



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

PRODUCT INFORMATION				
Company	Encube Ethicals Pvt. Ltd			
Product trade name	Market	Strength	Package size & type	Name on the Marketing Authorization
	☐ DE	20 mg/ 1mg/g	5 g	Betagen Plus Fusidinsure 1mg/g + 20 mg/g Crème
	☐ DE	20 mg/ 1mg/g	15 g	Betagen Plus Fusidinsure 1mg/g + 20 mg/g Crème
	☐ DE	20 mg/ 1mg/g	30 g	Betagen Plus Fusidinsure 1mg/g + 20 mg/g Crème
	☐ DE	20 mg/ 1mg/g	60 g	Betagen Plus Fusidinsure 1mg/g + 20 mg/g Crème
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					



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

Activity: Intermediate manufacturer									
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments				
	Local	xiang20180090	23/03/2023	6 years	None				
	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.				



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

Comments	
----------	--

INTERMEDIATE MANUFACTURERS – BETAMETHASONE VALERATE MICRONIZER

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,	Audit ref.		Inspection date	Auditor	Comments
	A25242FYSMECKSCBS		28-29/05/2024	AuditGMP Pharma S.L.	None.



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

CV of the auditor available)													
CEP	CEP n. R1-CEP 2006-121-Rev002		Renewal due: Not applicable.										
Current dossier sections of 3.2.S. provided – current version.													
Comments													
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													
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								



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

	EU	2023/HPF/PT/011_P_2026	03/02/2023	4 years	None							
	FDA	3005669319	17/06/2025	Not applicable	None							
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			GALEN-KYMOS-ENCUBE (2025 v01)									
Current dossier sections of 3.2.P. provided – current version.												
Comments												
SUBCONTRACTORS												
☐ N/A	Company: Next Pharma Logistics GmbH Address: Eichenbusch 1, 59368 Werne Germany Activity: Physical importer and EU warehouse											
Certificates	Certificate	Certif. reference	Inspection/auth. date		Comments							
	GMP	DE_NW_01_GMP_2025_0016	26/03/2024		None							
	GDP	DE_NW_01_GDP_2025_24.05.06-020/2025-001	26/03/2024		None							
	WDA	DE_NW_01_WDA_2025_24.05.06-020/2025-001	04/09/2025		None							
	MIA	DE_NW_01_MIA_2023_0009/24.05.06-020	22/07/2025		None							
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments							

