set-point: 45.0 NOR/AOR ≥ 20%	-	☐	☐	☐
	22/28	<u>Cell density (OD₆₀₀)</u>		<u>NOR:1.0 - 3.0 AU</u> <u>AOR: 0.6 - 3.0 AU</u>	IPC	☐	☐	-
	CoA DS interm.	<u>Culture purity</u>	<u>Gram staining</u>	<u>Show typical morphology of E. coli, absence of non- host cell.</u>	IPC	☐	☐	-
Feed Tank Preparation	7/25+ Annex 05-02	Vent filters		Integrity test: Pass.	-	☐	☐	☐
Fermentation and Induced Expression	8/40+ Annex 06-02	Air inlet and exhaust filters		Integrity test: Pass.	-	☐	☐	☐
	21/40	Incubation temperature		Set-point: 37.0 °C NOR/AOR: 37.0 °C ± 2 °C	-	☐	☐	☐
		pH		Set-point: 7.0 NOR: 7.0 ± 0.2 AOR: 7.0 ± 0.4	KPP	☐	☐	☐
		Aeration rate		Set-point: 1000.0 - 36000.0 L/min NOR/AOR: 800.0 - 4000.0 L/min	-	☐	☐	☐
	26/40 + 36-39/ 40	<u>Feed flow rate for nitrogen source</u>		<u>Set-point: 10.5 L/h (8.3 mL/L/h).</u> <u>NOR: 8.4 to 12.6 L/h (8.3 ± 1.7 mL/L/h).</u> <u>AOR: 6.3 to 14.5 L/h (8.3 ± 3.3 mL/L/h).</u>	CPP	☐	☐	-
	27/40 + 36-39/ 40	Feed flow rate for carbon source		Set-point: 16.5 L/h (13.1 mL/L/h) NOR: 14.3 to 18.7 L/h (13.1 ± 1.8 mL/L/h) AOR: 11.9 to 20.9 L/h (13.1 ± 3.6 mL/L/h).	KPP	☐	☐	☐
	28/40 + 37-39/ 40	<u>Induction temperature</u> <u>(induction start: EFT 6 – 9 h, usually coinciding with a rapid DO increase)</u>		<u>Set-point: 25 °C.</u> <u>NOR/AOR: 25 ± 4 °C.</u>	CPP	☐	☐	-
	31/40 + 36-39/ 40	<u>Dissolved oxygen</u>		<u>Set-point: 45%</u> <u>NOR: The duration for dissolved oxygen to be less than 20% is NMT 2.5h.</u>	CPP	☐	☐	-

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Customer		Product		Batch
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection		

	+ Annex 06-05			<u>AOR: The duration for dissolved oxygen to be less than 20% is NMT 2.5h.</u>				
	31/40+ Annex 06-02	Air inlet filter		Integrity test: Pass.	-	☐	☐	☐
	CoA DS interm.	<u>Culture purity</u>	<u>Gram staining</u>	<u>Show typical morphology of E. coli, absence of non- host cell.</u>	IPC	☐	☐	-
			<u>Differential agar plates</u>	<u>Show no evidence of contaminating organisms.</u>	IPC	☐	☐	-
Harvest and Protein Extraction	30/52	pH adjustment of cell breaking liquid		Set-point: 4.4 NOR: 4.3 to 4.5 AOR: 4.2 to4.5	KPP	☐	☐	☐
	31/52	Heating temperature of cell breaking liquid		Set-point: 50 °C NOR: 50 ± 2 °C AOR: 50 ± 5 °C	KPP	☐	☐	☐
	Annex 07-06+ CoA DS interm.	<u>Target Protein expression level</u>		<u>≥ 10 mg/L fermentation broth</u>	IPC	☐	☐	-
	Annex 07-07	Trend of room temperature		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. 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 <u>WCB inoculation time</u>).	Monitoring of microbes is available and within the acceptance criteria.	Surface microbe	☐	☐	-		
			Settling microbe	☐	☐	-		
			Airborne microbe	☐	☐	-		
			Personnel	☐	☐	-		
		Monitoring of non-viable airborne particles is available and within the acceptance criteria.		☐	☐	-		
Comments								
Purification Process (Downstream)								
Batch manufacturing record edition. Master batch record available.		Section			Code	Version		
		Cover page			BPR-D02-0001-0			
		Buffer preparation			BPR-D02-0009-0			
		Cation exchange chromatography 1			BPR-D02-0010-0			
		Affinity chromatography			BPR-D02-0011-0			

