



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

PRODUCT INFORMATION			
Company	Zakłady Farmaceutyczne Polpharma, S.A.		
Product trade name	Market	Strength	Name on the Marketing Authorization
	☐ LT	20 mg/ 1mg/g	Enosat 20 mg/ 1 mg/g Kremas Fuzido Rugstis/Betametazonas
	☐ LV	20 mg/ 1mg/g	Enosat 20 mg/ 1 mg/g Krems Fusidicum/Betamethasonum
	☐ PL	20 mg/ 1mg/g	Dermisil (20 MG + 1 MG) / G Krem Acidum Fusidicum + Betamethasonum
Batch number			
Manuf. date			
Expiry date			Approved shelf life 36 months

MANUFACTURER AND PRODUCT FILE					
INTERMEDIATE MANUFACTURERS – INTERMEDIATE BETAMETHASONE					
Company: Henan Lihua Pharmaceutical Co., Ltd.					
Address: Anyang Hi-Tech Industry, 455000, China					
Activity: Intermediate manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	HA260009	22/09/2025	Until 19/01/2029	NA
	EU	NA	NA	NA	NA
	FDA	NA	NA	NA	NA
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.		Inspection date	Auditor	Comments
	STH22R347		12-13/07/2022	Sisthema	None
Comments					
INTERMEDIATE MANUFACTURERS – INTERMEDIATE BETAMETHASONE					
Company: Hunan Yuxin Pharmaceutical					
Address: Shaoyang City, 422001, China					
Activity: Intermediate manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	xiang20180090	23/03/2023	6 years	None



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	EU	NA	NA	NA	NA
	FDA	NA	NA	NA	NA
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.		Inspection date	Auditor	Comments
	STH23R542		29/08/2023	Eurofins HealthCare Assurance	None

Comments

INTERMEDIATE MANUFACTURERS – BETAMETHASONE VALERATE MICRONIZER

Company: IMS s.r.l.

Address: Milano, 20157, Italy

Activity: Intermediate manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	IT- API/90/H/2025	04/04/2025	3 years	None
	EU				
	FDA	NA	NA	NA	NA
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.		Inspection date	Auditor	Comments
	NA		23/08/2022	Farmabios S.p.A.	Currently, only this GMP audit report is available. Encube is coordinating a date for a re- audit with the manufacturer and will keep us informed if any additional reports become available.

Comments

INTERMEDIATE MANUFACTURERS – BETAMETHASONE VALERATE MICRONIZER



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Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

Company: Microchem s.r.l.**Address:** Fiorenzuola, 29017, Italy**Activity:** Intermediate manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	IT- API/93/H/2024	25/01/2024	3 years	None
	EU	IT-API/93/H/	25/01/2024	3 years	None
	FDA	NA	NA	NA	NA
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.		Inspection date	Auditor	Comments
	N/A		22/01/2025	Farmabios S.p.A.	None

Comments**API MANUFACTURER – FUSIDIC ACID****Company:** ERCROS, S.A.**Address:** Paseo del Deleite, s/n 28300 – Aranjuez (Madrid)**Activity:** API manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	N/A
	EU	ES/076/24	15/03/2024	3 years	Issued by Spanish Agency of Medicines and Medical devices
	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
	A25242FYSMECKSCBS		28-29/05/2024	AuditGMP Pharma S.L.	None.



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Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

CEP	CEP n. R1-CEP 2006-121-Rev002	Renewal due: Not applicable.
Current dossier sections of 3.2.S. provided – current version.		

Comments	
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API MANUFACTURER – BETHAMETHASONE VALERATE CREAM

Company: Farmabios S.P.A.

Address: Gropello Cairoli, 27027, Italy

Activity: API manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	N/A	N/A	N/A	N/A
	EU	IT- API/26/H/2024	29/11/2023	3 years	Issued by Italian Medicines Agency.
	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-1742		06-07/06/2023	Rephine	None

CEP	CEP No. R1-CEP 2002-078-Rev03	Renewal due: Not applicable.
Current dossier sections of 3.2.S. provided – current version.		

