

CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
Customer	Product	Batch
Celltrion, Inc.	CT-P39 fDP	

PRODUCT INFORMATION			
Company	CELLTRION Inc		
Product	☐ Omalizumab 75mg Drug Product ☐ Omalizumab 150mg Drug Product		
Dosage form	☐ Autoinjector ☐ Pre-filled syringe		
Batch number			
Manuf. date			
Expiry date		Approved shelf life	24 months

MANUFACTURER AND PRODUCT FILE						
FINISHED PRODUCT MANUFACTURER						
☐ N/A	Company: Celltrion Pharm, Inc Address: 82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea Activity: Finished product manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments	
	Local	2024-G1-2178	11/12/2024	N/A	None	
	EU	33842	20/06/2025	3 years	Issued by Authority of Ireland	
	FDA	3012279978	23/07/2024	N/A	None	
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor		Comments
		91343	28-30/04/2025	Jin Kyu Suk Soo Ji Lee Sue Young Jang Jung Won Seo Min Young Seo Hye Lee Son Se Chan Son Young Min Kim Won Joon Kim		The full audit report is available in Korean. English version requested.
Annual PQR reports received and reviewed.			☐ Yes ☐ No, explain:			
On-Going Stabilities results updated and reviewed. All results are within the registered specifications (at least 1 batch/dose/year)			☐ Updated on-going stability received. ☐ Pending to receive an update; requested.			
Quality Technical Agreement in place			QAG-23-004 Version 4.0, effective on 06/2025.			
Current dossier sections of 3.2.P. provided – current version.						

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Comments					
☐ N/A	Company: Egis Gyógyszergyár Zrt. Address: Bökényföldi út 118-120, Budapest, 1165, Hungary Activity: Finished product manufacturer				
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	Same as EU
	EU	NNGYK/23268-8/2025	20/03/2025	3 years	Issued by National Centre for Public Health and Pharmacy
	FDA	3002806880	06/08/2018	N/A	N/A
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)		Audit ref.	Inspection date	Auditor	Comments
		94269	14-15/05/2025	Véronique PAGE Fanny GERVAISE JungYoon Kim JangKyung Kim	None.
Annual PQR reports received and reviewed.			☐ Yes ☐ No, explain:		
On-Going Stabilities results updated and reviewed. All results are within the registered specifications (at least 1 batch/dose/year)			☐ Updated on-going stability received. ☐ Pending to receive an update; requested.		
Quality Technical Agreement in place			Version 1.0, effective on 12/2025.		
Current dossier sections of 3.2.P. provided – current version.					
Comments					