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

	Anion exchange chromatography	BPR-D02-0012-0
	Cation exchange chromatography 2	BPR-D02-0013-0
	Size Exclusion chromatography	BPR-D02-0014-0
	Formulation and filtration	BPR-D02-0015-0
	Comments	

Key Excipients

Excipient	Batch No.	CoA number	Specifications reference	Identified and traceable in BR	NA
Histidine			QS-330300008114-3.0	☐	-
				☐	☐
Histidine Hydrochloride			QS-330300015603-3.0	☐	-
				☐	☐
Polysorbate 20			QS-310900012446-3.0	☐	-
				☐	☐
Trehalose			QS-311600004316-2.0	☐	-
				☐	☐

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Step	Page (guidance)	Parameter /Process	Specification	CPP /IPC	Compliance		
					C	NC	NA
Cover page	4/6	Batch size	1.47 L – 3.93 L (1.52 kg – 4.07 kg)	-	☐	☐	☐
		Manuf. date	(DD/MM/YYYY):				
		Expiry date	(DD/MM/YYYY):				
		Shelf-life	Expiry date in accordance with approved shelf life: 24 months (at -20 °C ± 5 °C)	-	☐	☐	-
Buffer preparation	All section	Materials and equipment	Within their expiry/retest date and qualified.	-	☐	☐	☐
		Buffer preparation	The buffers comply with the Content registered in the CTD.	-	☐	☐	☐
	4/120	Key excipients batch No.	The recorded batch No. correspond to the batch No. in the provided CoA.	-	☐	☐	-

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	Annex 08-04	Key excipients CoA		Parameters compliance and CoA approval verified.	-	☐	☐	-
Cation Exchange Chromatography 1 (CEX1)	All section	Materials and equipment		Within their expiry/retest date and qualified.	-	☐	☐	☐
		Raw materials and reagents		Within their expiry date.	-	☐	☐	☐
	16/53 28/53	Equilibration	Conductivity	Set-point: 1.5 mS/cm NOR/AOR: 1.5 ± 0.3 mS/cm	KPP	☐	☐	☐
	20/53 31/53	Load	Load capacity	Set-point: N/A NOR/AOR: 0.6 - 2.0 g/L*r	KPP	☐	☐	☐
	22/53 33/53 + Annex 09-01	Elution	Starting point (A ₂₈₀)	Set-point: 0.28 AU/cm (0.14 AU for 0.5 cm) NOR/AOR: 0.17-0.40 AU/cm (0.085-0.20 AU for 0.5 cm)	KPP	☐	☐	-
			Ending point (A ₂₈₀)	Set-point: 0.20 AU/cm (0.10 AU for 0.5 cm) NOR/AOR: 0.19-0.40 AU/cm (0.095-0.20 AU for 0.5 cm)	KPP	☐	☐	-
	CoA DS interm.	SE-HPLC Purity		Monomer ≥ 98.0%	IPC	☐	☐	-
		Microbial Contam.	Bioburden	≤1000 CFU/10mL	IPC	☐	☐	-
Affinity Chromatography (AFC)	21-23 /62	Equilibration	pH	Set-point: 7.0 NOR/AOR: 7.0 ± 0.2	KPP	☐	☐	☐
	27/62 29/62 32/62	Load	Load capacity	Set-point: N/A NOR: 1.0 - 3.0 g/L*r AOR: 0.5 - 3.0 g/L*r	KPP	☐	☐	☐
	35-37 /62 + Annex 10-02	Elution	Starting point (A ₂₈₀)	Set-point: 0.1 AU/cm (0.05 AU for 0.5 cm) NOR/AOR: ≥ 0.1 AU/cm (≥ 0.05 AU/cm for 0.5 cm)	-	☐	☐	-
			Ending point (A ₂₈₀)	Set-point: 0.1 AU/cm (0.05 AU for 0.5 cm) NOR/AOR: ≥ 0.1 AU/cm (≥ 0.05 AU/cm for 0.5 cm)	-	☐	☐	-
	39-41 /62		pH adjustment	Set-point : 5.5 NOR/AOR : 5.5 ± 0.5	-	☐	☐	☐
	44/62	Filtration	Filtration capacity	Set-point: N/A NOR/AOR: ≤ 600 g/m ²	-	☐	☐	☐
	CoA DS interm.	Microbial Contam.	Bioburden	≤1000 CFU/10mL	IPC	☐	☐	-
		Residual protein G		≤ 30 ng/mg	IPC	☐	☐	-
	5/42		pH	Set-point: 8.25	CPP	☐	☐	-