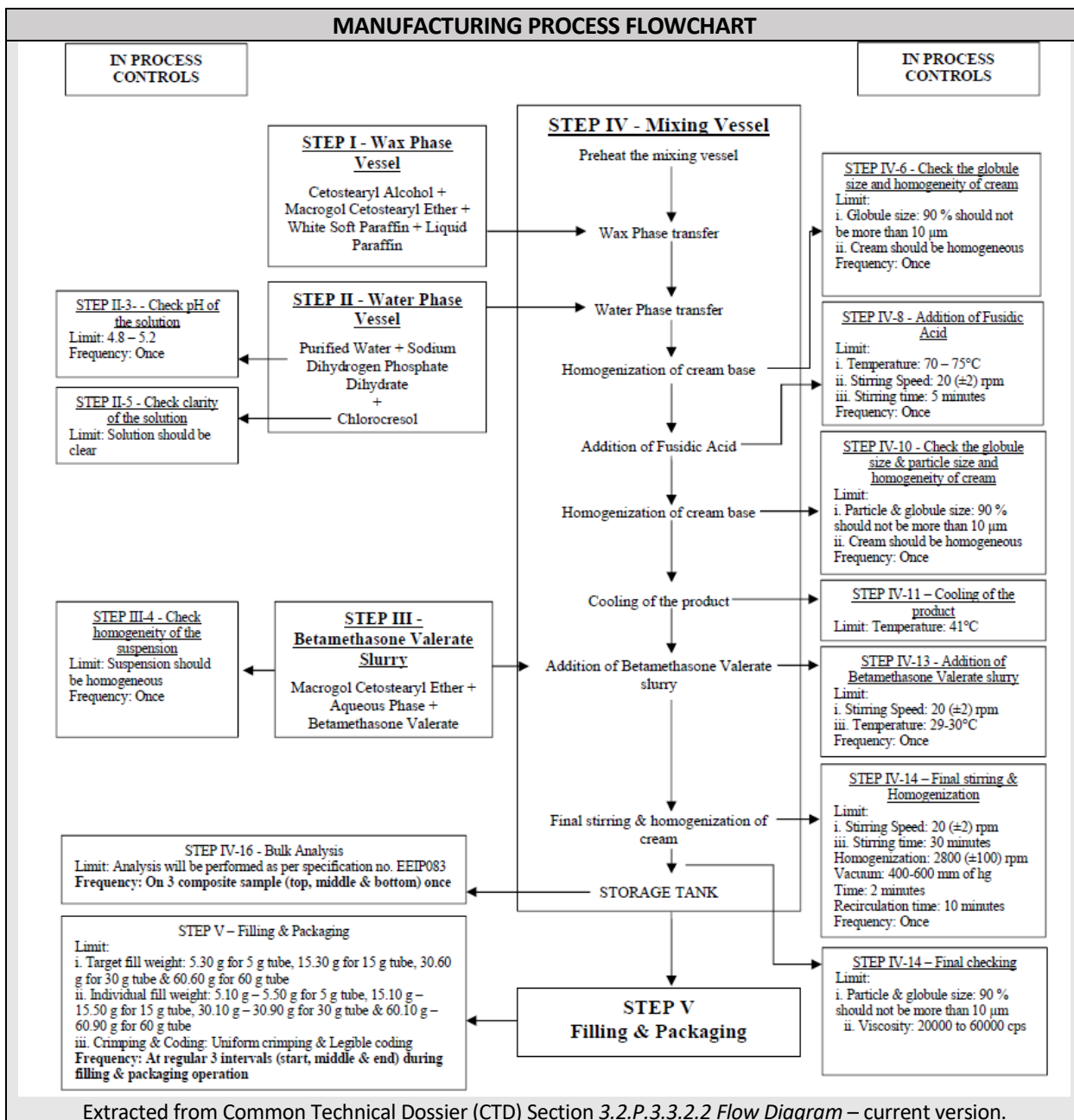


CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

	EXISTING_A UDIT- REPORT- NEXTPHARM A- LOGISTICS_2 02507_GALE N	08/07/2025	Qualifyze	Available and Compliant	None
--	---	------------	-----------	----------------------------	------



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	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.)	Specifications reference	Identified and traceable in BR (9-10/38)	N/A



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	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)					
Betamethasone Valerate Cream	Farmabios (API manuf)				☐	-
	Encube (FP manuf)					
	Farmabios (API manuf)				☐	☐
	Encube (FP manuf)					
	Farmabios (API manuf)				☐	☐
	Encube (FP manuf)					

A certificate of suitability (R1-CEP 2006-121-Rev 02) has been granted for Fusidic Acid manufactured by Ercros S.A., Spain (section 3.2.R). 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.