Comments	
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FINISHED PRODUCT MANUFACTURER

Company: Encube Ethicals Pvt. Ltd

Address: Mardol, Ponda, Goa – 403 404, India

Activity: Finished product manufacturer

cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	502/MFG/DFDA /CERT/2026/30 22	22/01/2026	1 year	None
	EU	2023/HPF/PT/0 11_P_2026	03/02/2023	4 years	None
	FDA	3005669319	17/06/2025	Not applicable	None



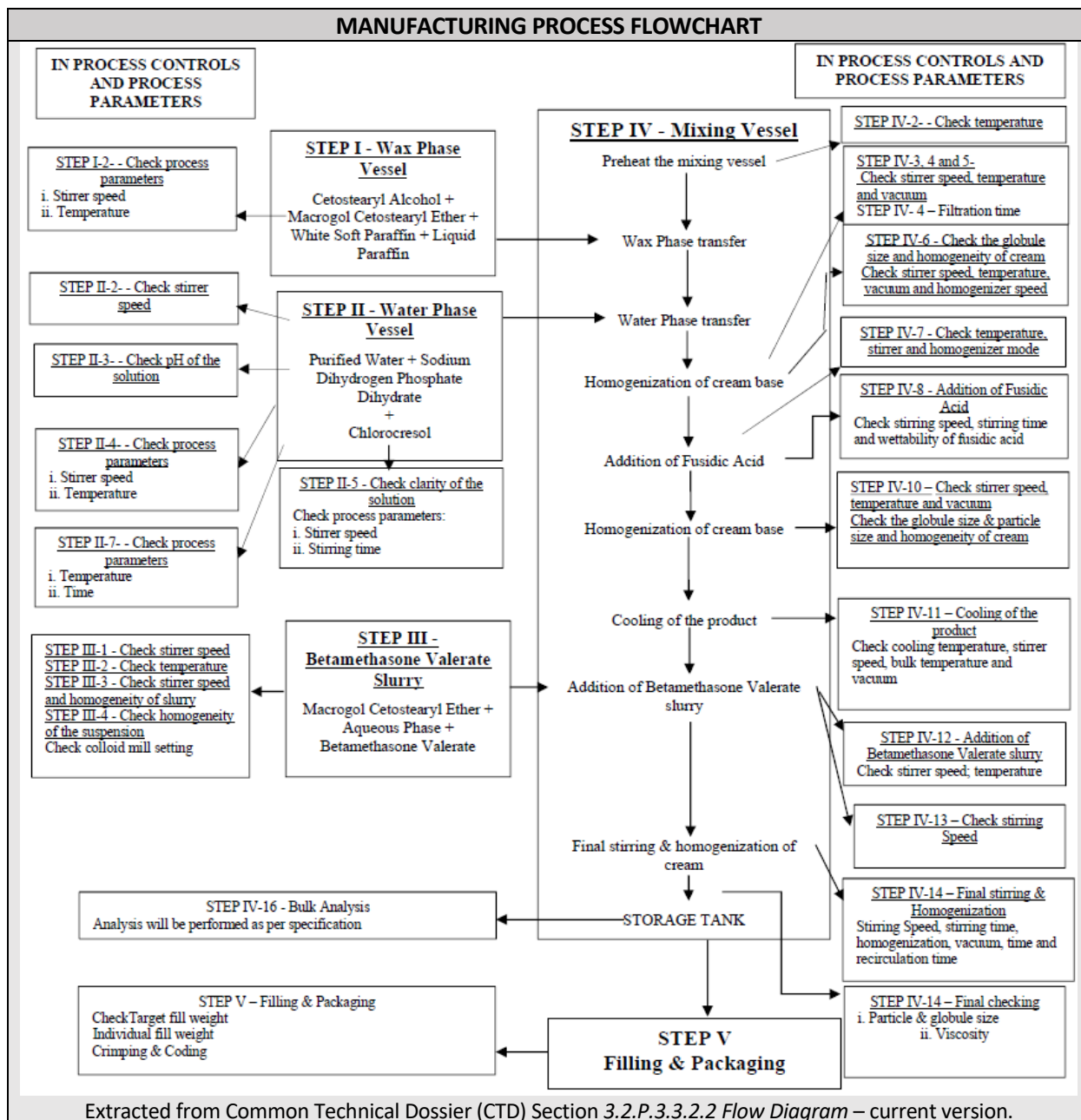
CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.	Inspection date	Auditor	Comments	
	NA	05/12/2022	Polpharma	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		UT/FDF/115 Rev: 06, effective on 11/2024.			
Current dossier sections of 3.2.P. provided – current version.					
Comments					
SUBCONTRACTORS					
☐ N/A	Company: Zakłady Farmaceutyczne Polpharma S.A. Address: Ul pelplinska 19, Starogard DGanski, 83-200, Poland Activity: Warehouse. Sampling of the product is performed by the Importer and MAH Polpharma in their premises ul. Pelplinska.				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	WTC/0105_02_06/3 8	12-15.12.2023	None	
	GDP	NA	NA	NA	
	WDA	040/0105/15	NA	NA	
	MIA	040/0105/15	06/10/2020	NA	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	NA	NA	NA	NA	No audit is performed, only sampling after importation carried out.