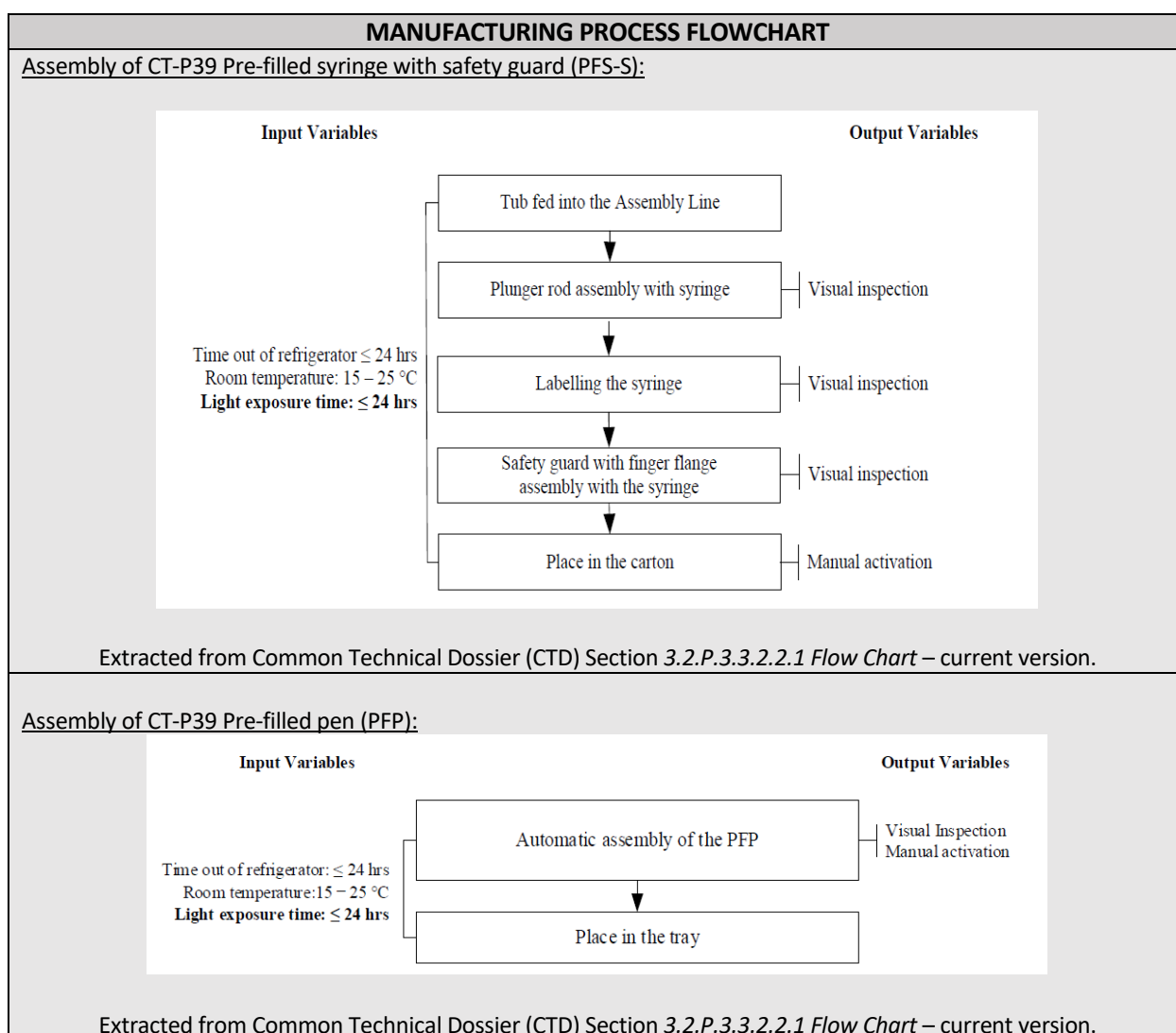
SUBCONTRACTORS					
☐ N/A	Company: Celltrion Healthcare Hungary Address: 2040 Budaörs, Vasut utca 13, Bet Pharma Kft. Activity: Physical importer				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	OGYÉI/66907-7/2023	13/11/2023	N/A	
	GDP	NNGYK/GYSZ/22722-8/2024	07/05/2024	N/A	
	WDA	HU-D-CELL	N/A	N/A	
	MIA	HU-M-CELL	N/A	N/A	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments

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	A/25.005	16/05/2025	Véronique Page Fanny Gervaise JungYoon Kim Jangkyung Kim	3 major 7 minor 4 comments	None.
☐ N/A	Company: Oktal Pharma d.o.o. Address: Utinjska ulica 40, 10020 Zagreb, Croatia Activity: Physical importer				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	UP/I-530-01/25-25/14; 381-13-08/256-25-04	27/06/2025	Updated requested	
	GDP	534-08-2/2-19-06	09/08/2019 (5 years)	Celltrion confirmed that Oktal had inspection from Ministry of Health in January 2025 and the new GDP certificate is still on-going. When they receive it, they will provide as requested.	
	WDA	UP/I-530-01/14-01/14	N/A	N/A	
	MIA	UP/I-530-01/13-03/13	N/A	N/A	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	92723				Pending to receive full report audit.
☐ N/A	Company: Brocacef Healthcare Logistics B.V. Address: Frankeneng 18 A, Ede Gld, 6716 AA, Netherlands Activity: Physical importer				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	NL/H 24/2053850	23/10/2024	N/A	
	GDP	NL/G 25/2053850	23/10/2024	N/A	
	WDA	4478G	11/07/2023	N/A	
	MIA	15196 F	N/A	N/A	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments

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	N/A	N/A	N/A	N/A	No audit is carried out according to Celltrion's SOP since this site is classified as non-critical and it is qualified based on a quality questionnaire approved on 16.06.2025 PR ID:93301.
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GENEALOGY
BATCH MANUFACTURING RECORD OF DRUG SUBSTANCE

CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
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Batch identification	Deviations reference	Certificate of Compliance	Company certifying DS	N/A
				-
				☐
				☐
				☐
				☐
				☐
				☐