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB								
Customer			Product			Batch		
Qilu Pharma Spain, S.L.			Ranibizumab solution for injection					

Anion Exchange Chromatography (AEX)		Elution: 20 mmol/L Tris-HCl	Conductivity	NOR/AOR: 8.25±0.15 Set-point: N/A NOR: 0.7-1.0 mS/cm AOR: 0.7-1.1 mS/cm	CPP	☐	☐	-
	19/42	Loading	pH	Set-point: 9.0 NOR/AOR: 9.0 ± 0.2	KPP	☐	☐	☐
	20/42		Load capacity	Set-point: N/A NOR/AOR: 1.4 - 7.0 g/L*r	KPP	☐	☐	☐
	22/42 + Annex 11-02	Elution	Starting point (A ₂₈₀)	Set-point: 0.725 AU/cm (0.3625 AU for 0.5 cm) NOR/AOR: 0.10-1.35 AU/cm (0.05-0.675 AU for 0.5 cm)	KPP	☐	☐	-
			Ending point (A ₂₈₀)	Set-point: 0.215 AU/cm (0.1075 AU for 0.5 cm) NOR/AOR: 0.16-0.27 AU/cm (0.08-0.135 AU for 0.5 cm)	KPP	☐	☐	-
	24/42		pH adjustment	Set-point : 5.5 NOR/AOR : 5.5 ± 0.2	-	☐	☐	☐
	27/42	Filtration	Filtration capacity	Set-point: N/A NOR/AOR: ≤ 600 g/m ²	-	☐	☐	☐
	CoA DS interm.	Microbial Contam.	Bioburden	≤ 200 CFU/10mL	IPC	☐	☐	-
			Endotoxin	< 0.2 EU/mg protein	IPC	☐	☐	-
Cation Exchange Chromatography 2 (CEX2)	18/41	Loading	pH	Set-point: 5.5 NOR: 5.3-5.7 AOR: 5.1-5.9	CPP	☐	☐	-
	19/41		Load capacity	Set-point: N/A NOR/AOR: 9 - 40 g/L*r	KPP	☐	☐	☐
	20/41 22/41	Washing 2	Washing volume (CV)	Set-point: Y* NOR and AOR: Y*±0.5	CPP	☐	☐	-
		*Y= -0.2258X+12.032, Y: washing volume (CV); X: loading capacity (g/L*r)						
	22/41	Washing 1	Washing volume	Set-point: 3.3 CV NOR: 3.2 – 3.4 CV AOR: 3.2 – 3.5 CV	KPP	☐	☐	☐
	23/41+ Annex 12-01	Elution	Starting point (A ₂₈₀)	Set-point: 2.0 AU/cm (1.0 AU for 0.5 cm) NOR/AOR: ≥ 2.0 AU/cm (≥ 1.0 AU for 0.5 cm)	KPP	☐	☐	-
			Ending point (A₂₈₀)	Set-point: 75% PV NOR: ≥40% PV AOR: ≥25% PV	CPP	☐	☐	-
	CoA DS interm.	Microbial Contam.	Bioburden	≤ 200 CFU/10mL	IPC	☐	☐	-
			IE-HPLC purity	Main peak ≥96.8% Acidic peaks ≤ 1.4% Basic Peaks ≤ 2.3%	IPC	☐	☐	-