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FUSIDIC ACID AND METAMETHASONE VALERATE CREAM**

Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	



BATCH RECORDS REVIEW

API AND CRITICAL EXCIPIENTS

API Manufacturer: Ercros S.A. (Fusidic Acid manufacturer) and Farmabios S.P.A. (Betamethasone Valerate manufacturer)

Name	Batch number	CoA number (A.R. No.)	Specification s reference	Identified and traceable in BR (9-10/38)	N/A
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Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

				(According to CTD)		
Fusidic Acid	Ercros (API manuf)				☐	-
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP manuf)					
Betamethason e Valerate Cream	Farmabio s (API manuf)				☐	-
	Encube (FP manuf)					
	Farmabio s (API manuf)				☐	☐
	Encube (FP manuf)					
	Farmabio s (API manuf)				☐	☐
	Encube (FP manuf)					

A certificate of suitability has been granted for Fusidic Acid manufactured by Ercros S.A., Spain (section 3.2.R) (CEP requirements 2006-121). The retained specifications are in line with the European Pharmacopoeia monograph 798 current edition. Therefore, the relevant information has been assessed and found acceptable by EDQM.

A certificate of suitability (No. R1-CEP 2002-078) has been granted for Betamethasone Valerate manufactured by Farmabios SpA, Italy (section 3.2.R). Therefore the relevant information has been assessed and found acceptable by the EDQM. In addition to the specifications of the European Pharmacopoeia and of the certificate of suitability, the following tests for residual solvents and particle size distribution are tested.



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Parameter	Specifications	Ph. Eur Specifications
<u>Related substances</u>		
Betamethasone (Impurity A)	≤ 0.1%	≤ 0.7%
16β- Methyl epoxide	≤ 0.10%	≤ 0.10%
16β- Methyl epoxide - 17 - valerate	≤ 0.10%	≤ 0.10%
Beclomethasone 17-valerate (Impurity H)	≤ 0.10%	≤ 0.15%
16β- Methyl - 9α – bromo – prednisolone 17 – valerate (Impurity D)	≤ 0.10%	≤ 0.10%
Betamethasone 21-valerate (Impurity E)	≤ 0.3%	≤ 0.3%
Δ9-11 - 16β – Methyl prednisolone – 17- valerate (Impurity F)	≤ 0.10%	≤ 0.10%
Each unspecified impurity	≤ 0.10%	≤ 0.10%
Total impurities	≤ 1.0 %	≤ 1.5 %