BATCH MANUFACTURING RECORD OF uDP

Batch identification	Deviations reference	Certificate of Compliance	Company certifying uDP

BATCH MANUFACTURING RECORD OF aDP

☐ N/A, it is PFS

Batch identification	Deviations reference	Certificate of Compliance	Company certifying aDP

BATCH PACKAGING RECORDS OF MARKETED FINISHED PRODUCT

Batch identification	5M5P08S51		
Batch manufacturing record edition. Master batch record approved and batch size is reviewed and in accordance with the CTD (3.2.P) and Marketing Authorization.	☐ Manual Labelling Process: ☐ Assembly and Packaging Process: ☐ Outer cartooning Process: ☐ Manual Packaging process: ☐ Packaging process: ☐ De-packaging: ☐ Re-packaging:		
	Comments	N/A	

Batch Manufacturing Record and Critical Controls review (Critical Process Parameters are indicated with ***bold, underlined and italic*** format.)

Step	Parameter /Process	Specification	Compliance	
			C	NC
Step	Manuf. date	03/03/2025		
	Expiry date	28/02/2027		
	Shelf-life	Expiry date in accordance with approved shelf life: 24 months	☐	☐

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Manual Labelling Process ☐ N/A	<u>Temperature</u>	15-25 °C	☐	☐
	Humidity	≤ 65 %RH	☐	☐
	Time out of refrigerator and light exposure	≤ 24h	☐	☐
	Process Yield	99.0 -100.0 %	☐	☐
	Line clearance	Absence of material and documentation from previous batches	☐	☐
		Cleaning status label of equipments and room	☐	☐
Assembly and Packaging Process ☐ N/A	Temperature	15-25 °C	☐	☐
	Humidity	≤ 65 %RH	☐	☐
	Time out of refrigerator	≤ 12h	☐	☐
	Light exposure	≤ 24h	☐	☐
	Line clearance	Absence of material and documentation from previous batches	☐	☐
	Cleaning status label of equipments and room	Equipment and rooms are clean and have a valid cleaning status	☐	☐
	Reconciliation of packaging materials and units of finished products	Results meet the defined acceptance criteria	☐	☐
	Process Yield	99.0 -100.0 %	☐	☐
	Retention sample	The retention sample is complete and in accordance with the final packaging.	☐	☐
Packaging process ☐ N/A	Temperature	15-25 °C	☐	☐
	Humidity	≤ 65 %RH	☐	☐
	Time out of refrigerator	≤ 12h	☐	☐
	Line clearance	Absence of material and documentation from previous batches	☐	☐
	Cleaning status label of equipments and room	Equipment and rooms are clean and have a valid cleaning status	☐	☐

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	Reconciliation of packaging materials and units of finished products	Results meet the defined acceptance criteria			☐	☐
	Process Yield	99.0 -100.0 %			☐	☐
	Retention sample	The retention sample is complete and in accordance with the final packaging.			☐	☐
Outer cartooning Process ☐ N/A	Syringes	The qty. received is consistent with the qualified qty. from the previous step.			☐	☐
	Temperature	15-25 °C			☐	☐
	Humidity	≤ 65 %RH			☐	☐
	Time out of refrigerator	≤ 12h			☐	☐
	Retention sample	The retention sample is complete and in accordance with the final packaging.			☐	☐
Artworks	<u>Label</u>	☐ <u>Carton</u>	☐ <u>Inner carton</u>	☐ <u>Outer carton</u>	<u>Leaflet</u>	

GENERAL ASPECTS		Comply	
		C	NC
In the Batch Record and supporting documentation, the raw data and packaging operations are recorded according to Good Documentation Practices		☐	☐
Primary and secondary packaging material and leaflet are approved with a copy endorsed in the batch record.		☐	☐
Environmental controls within the acceptance limit according to Memorandum's manufacturer.		☐	☐
Comments	N/A		

CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER	
Name of the product	
Strength	
Dosage form	
Batch number	
Quantity released	
Manufacturing date	
Expiry date (24 months)	
Certification statement	