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB								
Customer			Product			Batch		
Qilu Pharma Spain, S.L.			Ranibizumab solution for injection					

Size Exclusion Chromatography (SEC)	18/36	<u>Loading</u>	<u>Load capacity</u>	<u>Set-point: N/A</u> <u>NOR: 15%-30% CV</u> <u>AOR: 10%-35% CV</u>	CPP	☐	☐	-
	20/36 + Annex 13-01	Elution	Starting point (A ₂₈₀)	Set-point: 4.4 AU/cm (2.2 AU for 0.5 cm) NOR/AOR: 3.7 – 5.1 AU/cm (1.85-2.55 AU for 0.5 cm)	KPP	☐	☐	-
			Ending point (A ₂₈₀)	Set-point: 4.4 AU/cm (2.2 AU for 0.5 cm) NOR/AOR: 3.7 – 5.1 AU/cm (1.85-2.55 AU for 0.5 cm)	KPP	☐	☐	-
	Annex 13-04+ CoA DS interm	<u>Protein concentration (UV)</u>		<u>≥ 12 mg/mL</u>	IPC	☐	☐	-
	CoA DS interm.	<u>Microbial Contam.</u>	<u>Bioburden</u>	<u>≤ 200 CFU/10mL</u>	IPC	☐	☐	-
Bulk drug substance preparation	14/27	Mixing time		Set-point: N/A NOR/AOR: ≥ 5 min	KPP	☐	☐	☐
	15/27	Filtration capacity		Set-point: N/A NOR/AOR: ≤ 4200 g/m ²	KPP	☐	☐	☐
	17/27	Filtration flow rate		Set-point: 200 mL/min NOR/AOR: 200 ± 50 mL/min	KPP	☐	☐	☐
	19/27	Filtration period		(DD/MM/YYYY HH:MM – HH:MM)				
	20/27	Net Weight of DS		Complies with the registered batch size: 1.52 kg – 4.07 kg	-	☐	☐	☐
	Annex 14-03			Weight ticket reviewed and compliant.	-	☐	☐	-
	21/27	Storage conditions		☐ 2 – 8 °C for no more than 7 days ☐ - 20 °C and below for up to 24 months				
	22/27 + Annex 14-03	<u>Filter Integrity Test</u>		<u>Bubble point ≥ 50 psi</u> (For filter SN, see page 6/27)	IPC	☐	☐	-
Annex 14-05	Temperature		Room temperature (10-25 °C)	-	☐	☐	☐	
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					☐	☐	-

CHECKLIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

Supporting documentation	Environmental monitoring records <i>(Traceability through filtration period).</i>	Monitoring of microbes is available and within the acceptance criteria.	Surface microbe	☐	☐	-
			Settling microbe	☐	☐	-
			Airborne microbe	☐	☐	-
			Personnel	☐	☐	-
	Assessment report of Drug Substance	Monitoring of non-viable airborne particles is available and within the acceptance criteria.		☐	☐	-
		Manufacturing process Deviations, CAPA and Change Controls (Ref. No.) and Comments:				
	Storage temperature record of DS	The record covers the storage period of the DS (from end of DS filtration to start of DP bulk manufacturing).		☐	☐	-
		Temperature remains within 2 – 8 °C and/or within -20 – -40 °C. Any excursions are properly justified.		☐	☐	-

Comments

Certificate of analysis (CoA) of Drug Substance

CoA reference number	
Specification number	QS-210500016002-4.0

Analytical parameters, specifications and analytical methods according to CTD and Marketing authorization

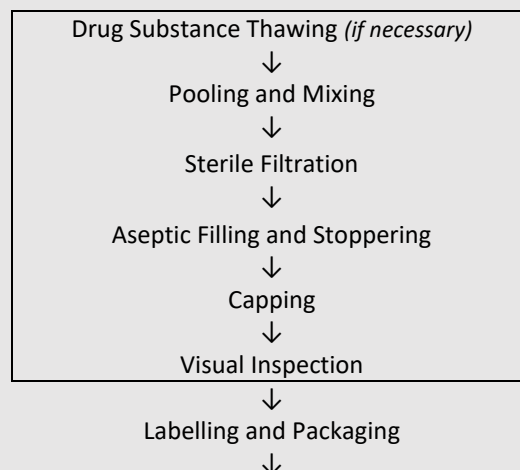
Deviations and OOS reference available, if any	☐ No deviation and/or OOS registered.
	☐ Reference:

Results: complies.