Parameter	Specifications	Ph. Eur Specifications
Residual solvents		
Methanol	Not more than 200 ppm	Not more than 3000 ppm
Acetone	Not more than 3000 ppm	Not more than 5000 ppm
Tetrahydrofuran	Not more than 100 ppm	Not more than 720 ppm
Pyridine	Not more than 50 ppm	Not more than 200 ppm

Parameter	CEP Specifications	API Specifications
Particle size		
	Particles ≤ 20 μm - NLT 99 %	D10 Less than 3.0 μm
	Particles ≤ 10 μm - NLT 90 %	D50 Less than 5.0 μm
	Particles ≤ 5 μm - NLT 80 %	D90 Less than 10.0 μm

API specifications, extracted from CTD Section 3.2.S.4.5 – current version.

Excipients

Verify that the CoA is available for each of the excipients listed below.

Excipient	Batch number	CoA Encube provided	CoA supplier provided	Identified and traceable in BR (9-10/38)	N/A
Cetostearyl alcohol		☐	☐	☐	-
		☐	☐	☐	☐
Sodium Hydroxide Pellets		☐	☐	☐	-
		☐	☐	☐	☐
Chlorocresol		☐	☐	☐	-
		☐	☐	☐	☐
Liquid Paraffin		☐	☐	☐	-



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		☐	☐	☐	☐
Sodium Dihydrogen Phosphate Dihydrate		☐	☐	☐	-
		☐	☐	☐	☐
White Soft Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
SP Cetomacrogol 1000 MBAL- PA-(RB)		☐	☐	☐	-
		☐	☐	☐	☐

BATCH MANUFACTURING RECORDS OF BULK AND/OR FINISHED PRODUCT (According to CTD)

Bulk batch identification					
Batch manufacturing record edition. Master batch record available.	Strength	Batch Record code and version.			
	15g tube	☐ 260A3 revision 08			
	Strength	Market	Packaging Repertoire Sheet code and version		
	15g tube	LT	☐	260S revision 10	
		LV	☐	260T revision 08	
		PL	☐	260R revision 09	
Comments					

Batch Manufacturing Record and Critical Controls review

Critical Process Parameters and In Process Controls are indicated with ***bold, underlined and italic*** format.

Step	Page	Parameter /Process	Specification	IPC/ CPP	Compliance	
					C	NC
Batch Record	1/38	Ref. MFR No.	260	NA	☐	☐
		Batch size	☐ 60 kg ☐ 600 kg	NA	☐	☐
		Manuf. date				
		Expiry date				
		Date of commencement				
		Shelf-life	Expiry date in accordance with approved shelf life: 36 months	NA	☐	☐
Step I- Wax Phase Vessel	23/38	<u>Stirrer speed</u>	<u>Limit: 900 ± 100 rpm</u>	IPC	☐	☐
	24/38	<u>Temperature</u>	<u>Limit: 78-80° C</u>	IPC	☐	☐
	24/38	<u>Stirrer speed</u>	<u>Limit: 900 ± 100 rpm</u>	IPC CPP	☐	☐
	24/38	<u>pH of the solution</u>	<u>Limit: 4.8 – 5.2</u>	IPC CPP	☐	☐