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CoC signed by QP or QA Manager	Date:
uDP 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.	
☐ N/A, it is PFS	aDP 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	☐ N/A	Route for uDP	If uDP manufacturing site is different from fDP manufacturing site, please register below: <table border="1"> <thead> <tr> <th>Route</th> <th>Dataloggers ID</th> <th>T_{max}</th> <th>T_{min}</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> Regarding the temperatures previously assessed, it can be determined that: ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. A deviation has been opened. See comments.	Route	Dataloggers ID	T _{max}	T _{min}																				
	Route	Dataloggers ID	T _{max}	T _{min}																							
☐ N/A, it is PFS	Route for aDP	If aDP manufacturing site is different from fDP manufacturing site, please register below: <table border="1"> <thead> <tr> <th>Route</th> <th>Dataloggers ID</th> <th>T_{max}</th> <th>T_{min}</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>	Route	Dataloggers ID	T _{max}	T _{min}																					
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		Regarding the temperatures previously assessed, it can be determined that: ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. A deviation has been opened. See comments.												
	Route for fDP	☐ Celltrion Pharm (Korea) > Celltrion Healthcare Hungary ☐ Celltrion Pharm (Korea) > Oktal Pharma d.o.o. ☐ Celltrion Pharm (Korea) > Brocacef Healthcare Logistics B.V. ☐ Egis Gyógyszergyár Zrt. (Hungary) > Celltrion Healthcare Hungary ☐ Egis Gyógyszergyár Zrt. (Hungary) > Oktal Pharma d.o.o. If any other different route, please register it below: Assess below the temperatures during shipping: <table border="1"> <thead> <tr> <th>Datalogger reference</th><th>T_{max}</th><th>T_{min}</th></tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table> Regarding the temperatures previously assessed, it can be determined that: ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. A deviation has been opened. See comments.	Datalogger reference	T _{max}	T _{min}									
Datalogger reference	T _{max}	T _{min}												
Deviations available, if any		☐ No deviation and/or OOS registered. ☐ Deviation reports are provided, reviewed and accepted. Reference:												
Comments														
STORAGE CONDITIONS UNTIL RELEASE														
Storage temperature records for products requiring special storage conditions (e.g., 2-8°C, -20°C) should be available, reviewed, and within the acceptance criteria.		Complies ☐												
PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES														
	Route	Doc. reference	Received on	Units to be received	Units received	N/A								
Packing list	uDP manufacturing site to fDP manufacturing site				☐ C ☐ NC	☐								

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	fDP batch from fDP manufacturing site to EU warehouse			CoC released qty + retention sample	☐ C ☐ NC	☐					
Incoming inspection of goods into warehouse	Reception number: ☐ Compliant. ☐ Not compliant, justify:										
Reference samples	Kymos										
Retention sample											
Comments											
COMMISSIONING OF THE BATCH, QC, REFERENCE AND RETENTION SAMPLES					C	NC					
EU/EEA ☐	Commissioning records are provided, reviewed, and correspond with released units, QC, and reference and retention samples. The rows in the serialization Excel document match the market units. (CoC)					☐	☐				
	The released units match those in the document Summary of product and packaging information under the pharmaceutical track and trace system.					☐	☐				
UK ☐	Commissioning records are provided, reviewed, and correspond with released units, QC, and reference and retention samples. The rows in the serialization Excel document match the market units. (CoC)					☐	☐				
IT ☐	For Italian market batches, the bollini reconciliation matches the released units + the retention sample.					☐	☐				
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					
					☐	☐					

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BATCH RELEASE CERTIFICATE (LIMS Batch Release Certificate)				
Product Trade Name	Market	Dosage	PFS/ AI	Name on the Marketing Authorization
	☐ PL/LT/LV	75 mg	PFS	Omlyclo 75 mg Roztwór do wstrzykiwań w ampułko-strzykawce / Injekcinis tirpalas užpildytame švirkšte / Šķīdums injekcijām pilnšļircē
	☐ PL/LT/LV	75 mg	AI	Omlyclo 75 mg Roztwór do wstrzykiwań we wstrzykiwaczu /Injekcinis tirpalas užpildytame švirkštiklyje/ Šķīdums injekcijām pildspalvveida pilnšļircē
	☐ PL/LT/LV	150 mg	PFS	Omlyclo 150 mg Roztwór do wstrzykiwań w ampułko-strzykawce / Injekcinis tirpalas užpildytame švirkšte / Šķīdums injekcijām pilnšļircē
	☐ PL/LT/LV	150 mg	AI	Omlyclo 150 mg Roztwór do wstrzykiwań we wstrzykiwaczu /Injekcinis tirpalas užpildytame švirkštiklyje/ Šķīdums injekcijām pildspalvveida pilnšļircē
	☐ HU/RO/BG	75 mg	PFS	Omlyclo 75 mg Oldatos injekció előretöltött fecskendőben / Soluție injectabilă în seringă preumplută / Инжекционен разтвор в предварително напълнена спринцовка
	☐ HU/RO/BG	75 mg	AI	Omlyclo 75 mg Oldatos injekció előretöltött injekciós tollban /Soluție injectabilă în stilou injector preumplut /Инжекционен разтвор в предварително напълнена писалка
	☐ HU/RO/BG	150 mg	PFS	Omlyclo 150 mg Oldatos injekció előretöltött fecskendőben / Soluție injectabilă în seringă preumplută / Инжекционен разтвор в предварително напълнена спринцовка