DRUG PRODUCT - BULK

DP Bulk batch identification	
DP Bulk was revised during the revision of:	☐ This batch. ☐ A previous batch, specify:

Flow chart for the manufacturing process of Drug Product:



CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

Drug Product Storage								
Batch manufacturing record edition. Master batch record available.	Section		Code	Version				
	Cover page		BPR-D03-0006-0					
	List of production equipment, Material and formulation		BPR-D03-0006-0-01					
	Cleaning and sterilization of vials		BPR-D03-0006-0-03					
	Formulation and filtration		BPR-D03-0006-0-04					
	Filling and stoppering		BPR-D03-0006-0-05					
	Capping		BPR-D03-0006-0-06					
	Visual Inspection		BPR-D03-0006-0-07					
	Preparation		BPR-D03-0006-0-02					
	Material reconciliation		BPR-D03-0006-0-08					
	Comments							

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. The parameters containing “□” in the NA column are designated solely for extensive review.

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
Cover page	1/3	Batch size	7 000 to 10 000 vials	-	☐	☐	☐
		Manuf. date	(DD/MM/YYYY):				
		Expiry date	(DD/MM/YYYY):				
		Shelf-life	36 months at 2-8 °C	-	☐	☐	-
Cleaning and sterilization of vials	5/21	Batch No. vials	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
	15/21	Sterilization/ depyrogenation	Vials are sterilized/depyrogenated by dry heat.	-	☐	☐	☐
Drug Substance Thawing	4/21	Batch No. DS	The recorded batch No. corresponds to the batch No. of the DS.	-	☐	☐	-
	Storage T record of DS	DS thawing temperature	2 – 8 °C	KPP	☐	☐	☐
		DS thawing time	4 – 6 days	KPP	☐	☐	☐
		6/21	Hold time for thawed DS	≤ 5 days at 2 – 8 °C	-	☐	☐
Pooling and mixing	10/21	Mixing speed	100 – 200 rpm	KPP	☐	☐	☐
		Mixing time	5 – 10 min	KPP	☐	☐	☐
	11/21	pH	5.2 to 5.8	IPC	☐	☐	-
	Analysis report		Bioburden	≤10 cfu/100 mL	IPC	☐	☐

CHECKLIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS - RANIBIZUMAB							
Customer		Product			Batch		
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection					