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Step II – Water Phase Vessel	24/38	<u>Heating of the water phase</u>	<u>Stirrer speed Limit: 900 ± 100 rpm</u>	IPC	☐	☐
	24/38		<u>Temperature Limit: 78-80° C</u>	IPC	☐	☐
	24/38	<u>Addition rinse solution to the aqueous phase vessel.</u>	<u>Limit: Solution should be clear</u>	IPC	☐	☐
	24/38		<u>Stirring Limit: speed 900 ± 100 rpm</u> <u>Time: 5 minutes</u>	IPC	☐	☐
	24/38	<u>Cooling of water phase</u>	<u>Temperature Limit: 70°C – 75°C</u>	IPC	☐	☐
	24/38		<u>Time: 5 minutes</u>	IPC	☐	☐
Step III Betamethason e Valerate Slurry	26/38	<u>Dissolution of Macroglol into aqueous phase</u>	<u>Stirrer speed Limit: 400 – 700 rpm</u>	IPC	☐	☐
	26/38	<u>Cooling of solution</u>	<u>Temperature Limit: 20°C – 22°C</u>	IPC	☐	☐
	26/38	<u>Mixing Betamethasone Valerate with aqueous phase</u>	<u>Stirrer speed Limit: 400 – 700 rpm</u>	IPC	☐	☐
	26/38	<u>Homogeneity of the slurry</u>	<u>Limit: Suspension should be homogeneous</u>	IPC	☐	☐
	26/38	<u>Check homogeneity of the</u>	<u>Colloid mill setting: 0' setting</u>	IPC	☐	☐
	27/38	<u>Betamethasone valerate suspension</u>	<u>Limit: Suspension should be homogeneous</u>	IPC CPP	☐	☐
	29/38	<u>Preheating the mixing vessel</u>	<u>Temperature Limit: 35°C – 40°C</u>	IPC	☐	☐
	29/38	<u>Transfer of the wax phase into the mixing vessel</u>	<u>Stirrer speed Limit: 20 (±2) rpm</u>	IPC	☐	☐
	29/38		<u>Temperature Limit: 70 °C – 75°C</u>	IPC	☐	☐
	29/38		<u>Vacuum Limit: 400 – 600 mm of Hg</u>	IPC	☐	☐
	29/38	<u>Transferring of water phase into the mixing vessel</u>	<u>Stirrer speed – 20 (±2) rpm</u>	IPC	☐	☐
	29/38		<u>Temperature – 70 °C – 75°C</u>	IPC	☐	☐
	29/38		<u>Vacuum – 400 – 600 mm of Hg</u>	IPC	☐	☐
	29/38		<u>Filtration time approx. 30 minutes</u>	IPC	☐	☐
	29/38	<u>Transferring remaining</u>	<u>Stirrer speed – 20 (±2) rpm</u>	IPC	☐	☐
	29/38		<u>Temperature – 70 °C – 75°C</u>	IPC	☐	☐
	29/38		<u>Vacuum – 400 – 600 mm of Hg</u>	IPC	☐	☐



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Step IV Mixing Vessel		<u>quantity of water phase, into the mixing vessel</u>				
	30/38	<u>Globule size & particle size</u>	<u>Limit for particle and globule: 90% should not be more than 10µm</u>	IPC CPP	☐	☐
	30/38	<u>Stirrer speed</u>	<u>Limit: – 20 (±2) rpm</u>	IPC		
	30/38	<u>Temperature</u>	<u>Limit: – 70 °C – 75°C</u>	IPC	☐	☐
	30/38	<u>Vacuum</u>	<u>Limit: 400 – 600 mm of Hg</u>	IPC	☐	☐
	30/38	<u>Homogenizer speed</u>	<u>Limit: 2800 ± 100 rpm</u>	IPC	☐	☐
	30/38	<u>Addition of Fusidic Acid</u>	<u>Temperature Limit: 70 °C – 75°C</u>	IPC CPP	☐	☐
	30/38		<u>Stirrer mode – OFF</u>	IPC CPP	☐	☐
	31/38		<u>Homogenizer mode ON/OFF</u>	IPC	☐	☐
	31/38	<u>Wettability of Fusidic acid</u>	<u>Stirring speed: 20 ± 2 rpm</u>	IPC CPP	☐	☐
	31/38		<u>Stirring time: 5 minutes</u>	CPP	☐	☐
	31/38		<u>Cream should be homogeneous</u>	CPP	☐	☐
	31/38		<u>Wettability Limit: Comply</u>	IPC	☐	☐
	31/38	<u>Homogenization of cream base</u>	<u>Stirrer speed Limit: 28 (±2) rpm</u>	IPC	☐	☐
	31/38		<u>Stirring time: 25 minutes</u>	IPC	☐	☐
	31/38		<u>Temperature Limit: 70 °C – 75°C</u>	IPC	☐	☐
	31/38		<u>Vacuum Limit: 400 – 600 mm of Hg</u>	IPC	☐	☐
	31/38		<u>Homogenizer speed: 2500 ± 100 rpm</u>	IPC	☐	☐
	31/38	<u>Cooling to 55°C</u>	<u>Stirrer speed – 28 (±2) rpm</u>	IPC	☐	☐
	31/38		<u>Temperature – 55°C</u>	IPC	☐	☐
	32/38		<u>Vacuum – 400 – 600 mm of Hg</u>	IPC	☐	☐
	32/38		<u>Particle and globule size - 90 % should not be more than 10 µm</u>	IPC CPP	☐	☐
	32/38		<u>Cream should be homogeneous</u>	IPC	☐	☐
	32/38		<u>Temperature: NMT 41° C</u>	IPC CPP	☐	☐