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	☐	HU/RO/BG	150 mg	AI	Omlyclo 150 mg Oldatos injekció előretöltött injekciós tollban /Soluție injectabilă în stilou injector preumplut /Инжекционный раствор в предварительно наполнена писалка
	☐	DE	75 mg	PFS	Omlyclo 75 mg Injektionslösung in einer Fertigspritze
	☐	DE	75 mg	AI	Omlyclo 75 mg Injektionslösung im Fertigpen
	☐	DE	150 mg	PFS	Omlyclo 150 mg Injektionslösung in einer Fertigspritze
	☐	DE	150 mg	AI	Omlyclo 150 mg Injektionslösung im Fertigpen
	☐	BE/NL/LU	75 mg	PFS	Omlyclo 75 mg oplossing voor injectie in een voorgevulde spuit / Injektionslösung im Fertigspritze / solution injectable en seringue préremplie
	☐	BE/NL/LU	75 mg	AI	Omlyclo 75mg oplossing voor injectie in een voorgevulde pen / Injektionslösung im Fertigpen / solution injectable en stylo prérempli
	☐	BE/NL/LU	150 mg	PFS	Omlyclo 150 mg oplossing voor injectie in een voorgevulde spuit / Injektionslösung im Fertigspritze / solution injectable en seringue préremplie
	☐	BE/NL/LU	150 mg	AI	Omlyclo 150 mg oplossing voor injectie in een voorgevulde pen / Injektionslösung im Fertigpen / solution injectable en stylo prérempli
	☐	CZ/SK	75 mg	PFS	Omlyclo 75 mg inječní roztok v předplněné injekční stříkačce / injekčný roztok v naplnenej injekčnej striekačke

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	☐	CZ/SK	75 mg	AI	Omlyclo 75 mg injekční roztok v předplněném peru / injekční roztok v naplnenom pere
	☐	CZ/SK	150 mg	PFS	Omlyclo 150 mg injekční roztok v předplněné injekční stříkačce / injekční roztok v naplnenej injekčnej striekačke
	☐	CZ/SK	150 mg	AI	Omlyclo 150 mg injekční roztok v předplněném peru / injekční roztok v naplnenom pere
	☐	ES/PT	75 mg	PFS	Omlyclo 75mg solución inyectable en jeringa precargada/solução injetável em seringa pré-cheia
	☐	ES/PT	75 mg	AI	Omlyclo 75mg solución inyectable en pluma precargada/solução injetável em caneta pré-cheia
	☐	ES/PT	150 mg	PFS	Omlyclo 150 mg solución inyectable en jeringa precargada/solução injetável em seringa pré-cheia
	☐	ES/PT	150 mg	AI	Omlyclo 150 mg solución inyectable en pluma precargada/solução injetável em caneta pré-cheia
	☐	FI/SE/EE	75 mg	PFS	Omlyclo 75 mg injektioneste, liuos, esitäytetty ruisku / injektionsvätska, lösning i förfylld spruta / süstelahus süstlis
	☐	FI/SE/EE	75 mg	AI	Omlyclo 75 mg injektioneste, liuos, esitäytetty kynä / injektionsvätska, lösning i förfylld penna / süstelahus pen-süstlis
	☐	FI/SE/EE	150 mg	PFS	Omlyclo 150 mg injektioneste, liuos, esitäytetty ruisku / injektionsvätska, lösning i förfylld spruta / süstelahus süstlis
	☐	FI/SE/EE	150 mg	AI	Omlyclo 150 mg injektioneste, liuos, esitäytetty kynä / injektionsvätska, lösning i