	Analysis report	<u>Protein concentration</u>	<u>9.0 to 11.0 mg/mL</u>	IPC	☐	☐	-	
Sterile Filtration	14/21	Filtration speed	≤ 250 mL/min	KPP	☐	☐	☐	
		Filtration time	≤ 6 h (from opening of DS (page 9/21) to end of sterile filtration)	KPP	☐	☐	☐	
	15/21 + Annex 04-03	<u>Filter integrity testing (primary and secondary filters)</u>	<u>Post-filtration: ≥50 psi (water bubble point)</u>	CPP IPC	☐	☐	-	
	Bulk CoA	<u>Protein concentration</u>	<u>9.0 to 11.0 mg/mL</u>	IPC	☐	☐	-	
		<u>Endotoxin</u>	<u>< 0.2 EU/mg protein</u>	IPC	☐	☐	-	
		<u>Sterility</u>	<u>Sterile</u>	IPC	☐	☐	-	
Aseptic Filling and Stoppering	8/41	Stoppers sterilization	Sterilization is within expiry period: 48h at room temperature.	-	☐	☐	☐	
	19/41	Filling pump speed	1000 – 3000 rpm	KPP	☐	☐	☐	
	19/41 + 22/41	<u>Filling amount</u>	<u>Set-point: 270 mg NOR/AOR: 250 – 290 mg</u>	CPP	☐	☐	-	
	21/41	Filling speed	150 - 400 vials/min	-	☐	☐	☐	
	23/41	Hold times	From beginning of filling to end of filling: ≤ 8 h (480 min).	-	☐	☐	☐	
			From end of sterile filtration to end of filling: ≤ 12 h (720 min).	-	☐	☐	☐	
		Filling period	(DD/MM/YYYY, HH:MM – HH:MM):					
	27/41	Filling qualified quantity:						
	Att. 05-02	Environmental monitoring records	Monitoring of microbes within the acceptance criteria.	Surface microbe	-	☐	☐	-
				Settling microbe	-	☐	☐	-
				Airborne microbe	-	☐	☐	-
				Personnel	-	☐	☐	-
	Att. 05-02+ 05-03	(Traceability through filling period).	Monitoring of non-viable airborne particles within the acceptance criteria.	-	☐	☐	-	
	Att. 05-05	<u>Periodical weight check (once an hour)</u>	<u>0.24 to 0.28 mL</u>	IPC	☐	☐	-	
	Att. 05-07	Temperature	10 – 25 °C	-	☐	☐	☐	
Capping	5/24	Batch No. caps	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-	
	9/24	Capping pressure	Set-point: 300 kPa NOR/AOR: 110 – 320 kPa	KPP	☐	☐	☐	
	10/24	Capping speed	150 – 300 vials/min	-	☐	☐	☐	

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB							
Customer		Product		Batch			
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection					
	11-12 /24	Periodical tightness check (once an hour)	Tightness check qualified rate 100%.	IPC	☐	☐	-
	15/24	The qty. received is consistent with the qualified qty. from the previous step. Capping qualified quantity:		-	☐	☐	-
	Att. 06-04	Temperature	10 – 25 °C	-	☐	☐	☐
	Att. 06-05	Fine leak test	Results are qualified.	-	☐	☐	-
Visual inspection	7/33	Sampling quantity:					
	11/33	VI date	(DD/MM/YYYY):				
	12/33	Total rejected quantity:					
	12-14 /33	100% Visual Inspection, AQL Testing	No defects observed including visible foreign matters, defect seals, vial defects, abnormal filling volume defect, etc.	IPC	☐	☐	-
	17/33	Quantity to warehouse: Must match: Capping qualified qty. (15/24) – VI sampling qty. (7/33) – VI rejected qty. (12/33)					
	Att. 07-01	Temperature	10 – 25 °C	-	☐	☐	☐
	Att. 07-02	Light intensity	2000 – 3000 lx	-	☐	☐	-
Preparation	14/39 + Annex 02-01	Filter integrity testing (primary and secondary filters)	Pre-filtration: ≥50 psi (water bubble point).	CPP IPC	☐	☐	-
	28/39	Batch No. stoppers	The recorded batch No. corresponds to the batch No. in the provided CoA.	-	☐	☐	-
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	Assessment report of Drug Product - Bulk	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.) and Comments:					
	Storage temperature record of DP Bulk	The records cover the storage period of the DP Bulk (from end of DP bulk visual inspection to start of DP packaging).			☐	☐	-
		Temperature remains within 2 – 8 °C. Any excursions are properly justified.			☐	☐	-
Comments							