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

Sr. No.	TEST	SPECIFICATIONS	METHOD REFERENCE
1.	Description	A white or almost white, crystalline powder.	Ph.Eur.
2.	Solubility	Practically insoluble in water Freely soluble in ethanol (96%v/v)	Ph.Eur.
3.	Identification		
A.	By IR	The infra-red absorption spectrum of sample is concordant with the reference spectrum of Fusidic acid RS/WS.	Ph.Eur. 2.2.24
B.	Reaction (a) of Sodium	The residue does not give reaction (a) of sodium.	Ph.Eur. 2.3.1
4.	Related substances		
i.	Impurity M	≤ 1.0 %	Ph.Eur. 2.2.29
ii.	Impurity G	≤ 0.7 %	
iii.	Impurity L	≤ 0.5 %	
iv.	Impurity B	≤ 0.4 %	
v.	Impurity A	≤ 0.3 %	
VI.	Impurities C, D, F, I, K, N	≤ 0.2 %	
vii.	Unspecified impurities	≤ 0.10 %	
viii.	Total	≤ 2.0 %	
5.	Sulphated ash	≤ 0.2 %w/w	Ph.Eur.2.4.14
6.	Water	1.4 % to 2.0. % w/w	Ph.Eur.2.5.12
7.	Assay	97.5% to 101.0% of C ₃₁ H ₄₅ O ₆ calculated with reference to anhydrous substances.	Ph.Eur
8.	Residual solvents		
i.	Ethanol	NMT 100 ppm	In-House
9.	Particle Size by Laser Diffraction		
i.	10% Particles below (d10)	Less than 2 µm	In-House
ii.	50% Particles below (d50)	Less than 3 µm	In-House
iii.	90% Particles below (d90)	Less than 7 µm	In-House
API specifications, extracted from CTD Module 3.2.S.4.2 – current version.			
A certificate of suitability (No. R1-CEP 2002-078-Rev 03) has been granted for Betamethasone Valerate manufactured by Farmabios SpA, Italy (section 3.2.R). Therefore the relevant information has been assessed and			



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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 were tested.

Parameter	Limits	Method
Appearance	A white or almost white, crystalline powder.	Ph. Eur.
Solubility	Practically insoluble in water (0.01 g in 100 mL and over) Freely soluble in acetone (0.1 g in 1 mL) Freely soluble in methylene chloride (0.1 g in 1 mL). Soluble in ethanol (96%) (0.1 g in 3 mL).	Ph. Eur.
Melting point	About 192°C (with decomposition)	Ph. Eur.
Identification		
A	The infra-red absorption spectrum of sample is concordant with the reference spectrum of Betamethasone Valerate WS	IR spectrum (Ph. Eur. 2.2.24)
B	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to principal peak in the chromatogram obtained with reference solution (b).	Test for related substances - Ph. Eur.
Specific optical rotation	+77 to +83 (dried substance)	Ph. Eur. 2.2.27
Purity		
Related substances		HPLC (Ph. Eur. 2.2.29)
Betamethasone (Impurity A)	≤ 0.1%	Ph. Eur.
16β- Methyl epoxide	≤ 0.10%	Ph. Eur.
16β- Methyl epoxide - 17 - valerate	≤ 0.10%	Ph. Eur.
Beclomethasone 17-valerate (Impurity H)	≤ 0.10%	Ph. Eur.
16β- Methyl - 9α - bromo - prednisolone 17 - valerate (Impurity D)	≤ 0.10%	Ph. Eur.
Betamethasone 21-valerate (Impurity E)	≤ 0.3%	Ph. Eur.
Δ9-11 - 16β - Methyl prednisolone - 17-valerate (Impurity F)	≤ 0.10%	Ph. Eur.
Each unspecified impurity	≤ 0.10%	Ph. Eur.
Total impurities	≤ 1.0 %	Ph. Eur.
Loss on drying	Not more than 0.5%	Ph. Eur. 2.2.32
Residual solvents		In house (additional test)
Methanol	Not more than 200 ppm	
Acetone	Not more than 3000 ppm	
Tetrahydrofuran	Not more than 100 ppm	
Pyridine	Not more than 50 ppm	
Assay	97.0% to 103.0% (dried substance)	Ph. Eur. (Spectrophotometry)
Particle size*		Laser diffraction (CEP)
D10	Less than 3.0 μm	
D50	Less than 5.0 μm	
D90	Less than 10.0 μm	

* Note : the particle size mentioned in the Certificate of Suitability is reported as Not less than 99% Not more than 20 μm
Not less than 90% Not more than 10 μm
Not less than 80% Not more than 5 μm

Whereas the proposed specifications for particle size reported for Betamethasone Valerate micronized are expressed as D10, D50 and D90 values with D90 value less than 10.0 μm consistent with Not less than 90% Not more than 10 μm.

