



CHECKLIST FOR BATCH RELEASE OF MARKETING SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND BETAMETHASONE VALERATE CREAM (PHARMASCIENCE)		
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		
	☐ UK	20 mg/1mg/g	30 g	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream		
	☐ UK	20 mg/1mg/g	60 g	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream		
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



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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

	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



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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

				reports become available.
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Comments	
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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/202 4	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	
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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



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Encube Ethicals Pvt. Ltd	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				
	A25242FYSMECKSCBS	28-29/05/2024	AuditGMP Pharma S.L.	None.				
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								
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								



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Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

Activity: Finished product manufacturer					
cGMP	Certificate	Certif. reference	Inspection date	Validity	Comments
	Local	502/MFG/DFD A/CERT/2026/3022	22/01/2026	1 year	None
	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
	Audit ID: recr19GK5Y19XwOx		15/Feb/2023 – 16/Feb/2023	Qualifyze	Pharmascience confirmed that next audit is scheduled for Q4 2026.
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			QTA 001/01		
Current dossier sections of 3.2.P. provided – current version.					
Comments					
SUBCONTRACTORS					
☐ N/A	Company: KUEHNE & NAGEL (AG & Co.) KG Address: Branch Office Leipzig, Am Jaegerhaus 1 D-04158 Leipzig, GERMANY Activity: EU Warehouse, Physical Importer				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	DE_SN_01_GMP_2021_0042 vom. 26 November 2021	05/08/2025	None	
	GDP	NA	NA	Local Authority information includes all "GMP" "GDP"	