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

DRUG PRODUCT - PACKAGING							
Packaging batch identification							
Flow chart for the manufacturing process of Drug Product: <pre> graph TD A[Drug Substance Thawing (if necessary)] --> B[Pooling and Mixing] B --> C[Sterile Filtration] C --> D[Aseptic Filling and Stoppering] D --> E[Capping] E --> F[Visual Inspection] F --> G[Labelling and Packaging] G --> H[Drug Product Storage] </pre>							
Batch manufacturing record edition. Master batch record available.	Section	Code		Version			
	Packaging	BPR-D03-0006-1-09					
	Comments						
Batch Manufacturing Record and Critical Controls review Instructions for Routine review: No CPPs nor IPCs are defined for packaging. The parameters containing "□" in the NA column are designated solely for extensive review. <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		
Cover page	N/A	Manuf. date	(DD/MM/YYYY):				
Packaging	1/46	Disposable filter needle	Batch No.:				
			(For expiry calculation)				
		DP Expiry date	Expiry (DD/MM/YYYY):				
			(DD/MM/YYYY):				
		Corresponds to the expiry date of: (earliest date)	☐ DP bulk ☐ Disposable filter needle				
	DP Shelf-life	36 months at 2-8 °C	-	☐	☐	-	
	Incoming vials	Single packaging: Matches the DP-bulk qty. for warehouse. Multiple packaging: The total of all packaging operations matches DP-bulk qty. for warehouse.	-	☐	☐	-	
	5/46	Batch No.					

CHECKLIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS - RANIBIZUMAB						
Customer		Product			Batch	
Qilu Pharma Spain, S.L.		Ranibizumab solution for injection				

		Disposable filter needle	The recorded batch No./Nos. correspond to the batch No. in the provided CoA.	-	☐	☐	-
6/46 21/46		Temperature	10 – 28 °C	-	☐	☐	☐
7/46 22/46		Packaging date	(DD/MM/YYYY):				
15/46 30/46		QA sampling quantity:					
18/46 33/46		Unqualified quantity:					
N/A		Qualified quantity	Calculation: Incoming vials – sampling quantity (only retention samples) – unqualified vials.				
44-45 /46	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. (SN and Data Matrix N/A for UK and IT).		-	☐	☐	-
	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.		-	☐	☐	-
	Leaflet contents	Copy endorsed in the BPR.		-	☐	☐	-
		Name of the product, strength and dosage form follow the CTD and MA.		-	☐	☐	-
	Artwork verification	The label, carton and leaflet artworks correspond to the currently approved artworks (according to the table below).		-	☐	☐	-
Market		Label	Carton	Leaflet			
☐	DE	34040137204A	34040137201A	34040137211A			
☐	DK/SE	34040148504A	34040148501A	34040148511B			
☐	ES	34040137504A	34040137501A	34040137511A			
☐	ES/PT	34040149304A	34040149301A	34040149311A			
☐	FI/SE	34040148404A	34040148401A	34040148411B			
☐	FR	34040137404A	34040137401A	34040137411A			
☐	IT	34040137704A	34040137701A	34040137711A			
☐	LT/EE	34040161204A	34040161201A	34040161211A			

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

☐	LT/LV	34040161104A	34040161101A	34040161111A
☐	NO/SE	34040150304A	34040150301A	34040150311A
☐	PL	34040137304A	34040137301A	34040137311A
☐	UK	34040137104A	34040137101B	34040137111B

Supporting documentation	Assessment report of Finished Drug Product	Manufacturing process Deviations, CAPA and Change Controls (Ref. No.):			
	Storage temperature record of Finished DP	The record covers the storage period of the Finished DP (from end of DP packaging to shipping date).	☐	☐	-
		Temperature remains within 2 – 8 °C. Any excursions are properly justified.	☐	☐	-

Comments

CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER

CoA reference number	
Specification number	QS-100300044004-9.0
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 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 KYMOS

CoA reference number	
Deviations and OOS reference available, if any	☐ No deviation and/or OOS registered. ☐ Reference:

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

Results: complies.

TRANSPORT AND STORAGE CONDITIONS								
Storage and transport conditions		2 – 8 °C						
Transport route and Data logger ID	Route	☐ Qilu Pharmaceutical Biological Industry Park (China) > Picking Pharma (Spain) > Samples: Kymos and Airpharm. ☐ Qilu Pharmaceutical Biological Industry Park > 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 with refrigerated transport. ☐ 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 (ref. PSV-100300044001-(R)-210208C+J+Y), the excursions do not have an impact on the quality of the batch stability. ☐						
Storage conditions for EU warehouse		The product has been stored in accordance with the approved storage conditions (2–8 °C) from receipt at the EU warehouse until the date of batch release. Supported by: ☐ Storage temperature records from the EU warehouse. ☐ Storage statement signed by MAH.						
Comments								
PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES								
Packing list	Route	Doc. reference	Dispatched on	Received on	Units to be received	Units received		N/A
	Qilu Pharm. to Picking Pharma				CoC released qty.	☐ C ☐ NC		☐
	Picking Pharma to Airpharm				☐ 375 vials ☐ Other:	☐ C ☐ NC		☐
	Picking Pharma to Kymos				☐ 213 vials ☐ Other:	☐ C ☐ NC		☐