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



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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 Picking List	N/A
Cetostearyl alcohol		☐	☐	☐	-
		☐	☐	☐	☐
Sodium Hydroxide Pellets		☐	☐	☐	-
		☐	☐	☐	☐
Chlorocresol		☐	☐	☐	-
		☐	☐	☐	☐
Liquid Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
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.	Batch size	Batch Manufacturing Record code and version.	
	600 Kg	☐ 1011A revision 00	
	Strength	Market	Packaging Repertoire Sheet code and version
	5g tube	DE	☐ 1011B revision 00 – 5g (PS)
	5g tube	DE	☐ 1011C revision 00 – 5g
	15g tube	DE	☐ 1011D revision 00
	30g tube	DE	☐ 1011E revision 00
	60g tube	DE	☐ 1011F revision 00
	Comments	The 5 g (PS) BPR was prepared with approved artwork labeled “Not for sale – Sample,” requiring separate FG and packaging material codes.	



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

		The 5 g Master BPR was prepared with independently approved artwork and assigned new FG and packaging material codes. As per Change Control no. SCC-E1-25-1060.
--	--	--

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	1/34	Ref. MFR No.	1011	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 II – Water Phase Vessel	17/34	<i>pH of the solution</i>	<i>4.8 – 5.2</i>	IPC CPP	☐	☐
	18/34	<i>Addition of Chlorocresol</i>	<i>Stirring speed Limit: 900 rpm (range: 800-1000 rpm)</i>	CPP	☐	☐
	18/34	<i>Clarity of the solution</i>	<i>Solution should be clear</i>	IPC	☐	☐
Step III – Betamethasone Valerate Slurry	20/34	<i>Preparation of Slurry</i>	<i>Suspension should be homogeneous</i>	IPC	☐	☐
			<i>Colloid mill setting: "0" setting</i>	CPP	☐	☐
Step IV Mixing Vessel	23/34	<i>Globule size and homogeneity of cream</i>	<i>90% should not be more than 10 µm</i>	IPC CPP	☐	☐
			<i>Cream should be homogeneous</i>	IPC CPP		
	24/34	<i>Addition of Fusidic Acid</i>	<i>Homogenizer: OFF</i>	CPP	☐	☐
			<i>Temperature 70°C – 75°C</i>	IPC CPP	☐	☐
			<i>Stirring speed 20 (± 2) rpm</i>	IPC CPP	☐	☐
			<i>Stirring time 5 minutes</i>	IPC CPP	☐	☐
	25/34	<i>Globule size & particle size and</i>	<i>90% should not be more than 10 µm</i>	IPC CPP	☐	☐



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

	25/34	<u>homogeneity of cream</u>	<u>Cream should be homogeneous</u>	IPC	☐	☐
	26/34	<u>Cooling of the product</u>	<u>Temperature Limit: NMT 41°C</u>	IPC	☐	☐
			<u>Stirring speed limit: 20 rpm (range: 18-22 rpm)</u>	CPP	☐	☐
			<u>Final temperature: below 30°C</u>	CPP	☐	☐
			<u>Vacuum: 400 to 600 mmHg</u>	CPP	☐	☐
	26/34	<u>Addition of Betamethasone Valerate slurry</u>	<u>Stirring speed 20 (± 2) rpm</u>	IPC	☐	☐
			<u>Temperature 29 – 30°C</u>	IPC	☐	☐
	26/34	<u>Final stirring & Homogenization</u>	<u>Stirring speed limit: 20 (± 2) rpm</u>	IPC	☐	☐
	27-28/34		<u>Stirring time: 30 minutes</u>	IPC	☐	☐
	27/34		<u>Homogenization: 2800 (± 100) rpm</u>	IPC	☐	☐
	27/34		<u>Vacuum: 400 – 600 mm of hg</u>	IPC	☐	☐
	27-28/34		<u>Homogenization Time: 2 minutes (at 10th 20th and 30th min)</u>	IPC	☐	☐
	28/34		<u>Recirculation time: 10 minutes</u>	IPC	☐	☐
	Bulk CoA 1-2/2	<u>Final checking</u>	<u>90% should not be more than 10 µm</u>	IPC	☐	☐
			<u>Viscosity: 20000 to 60000 cps</u>	IPC	☐	☐
	Bulk CoA 2/2	Bulk Analysis	Limit: Analysis will be performed as per specification no. EEIP083	NA	☐	☐