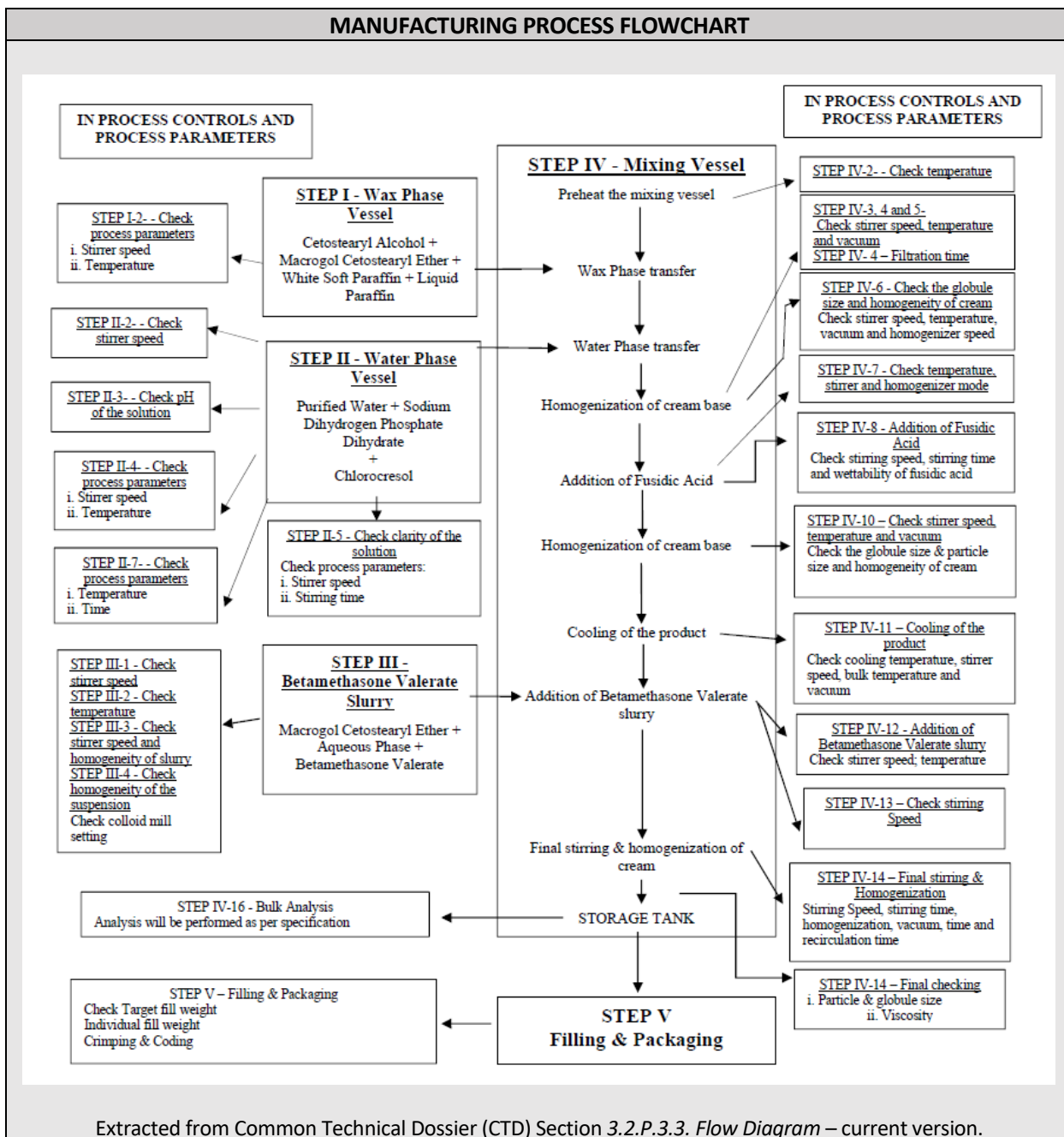


CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND BETAMETHASONE VALERATE CREAM (PHARMASCIENCE)		
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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

				aspects (see latest letter from Ministry / Authority attached. GDP- Zertifikaten from 01/08/2024)	
	WDA	NA	NA	WDA is not applicable to KN Leipzig, as the site operates under a valid Manufacturing and Importation Authorisation (MIA) which covers all required regulatory responsibilities related to manufacturing and importation activities and remains currently valid.	
	MIA	DE_SN_01_MIA_2018_0012	16/07/2025	There is confirmation from Pharmascience it is the current MIA and is valid until rejection. As this is a certificate with no valid time frame the document of the authority should be sufficient.	
GMP audit	Audit ref.	Inspection date	Auditor	CV and CAPA available	Comments
	186018	14/04/2025	Pharmascience	Available and Compliant	None



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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	





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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

BATCH RECORDS REVIEW						
API AND 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 (According to CTD)	Identified and traceable in BR (9-10/38)	N/A
Fusidic Acid	Ercros (API manuf)				☐	-
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP manuf)					
Betamethasone Valerate	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. 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.



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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 (d ₁₀)	Less than 2 µm	In-House
ii.	50% Particles below (d ₅₀)	Less than 3 µm	In-House
iii.	90% Particles below (d ₉₀)	Less than 7 µm	In-House

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



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Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

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	

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



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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		☐	☐	☐	-
		☐	☐	☐	☐
Chlorocresol		☐	☐	☐	-
		☐	☐	☐	☐
Liquid Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
Sodium Dihydrogen Phosphate Dihydrate		☐	☐	☐	-
		☐	☐	☐	☐
White Soft Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
Macrogol Cetostearyl Ether		☐	☐	☐	-
		☐	☐	☐	☐

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	☐	260A3 revision 08
	Strength	Market	Packaging Repertoire Sheet code and version
	30g tube	UK	☐ 260X revision 02
	60g tube	UK	☐ 260Y revision 02
Comments			

Batch Manufacturing Record and Critical Controls review						
Critical Process Parameters and In Process Controls are indicated with <i>bold, underlined and italic</i> 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				



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Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