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					förfylld penna / süstelahus pen-süstlis
	☐	FR	75 mg	PFS	Omlyclo 75 mg solution injectable en seringue préremplie
	☐	FR	75 mg	AI	Omlyclo 75 mg solution injectable en stylo prérempli
	☐	FR	150 mg	PFS	Omlyclo 150 mg solution injectable en seringue préremplie
	☐	FR	150 mg	AI	Omlyclo 150 mg solution injectable en stylo prérempli
	☐	IE	75 mg	PFS	Omlyclo 75 mg solution for injection in pre-filled syringe
	☐	IE	75 mg	AI	Omlyclo 75 mg solution for injection in pre-filled pen
	☐	IE	150 mg	PFS	Omlyclo 150 mg solution for injection in pre-filled syringe
	☐	IE	150 mg	AI	Omlyclo 150 mg solution for injection in pre-filled pen
	☐	NO/DK/IS	75 mg	PFS	Omlyclo 75 mg Injeksjonsvæske, oppløsning i ferdigfylt sprøyte / Injeksjonsvæske, oppløsning i fylt injeksjonssprøtje / Stungulyf, lausn í áfylltri sprautu
	☐	NO/DK/IS	150 mg	PFS	Omlyclo 150 mg Injeksjonsvæske, oppløsning i ferdigfylt sprøyte / Injeksjonsvæske, oppløsning i fylt injeksjonssprøtje / Stungulyf, lausn í áfylltri sprautu
	☐	UK	75 mg	PFS	Omlyclo 75 mg Solution for injection in pre-filled syringe
	☐	UK	75 mg	AI	Omlyclo 75 mg solution for injection in pre-filled pen
	☐	UK	150 mg	PFS	Omlyclo 150 mg Solution for injection in pre-filled syringe
	☐	UK	150 mg	AI	Omlyclo 150 mg solution for injection in pre-filled pen
Destination country/ies	☐	Poland, Lithuania and Latvia (PL/LT/LV)			
	☐	Hungary, Romania and Bulgaria (HU/RO/BG)			
	☐	Germany (DE)			
	☐	Belgium, Netherlands and Luxembourg (BE/NL/LU)			
	☐	Czech Republic and Slovakia (CZ/SK)			

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MA Number	Europe	☐ Spain and Portugal (ES/PT)			
		☐ Finland, Sweden and Estonia (FI/SE/EE)			
		☐ France (FR)			
		☐ Ireland (IE)			
		☐ Norway, Denmark and Iceland (NO/DK/IS)			
		☐ United Kingdom (UK)			
		Dosage	PFS / AI	Type and size of packaging	MA number
		☐ 75 mg	PFS	1 x1 pre-filled syringe	EU/1/24/1817/001
		☐ 75 mg	PFS	3 (3 x 1) pre-filled syringes (multipack)	EU/1/24/1817/009
		☐ 75 mg	AI	1 pre-filled pen	EU/1/24/1817/005
		☐ 75 mg	AI	3 (3 x 1) pre-filled pens (multipack)	EU/1/24/1817/010
		☐ 150 mg	PFS	1 x1 pre-filled syringe	EU/1/24/1817/002
		☐ 150 mg	PFS	3 (3 x 1) pre-filled syringes (multipack)	EU/1/24/1817/011
		☐ 150 mg	PFS	6 (6 x 1) pre-filled syringes (multipack)	EU/1/24/1817/003
		☐ 150 mg	PFS	10 (10 x 1) pre-filled syringes (multipack)	EU/1/24/1817/004
		☐ 150 mg	AI	1 pre-filled pen	EU/1/24/1817/006
		☐ 150 mg	AI	2 (2 x 1) pre-filled pens (multipack)	EU/1/24/1817/012

CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
Customer	Product	Batch
Celltrion, Inc.	CT-P39 fDP	