Batch Packaging Record							
In Process Controls.							
Step	Page	Parameter/ Process	Specification			Compliance	
						C	NC
Filling and Packaging	16/64	Filling and packaging	Target fill weight	5g tube	5.30 g	☐	☐
				15g tube	15.30 g		
				30g tube	30.60 g		
				60g tube	60.60 g		
	17/64 -	Individual fill weight	5g tube	5.10 – 5.50 g	☐	☐	
			15g tube	15.10 – 15.50 g			



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

	33/64			30g tube	30.10 – 30.90 g		
			60g tube	60.10 – 60.90 g			
	Along BPR		Crimping and Coding: Uniform crimping & legible coding Frequency: At regular 3 intervals (start, middle & end) during filing & packaging operation				

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	
		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	☐	☐



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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
	☐ DE	Betagen Plus Fusidinsäure 1mg/g + 20 mg/g Crème
Importing Country	☐ Germany (DE)	
Marketing Authorization Number	Market	Marketing Authorization number
	☐ DE	7010144.00.00
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	☐	5 g per tube
	☐	15 g per tube
	☐	30 g per tube
	☐	60 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	EERP686/00	
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:	
CERTIFICATE OF ANALYSIS (COA) ISSUED BY KYMOS		
CoA reference number		



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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) > Next Pharma Logistics (Germany) > QC and reference/retention samples: Kymos ☐ If other, explain:	
	Dataloggers	Shipment	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 Next Pharma Logistics				☐ C ☐ NC	☐
	Next Pharma Logistics to Kymos (QC samples)				☐ C ☐ NC	☐
	Next Pharma Logistics to Kymos (reference and retention samples)				☐ C ☐ NC	☐



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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		
	☐ DE	20 mg/ 1mg/g	Betagalen Plus Fusidinsure 1mg/g + 20 mg/g Crème		
Destination country/ies	☐ Germany (DE)				
Marketing Authorization Number	Market	Strength	Marketing Authorization number		
	☐ DE	20 mg/ 1mg/g	7010144.00.00		
Strength/Potency	☐ Fusidic acid 20mg/g cream (2.00% w/w) and Betamethasone valerate 1mg/g cream (0.10% w/w)				
Dosage form	Cream				
Type and size of packaging	☐ 5 g per tube				
	☐ 15 g per tube				
	☐ 30 g per tube				
	☐ 60 g per tube				
Batch number					
Quantity Released (packs)	Released by Encube	QC testing in Kymos	Ref./Ret. samples in Kymos	Other	Quantity Released
	-	-	-	-	=
Manufacture date (DD/MM/YYYY)					
Expiry date (DD/MM/YYYY)					
CoA number					



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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	GALENpharma GmbH
		Address	Wittland 13, Hasseldieksdamm, Kiel, Schleswig-Holstein, 24109, Germany
		Auth. No	-
		Activity	Marketing Authorization Holder
	Site 3	Name	Kymos, S.L.
		Address	Ronda de Can Fatjó, 7B (Parc Tecnològic del Vallès), 08290 Cerdanyola del Vallès, Barcelona, Spain
		Auth. No	6317E
		Activity	Quality Control, Batch Release
Certification statement duly completed			
Batch Release Certificate sent to QP in LIMS System.			

COMMENTS				
MANUFACTURING DEVIATIONS				
☐ No deviations recorded.				
☐ Deviations (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			



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND METAMETHASONE VALERATE CREAM		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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