		Expiry date				
		Date of commencement				
		<u>Shelf-life</u>	<u>Expiry date in accordance with approved shelf life: 36 months</u>	NA	☐	☐
Step I – Processing of Wax Phase	21/38	<u>Heating wax ingredients</u>	<u>Stirring speed: 900 (±100) rpm</u> <u>Temperature: 78°C-80°C</u>	IPC	☐	☐
	23/38	<u>Addition of Sodium Dihydrogen Phosphate</u>	<u>Stirring speed: 900 (±100) rpm</u>	IPC	☐	☐
Step II – Water Phase Vessel	23/38	<u>pH of the solution</u>	<u>4.8 – 5.2</u>	IPC CPP	☐	☐
	24/38	<u>Heating of water phase</u>	<u>Stirring speed: 900 (±100) rpm</u>	IPC	☐	☐
			<u>Temperature: 78°C-80°C</u>	IPC	☐	☐
	24/38	<u>Addition of Chlorocresol</u>	<u>Stirring speed Limit: 900 rpm</u> <u>(range: 800-1000 rpm)</u> <u>Stirring time: 5 minutes</u>	IPC	☐	☐
			<u>Solution should be clear</u>	IPC CPP	☐	☐
	24/38	<u>Preparation of Slurry Betamethasone Valerate</u>	<u>Temperature: 70°C – 75°C</u> <u>Time: 5 minutes</u>	IPC	☐	☐
Step III – Preparation of Betamethasone Valerate Slurry	26/38	<u>Dissolution of Macroqol Cetostearyl in aqueous phase</u>	<u>Stirring speed: 400-700 rpm</u>	IPC	☐	☐
	26/38	<u>Cooling of the solution</u>	<u>Temperature: 20°C-22°C</u>	IPC	☐	☐
	26/38	<u>Suspension of calculated quantity of</u>	<u>Stirring speed: 400-700 rpm</u>	IPC	☐	☐
	26/38	<u>Betamethasone Valerate</u>	<u>Suspension should be homogenous</u>	IPC	☐	☐
	26/38	<u>Passing the suspension</u>	<u>Colloid mill setting: 0' setting</u>	IPC	☐	☐
	26/38 - 27/38	<u>through colloid mill</u>	<u>Suspension should be homogenous</u>	IPC	☐	☐



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Step IV– Processing in Mixing Vessel	29/38	<u>Preheating of mixing vessel</u>	<u>Temperature: 35°C-40°C</u>	IPC	☐	☐
	29/38	<u>Transfer the wax phase into the mixing vessel</u>	<u>Stirring speed: 20 (±2) rpm</u>	IPC	☐	☐
			<u>Temperature: 70°C-75°C</u>	IPC	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐
	29/38	<u>Transferring 150L of water phase into the mixing vessel</u>	<u>Stirring speed: 20 (±2) rpm</u>	IPC	☐	☐
			<u>Temperature: 70°C-75°C</u>	IPC	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐
			<u>Filtration time: approx. 30 minutes</u>	IPC	☐	☐
	29/38	<u>Transferring remaining quantity of water phase</u>	<u>Stirring speed: 20 (±2) rpm</u>	IPC	☐	☐
			<u>Temperature: 70°C-75°C</u>	IPC	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐
	30/38	<u>Globule size & particle size and homogeneity of cream</u>	<u>90% should not be more than 10 µm</u>	IPC CPP	☐	☐
	30/38		<u>Cream should be homogeneous (Check after 10 min mixing and 2 minutes before homogenization)</u>	IPC CPP	☐	☐
			<u>Stirring speed: 20 (±2) rpm</u>	IPC CPP	☐	☐
			<u>Temperature: 70 °C – 75°C</u>	IPC CPP	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐
			<u>Homogenizer speed: 2800 ± 100 rpm</u>	IPC	☐	☐
	30/38		<u>Addition of Fusidic Acid</u>	<u>Homogenizer: OFF</u>	IPC CPP	☐
		<u>Temperature 70°C – 75°C</u>		IPC CPP	☐	☐
	31/38	<u>Stirring until Fusidic Acid is wetted</u>	<u>Stirring speed: 20 (±2) rpm</u>	IPC	☐	☐
			<u>Stirring time: 5 minutes</u>	IPC CPP	☐	☐
			<u>Wettability of Fusidic acid: Comply</u>	IPC	☐	☐
	31/38	<u>Homogenization of cream base</u>	<u>Stirring speed: 28 (±2) rpm</u>	IPC	☐	☐
			<u>Stirring time: 25 minutes</u>	IPC	☐	☐
			<u>Temperature 70°C – 75°C</u>	IPC	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐



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			<u>Homogenizer speed: 2500 ± 100 rpm</u>	IPC	☐	☐
	31/38	<u>1st Cooling of the product</u>	<u>Stirring speed: 28 (±2) rpm</u>	IPC	☐	☐
			<u>Temperature: 55°C</u>	IPC	☐	☐
			<u>Vacuum: 400 – 600 mm of Hg</u>	IPC	☐	☐
	32/38	<u>Check the globule and particle size and Homogeneity of cream</u>	<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 CPP	☐	☐
	32/38	<u>2nd Cooling of the product</u>	<u>Cool the product with cooling water</u>	IPC CPP	☐	☐
			<u>Temperature: NMT 41°C</u>			
			<u>Stirring speed: 20 ± 2 rpm</u>	IPC CPP	☐	☐
			<u>Bulk temperature: below 30° C</u>	IPC	☐	☐
			<u>Vacuum: 400-600 mm of Hg</u>	IPC	☐	☐
	32/38	<u>Addition of Betamethasone slurry to cream base</u>	<u>Stirring speed: 20 ± 2 rpm</u>	IPC CPP	☐	☐
			<u>Temperature: 29°C – 30 °C</u>	IPC CPP	☐	☐
	32/38	<u>Rinsing colloid mill with remaining aqueous phase</u>	<u>Stirring speed: 20 (±2) rpm</u>	IPC	☐	☐
	32/38		<u>Stirring speed: 20 (±2) rpm</u>	IPC CPP	☐	☐
	33/38	<u>Continued stirring for 30 mins</u>	<u>Stirring time at 10th, 20th and 30th minute: 2 minutes each</u>	IPC CPP	☐	☐
			<u>Homogenization: 2800 (±100) rpm</u>	IPC CPP	☐	☐
			<u>Vacuum: 400 to 600 mm of hg</u>	IPC CPP	☐	☐
			<u>Recirculation time: 10 minutes</u>	IPC CPP	☐	☐
	36/38	<u>Yield Calculation</u>	Desired Yield 582.00 Kg to 600.00 Kg (97.00%-100.00%)	NA	☐	☐
	Bulk CoA 1/2 - 2/2	<u>Final checking</u>	<u>Particle and globule size: 90 % should not be more than 10 µm</u>	IPC CPP	☐	☐
			<u>Viscosity: 20000 to 60000 cps</u>	IPC CPP	☐	☐



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

	Bulk CoA	Bulk Analysis	Limit: Bulk testing will be performed as per specification	IPC	☐	☐
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Batch Packaging Record							
In Process Controls							
Step	Page	Parameter/ Process	Specification			Compliance	
						C	NC
Filling and Packaging	16/55	Filling and packaging	Target fill weight	30g tube	30.60 g	☐	☐
	60g tube			60.60 g	☐	☐	
	17/55 - 26/55		Individual fill weight	30g tube	30.10 – 30.90 g	☐	☐
	Along BPR			60g tube	60.10 – 60.90 g	☐	☐
Crimping and Coding: Uniform crimping & legible coding Frequency: At regular 3 intervals (start, middle & end) during filing & packaging operation						☐	☐
VISUAL INSPECTION OF FINISHED PRODUCT The artwork of the used packaging materials corresponds to the current approved artwork (see below table)							
Market		Packaging size and type	Tube	Carton	Leaflet		
UK	☐	30g tube	PFC1A/02	PFC3A/01	PFC5/01		
UK	☐	60g tube	PFC1B/02	PFC3B/01	PFC5/01		
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							