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

	Qilu Pharm to Airpharm				CoC released qty.	☐	C	☐	
	Airpharm to Kymos				☐ 213 vials ☐ Other:	☐	NC 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	Name on the Marketing Authorization
	☐ DE	Rimmyrah 10 mg/ml Injektionslösung
	☐ DK/SE	Rimmyrah 10 mg/ml injektionsvæske, opløsning i fyldt injektionssprøjte/ injektionsvätska, lösning
	☐ ES	Rimmyrah 10 mg/ml solución inyectable
	☐ ES/PT	Rimmyrah 10 mg/ml solución inyectable/ solução injetável
	☐ FI/SE	Rimmyrah 10 mg/ml injektioneste, liuos/ injektionsvätska, lösning
	☐ FR	Rimmyrah 10 mg/ml solution injectable
	☐ IT	Rimmyrah 10 mg/ml soluzione iniettabile
	☐ LT/EE	Rimmyrah 10 mg/ml injekcinis tirpalas/ süstelahus
	☐ LT/LV	Rimmyrah 10 mg/ml injekcinis tirpalas/ šķīdums injekcijām
	☐ NO/SE	Rimmyrah 10 mg/ml injeksjonsvæske, oppløsning/ injektionsvätska, lösning
	☐ PL	Rimmyrah 10 mg/ml roztwór do wstrzykiwań
	☐ UK	Rimmyrah 10 mg/ml solution for injection
Destination country/ies	☐	Germany (DE)
	☐	Denmark (DK), Sweden (SE)
	☐	Spain (ES)
	☐	Spain (ES), Portugal (PT)
	☐	Finland (FI) and Sweden (SE)
	☐	France (FR)
	☐	Italy (IT)

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

	☐	Lithuania (LT), Estonia (EE)	
	☐	Lithuania (LT), Latvia (LV)	
	☐	Norway (NO), Sweden (SE)	
	☐	Poland (PL)	
	☐	United Kingdom (UK)	
Marketing Authorization Number	Market MA number		
	☐	EU EU/1/23/1779/002	
	☐	UK PLGB 44570/0033	
Strength/Potency	☐	10 mg/ml	
Dosage form	Solution for injection		
Type and size of packaging	☐	1 carton containing 1 vial of 0.23 ml and 1 needle with filter	
Batch number			
Quantity Released	Released by Qilu	QC testing in Kymos	
		Ref./Ret. samples in Airpharm	
		Other	
	- ☐ 213 vials	- ☐ 375 vials	
	- ☐ Other:	- ☐ Other:	
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 Pharmaceutical Co., Ltd.
		Address	8888 Lvyou Road, High Tech Zone, Jinan, Shandong, 250104, China
		Auth. No	Lu20160001
		Activity	Storage Working Cell Bank, Manufacturing Drug Substance, Quality Control Drug Substance, Manufacturing Drug Product, Quality Control Drug Product, Packaging
	Site 2	Name	Qilu Pharmaceutical Co., Ltd.
		Address	No 849, Dongjia Town, Licheng District, Jinan, Shandong, 250105, China
		Auth. No	Lu20160001
		Activity	Manufacturing Working Cell Bank, Quality Control MCB, Quality Control Working Cell Bank, Storage Working Cell Bank, Quality Control Drug Product
	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.

CHECKLIST FOR BATCH RELEASE OF MARKETING BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

	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:				
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				

CHECKLIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS - RANIBIZUMAB		
Customer	Product	Batch
Qilu Pharma Spain, S.L.	Ranibizumab solution for injection	

APPROVAL	
Performed by	Reviewed by