		☐	150 mg	AI	3 (3 x 1) pre-filled pens (multipack)	EU/1/24/1817/013							
		☐	150 mg	AI	6 (6 x 1) pre-filled pens (multipack)	EU/1/24/1817/007							
		☐	150 mg	AI	10 (10 x 1) pre-filled pens (multipack)	EU/1/24/1817/008							
	UK	☐	75 mg	PFS	1 x1 pre-filled syringe	PLGB 51808/0018							
		☐	75 mg	AI	1 pre-filled pen	PL 51808/0038							
		☐	150 mg	PFS	1 x1 pre-filled syringe	PLGB 51808/0019							
		☐	150 mg	AI	1 pre-filled pen	PL 51808/0039							
	Strength/Potency		☐	75mg/0.5mL									
		☐	150mg/1mL										
Dosage form		☐	Solution for injection in pre-filled syringe										
		☐	Solution for injection in pre-filled syringe in pre-filled pen										
Type and size of packaging		☐	1 pre-filled syringe										
		☐	3 (3 x 1) pre-filled syringes (multipack)										
		☐	6 (6 x 1) pre-filled syringes (multipack)										
		☐	10 (10 x 1) pre-filled syringes (multipack)										
		☐	1 pre-filled pen										
		☐	2 (2 x 1) pre-filled pens (multipack)										
		☐	3 (3 x 1) pre-filled pens (multipack)										
		☐	6 (6 x 1) pre-filled pens (multipack)										
		☐	10 (10 x 1) pre-filled pens (multipack)										
Batch number													
Quantity Released (packs)													
Manufacture date (DD/MM/YYYY)													
Expiry date (DD/MM/YYYY)													
CoA number		CoA Kymos uDP batch:											

CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
Customer	Product	Batch
Celltrion, Inc.	CT-P39 fDP	

			☐ N/a, it is PFS	CoA Kymos aDP batch:	
Comments/Remarks (deviations, customer's requirements, etc.)					
Transport Deviations (if any and not reportable in CoC)					
Sites	☐	Site 1	Name	Celltrion, Inc (CLT1)	
			Address	23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea	
			Auth. No	2569	
			Activity	Manufacturing Drug Substance, Quality Control Drug Substance, Storage Drug Substance	
	☐	Site 1	Name	Celltrion, Inc (CLT2)	
			Address	20, Academy-ro 51beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea	
			Auth. No	2569	
			Activity	Manufacturing Drug Substance, Quality Control Drug Substance, Storage Drug Substance	
	☐	Site 2 (if applicable)	Name	WuXi Advanced Therapies Inc.	
			Address	400 Rouse Blvd, Philadelphia, PA 19112, USA	
			Auth. No	GMP Number 32242	
			Activity	Quality Control Drug Substance	
	☐	Site 3	Name	Celltrion Pharm, Inc.	
			Address	82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea	
			Auth. No	1534	
			Activity	Manufacturing Drug Product, Packaging	
	☐	Site 3	Name	Egis Gyogyszergyar Zrt.	
			Address	Bökényföldi út 118-120, Budapest, 1165, Hungary	
			Auth. No	HU-M-EGIS	
			Activity	Packaging	
	☐	Site 4 (if applicable)	Name	Nuvisan France SARL	
			Address	2400, Route des Colles, 06410, Biot, France	
			Auth. No	2023_045_1_2	
			Activity	Batch release	
			Name	Midas Pharma GmbH	



CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
Customer	Product	Batch
Celltrion, Inc.	CT-P39 fDP	

	☐	Site 4 (if applicable)	Address	Rheinstrasse 49, West, Ingelheim Am Rhein, Rhineland-Palatinate, 55218, Germany
			Auth. No	DE_RP_01_MIA_2025_0026
			Activity	Batch release
	☐	Site 5	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
	☐	Site 6	Name	Celltrion Healthcare Hungary Kft.
			Address	2040 Budaörs, Vasút utca 13, Hungary
			Auth. No	HU-M-CELL
			Activity	☐ Importer (Only applies if the batch is shipped to Celltrion Healthcare Hungary) Marketing Authorization Holder
	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):			



CHECK LIST FOR BATCH RELEASE OF MARKETED BIOLOGICAL PRODUCTS – CT-P39 fDP		
Customer	Product	Batch
Celltrion, Inc.	CT-P39 fDP	

Code	Impact Assessment /Classification	Short Description	Status

TRANSPORT DEVIATIONS

☐

No deviations recorded.

☐

Deviations (deviations):

Code	Impact Assessment /Classification	Short Description	Status

ADDITIONAL COMMENTS

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APPROVAL	
Performed by	Reviewed by