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Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

SUPPORTING DOCUMENTATION REVIEW				
Record	Review	Comply		
		C	NC	N/A
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
	☐ UK	Fusidic Acid and Betamethasone Valerate Cream
Importing Country	☐ United Kingdom (UK)	
Marketing Authorization Number	Market	Marketing Authorization number
	☐ UK	PL 46740/0002
Strength	☐	Fusidic acid: 20mg/g & Betamethasone valerate 1mg/g (as the valerate ester)
Dosage form	Cream	
Packaging size and packaging type	☐	30 g per tube
	☐	60 g per tube
Batch number of Finished Product		
Date of manufacture		
Expiry date of product		
Quantity Released		
Deviations		



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

Results: Complies. Signed by:	
CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER	
Analytical parameters, specifications and analytical methods according to CTD and Marketing authorization.	
CoA reference number	
Quality Spec. number	EERP214/05
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	
Deviations and OOS reference available, if any	☐ No deviation and/or OOS registered. ☐ Deviations have been registered during batch testing. See comments. Reference:
Results: Complies.	

TRANSPORT AND STORAGE CONDITIONS			
Transport route and Data logger ID	Route	☐ Encube (India) > Kuehne & Nagel Leipzig (Germany) > QC and reference/retention samples: Kymos (Spain) ☐ If other, explain:	
	Dataloggers	Shipment Encube to K&N	Datalogger reference: Batch:
		Samples to Kymos	☐ Same dataloggers as shipment. ☐ Different from shipment. Dataloggers ref.:
Deviations available, if any		☐ No deviation registered during transport process. ☐ Deviation reports are provided, reviewed and accepted. Reference:	
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			



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

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 K&N Leipzig					☐ C ☐ NC	☐	
	K&N Leipzig to Kymos (QC samples)			☐ 30g	46	☐ C ☐ NC	☐	
				☐ 60g	23			
	K&N Leipzig to Kymos (reference and retention samples)			☐ 30g	138	☐ C ☐ NC	☐	
☐ 60g				69				
Incoming inspection of goods into warehouse		Reception number: ☐ Compliant. ☐ Not compliant, justify:						
Reference and retention samples location		Kymos S.L. or subcontracted warehouse						
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:								
BATCH RELEASE CERTIFICATE (LIMS Batch Release Certificate)								
Product Trade Name	Market	Strength	Name on the Marketing Authorization					
	☐ UK	20 mg/1mg/g	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream					
Destination country/ies	☐ United Kingdom (UK)							
Marketing Authorization Number	Market	Strength	Marketing Authorization number					
	☐ UK	20 mg/1mg/g	PL 46740/0002					
Strength/Potency	☐ Fusidic acid: 20mg/g & Betamethasone valerate 1mg/g (as the valerate ester)							
Dosage form	Cream							
Type and size of packaging	☐ 30 g per tube							
	☐ 60 g per tube							
Batch number								



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

Quantity Released (packs)		Package size & type	Released by Encube	QC testing in Kymos	Ref./Ret. samples in Kymos	Other	Quantity units to be released by Kymos						
		☐ 30 g		- 46	- 138	-	=						
		☐ 60 g		- 23	- 69	-	=						
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, Packaging										
	Site 2	Name	Pharmascience International Limited										
		Address	Lampousas 1, 1095 Nicosia, Cyprus										
		Auth. No	040										
		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.													



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

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 SMALL MOLECULE PRODUCTS – FUSIDIC ACID AND BETAMETHASONE VALERATE CREAM (PHARMASCIENCE)		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	Fusidic Acid and Betamethasone Valerate Cream	

APPROVAL	
Performed by	Reviewed by