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	32/38	<u>Cooling the product with water</u>	<u>Stirring speed: 20 ±2 rpm</u>	IPC CPP	☐	☐
	32/38		<u>Bulk temperature: below 30^o C</u>	IPC CPP	☐	☐
	32/38		<u>Vacuum: 400-600 mm of Hg</u>	IPC CPP	☐	☐
	32/38	<u>Addition of Betamethasone Valerate slurry</u>	<u>Stirring speed: 20 ±2 rpm</u>	IPC CPP	☐	☐
			<u>Temperature: 29-30°C</u>	IPC CPP	☐	☐
	32/38	<u>Betamethasone Valerate suspension addition.</u>	<u>Stirring speed – 20 (±2) rpm</u>	IPC	☐	☐
	32/38	<u>Final stirring & Homogenization</u>	<u>Stirring speed: 20 ±2 rpm</u>	IPC CPP	☐	☐
	33/38		<u>Stirring time: 30 minutes</u>	IPC CPP	☐	☐
			<u>Homogenization: 2800 ±100 rpm</u>	IPC CPP	☐	☐
			<u>Vacuum: 400-600 mmHg</u>	IPC CPP	☐	☐
			<u>Homogenization time: 2 minutes</u>	IPC CPP	☐	☐
			<u>Recirculation time: 10 minutes</u>	IPC CPP	☐	☐
	36/38	Yield calculation	97.00 – 100.00%	NA	☐	☐
	Bulk CoA 1/2	<u>Final checking</u>	<u>Particle and globule size: 90% should not be more than 10µm</u>	IPC CPP	☐	☐
			<u>Viscosity: 20000 to 60000 cps</u>	IPC CPP	☐	☐
Bulk CoA 2/2	Bulk Analysis	Limit: Bulk testing will be performed as per specification.	NA	☐	☐	
		Frequency: On 3 composite samples (top, middle & bottom) once	NA	☐	☐	

Batch Packaging Record In Process Controls.					
Step	Page	Parameter/ Process	Specification	Compliance	
				C	NC
	17/56	Filling and packaging	Average fill weight: 15.30g for 15g tube.	☐	☐



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Filling and Packaging	18/56 - 27/56		Individual fill weight: 15.10g-15.50g for 15g tube	☐	☐
	Along BPR		Crimping and Coding: Uniform crimping & legible coding	☐	☐
			Frequency: At regular 3 intervals (start, middle & end) during filing & packaging operation	☐	☐

Deviation/Remark:

VISUAL INSPECTION OF FINISHED PRODUCT					
The artwork of the used packaging materials corresponds to the current approved artwork (<i>see below table</i>)					

Market	Packaging size and type		Tube	Carton	Leaflet
LT	☐	15 g per tube	PEL1A/02	PEL3A/03	PEL5/04
LV	☐	15 g per tube	PEA1A/02	PEA3A/03	PEA5/03
PL	☐	15 g per tube	PFB1B/01	PFB3B/02	PFB5/04

Deviation/Remark:

MANUFACTURING PROCESS DEVIATIONS, CAPA AND CHANGE CONTROLS		
Type	Ref. No.	N/A
		☐
		☐
		☐
		☐

GENERAL ASPECTS		Comply	
		C	NC
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 yield of all relevant manufacturing steps registered and within the acceptance criteria		☐	☐
Comments			

SUPPORTING DOCUMENTATION REVISION		
Record	Review	Comply



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Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

		C	NC
Specimen	Tubes	☐	☐
	Inner cartons	☐	☐
	Leaflets	☐	☐
Line clearance checklist	Refer module page no.06, 08 and pg. no.17 of each batch	☐	☐
Cleaning records	Cleaning records of: - Colloid Mill - Slurry preparation vessel - Stirrers and Homogenizers - Storage tank	☐	☐
Dispensed material slips	It is in a separate document attached to BMR.	☐	☐
Picking list	It is in a separate document attached to BMR.	☐	☐
Labels	Released, cleaned, status and storage tank labels	☐	☐
Batch Details documents	It is in a separate document attached to BPR.	☐	☐
Other additional attachments		☐	☐

CERTIFICATE OF CONFORMITY (COC) ISSUED BY THE MANUFACTURER		
Name of the product	Market	Name on the Marketing Authorization
	☐ LT	Enosat 20 mg/ 1 mg/g Kremas Fuzido Rugstis/Betametazonas
	☐ LV	Enosat 20 mg/ 1 mg/g Krems Fusidicum/Betamethasonum
	☐ PL	Dermisil (20 MG + 1 MG) / G Krem Acidum Fusidicum + Betamethasonum
Importing Country	☐ Lithuania (LT)	
	☐ Latvia (LV)	
	☐ Poland (PL)	
Marketing Authorization Number	Market	Marketing Authorization number
	☐ LT	LT/1/16/3963/002
	☐ LV	16-0172
	☐ PL	23604
Strength	☐	Fusidic acid 20mg/g cream (2.00% w/w) and Betamethasone valerate 1mg/g cream (0.10% w/w)
Dosage form		Cream
Packaging size and packaging type	☐	15 g per tube
Batch number of Finished Product		
Date of manufacture		



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

Expiry date of product		
Quantity Released		
Deviations		
CERTIFICATE OF CONFORMITY (COC) ISSUED BY MAH (POLPHARMA)		
Name of the product	Market	Name on the Marketing Authorization
	☐ LT	Enosat 20 mg/ 1 mg/g Kremas Fuzido Rugstis/Betametazonas
	☐ LV	Enosat 20 mg/ 1 mg/g Krems Fusidicum/Betamethasonum
	☐ PL	Dermisil (20 MG + 1 MG) / G Krem Acidum Fusidicum + Betamethasonum
Importing Country	☐ Lithuania (LT)	
	☐ Latvia (LV)	
	☐ Poland (PL)	
Marketing Authorization Number	Market	Marketing Authorization number
	☐ LT	LT/1/16/3963/002
	☐ LV	16-0172
	☐ PL	23604
Strength	☐	Fusidic acid 20mg/g cream (2.00% w/w) and Betamethasone valerate 1mg/g cream (0.10% w/w)
Dosage form		Cream
Packaging size and packaging type	☐	15 g per tube
Batch number of Finished Product		
Date of manufacture		
Expiry date of product		
Quantity Released		
Deviations		
CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER		
CoA reference number		
Quality Spec. number		EERP298/01
Analytical parameters, specifications and analytical methods according to CTD and Marketing authorization		
Deviations and OOS reference available, if any	☐	No deviation and/or OOS registered.
	☐	Reference:
Results: complies. Signed by:		Position/title and date:



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

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	☐ Encube (India) > Polpharma (Poland) > QC and reference/retention samples: Kymos ☐ If other, explain:	
	Dataloggers	Shipment Encube to Polpharma	Datalogger reference: Batch:
		Samples to Kymos	☐ Same dataloggers as shipment. ☐ Different from shipment. Dataloggers ref.:
			☐ 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 Encube Ethicals PVT.LTD” available and approved. ☐ All transport conditions are within specification. ☐ There were temperature excursions during the shipping. Based on Freeze-Thaw studies, the excursions do not have an impact on the quality of the batch stability.	
Comments			

PACKING LIST, INSPECTION OF GOODS AFTER IMPORTATION AND SAMPLES						
Packing list	Route	Doc. reference	Received on	Units to be received	Units received	N/A
	Encube to Polpharma			CoC released qty.	☐ C ☐ NC	☐
	Polpharma to Kymos (QC samples)			60 units	☐ C ☐ NC	☐
	Polpharma to Kymos			122 units	☐ C ☐ NC	☐



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

	(reference and retention samples)					
Incoming inspection of goods into warehouse	Reception number: ☐ Compliant. ☐ Not compliant, justify:					
Reference and retention samples location	Kymos					
Comments						
COMMISSIONING AND DECOMMISSIONING OF THE BATCH, QC, REFERENCE AND RETENTION SAMPLES						
Commissioning and decommissioning records are provided, reviewed, and correspond with released units, QC, and reference and retention samples.				C	NC	N/A
				☐	☐	☐
If N/A, justify:						
VISUAL INSPECTION OF FINISHED PRODUCT						
Verification artworks and variable data are in accordance with the approved artworks and according to the manufacturing batch records.				C	NC	
				☐	☐	

BATCH RELEASE CERTIFICATE (LIMS Batch Release Certificate)			
Product Trade Name	Market	Strength	Name on the Marketing Authorization
	☐ LT	20 mg/ 1mg/g	Enosat 20 mg/ 1 mg/g Kremas Fuzido Rugstis/Betametazonas
	☐ LV	20 mg/ 1mg/g	Enosat 20 mg/ 1 mg/g Krems Fusidicum/Betamethasonum
	☐ PL	20 mg/ 1mg/g	Dermisil (20 MG + 1 MG) / G Krem Acidum Fusidicum + Betamethasonum
Destination country/ies	☐	Lithuania (LT)	
	☐	Latvia (LV)	
	☐	Poland (PL)	
Marketing Authorization Number	Market	Strength	MA number
	☐ LT	20 mg/ 1mg/g	LT/1/16/3963/002
	☐ LV	20 mg/ 1mg/g	16-0172
	☐ PL	20 mg + 1 mg/g	23604
Strength/Potency	☐	Fusidic acid 20mg/g cream (2.00% w/w) and Betamethasone valerate 1mg/g cream (0.10% w/w)	



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

Dosage form	Cream					
Type and size of packaging	☐	15 g per tube				
Batch number						
Quantity Released (packs)	Released by Encube	QC testing in Kymos	Ref./Ret. samples in Kymos	Other	Quantity Released	
		- 60 vials	- 122 vials	-		=
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	Encube Ethicals PVT. LTD.
		Address	C-1, Madkaim Industrial Estate, Madkaim, Mardol, Ponda Goa-403, India
		Auth. No	362
		Activity	Manufacturing Finished Product
	Site 2	Name	Zaklady Pharmaceutyczne, S.A.
		Address	Pelplinska 19, 83-200 Starogard Gdanski, Poland
		Auth. No	040/0105/15
		Activity	Importer, Marketing Authorization Holder
	Site 3	Name	Kymos, S.L.
		Address	Ronda de Can Fatjó, 7B (Parc Tecnològic del Vallès), 08290 Cerdanyola del Vallès, Barcelona, Spain
		Auth. No	6317E
		Activity	Quality Control, Batch Release
Certification statement duly completed			
Batch Release Certificate sent to QP in LIMS System.			

COMMENTS



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

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						

APPROVAL	
Performed by	Reviewed by



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Zakłady Farmaceutyczne Polpharma, S.A.	Fusidic Acid and Betamethasone Valerate Cream	

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