



CHECKLIST FOR BATCH RELEASE OF MARKETED SMALL MOLECULE PRODUCTS – FUSIDIC ACID (ISDIN)		
Customer	Product	Batch
Encube Ethicals Pvt. Ltd	ACIDO FUSIDICO ISDIN 20mg/g CREMA	

PRODUCT INFORMATION				
Company	Encube Ethicals Pvt. Ltd			
Product trade name	Market	Strength	Package size & type	Name on the Marketing Authorization
	☐ ES	20mg/g	15 g	ACIDO FUSIDICO ISDIN 20mg/g CREMA
	☐ ES	20mg/g	30 g	ACIDO FUSIDICO ISDIN 20mg/g CREMA
Batch number				
Manuf. date				
Expiry date			Approved shelf life	36 months

MANUFACTURER AND PRODUCT FILE					
API MANUFACTURER – FUSIDIC ACID					
Company: ERCROS, S.A. Pharmaceutical Division					
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.
CEP		CEP n. R1-CEP 2006-121-Rev002		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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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
GMP audit (full audit report, updated CAPA plan, CV of the auditor available)	Audit ref.		Inspection date	Auditor	Comments
	A23R0812_far		10-18/06/2022	Intertek	An statement issued by ISDIN confirms an established periodicity of 5- year basis audit
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/172/02		
Current dossier sections of 3.2.P. provided – current version.					
Comments					
SUBCONTRACTORS					
☐ N/A	Company: PICKING FARMA Address: C/Tramuntana 10-16, 08213 Polinyà Activity: Warehouse for receiving, storage and distribution				
Certificates	Certificate	Certif. reference	Inspection/auth. date	Comments	
	GMP	NA	NA	Picking Farma, Santa Perpètua de Mogoda site holds GMP Certificate NCF/2402/001/CAT. This site is used for EU sampling, reference and	

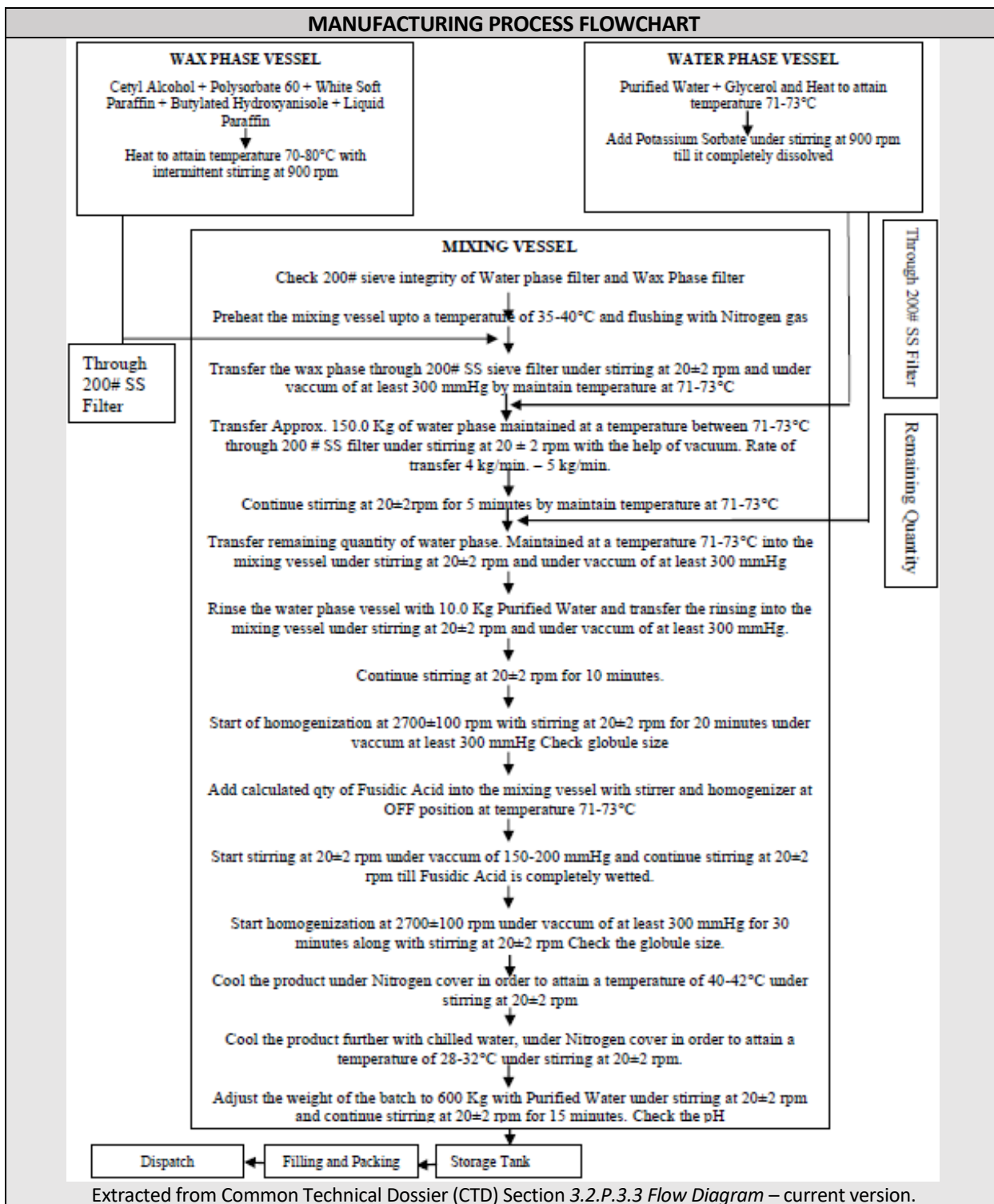


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				retention storage.	sample
	GDP	PCD/2513/001/CAT	28 and 30/10/2024	None	
	WDA	P08001678	30/01/2023	None	
	MIA	0367	30/09/2024	None	
GMP audit	Audit ref.	Audit date	Auditor	CV and CAPA available	Comments
	NA	17/10/2023	ISDIN	Compliant	None



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BATCH RECORDS REVIEW						
API AND EXCIPIENTS						
API Manufacturer: Ercros S.A. (Fusidic Acid 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 Micronized	Ercros (API manuf)				☐	-
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP manuf)					
	Ercros (API manuf)				☐	☐
	Encube (FP 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. Fusidic Acid is tested according to the requirements stated in current edition of monograph No. 0798 from European Pharmacopoeia. In addition, in-house tests for “Optical Rotation “, “Residual Solvents” and “Particle Size Distribution” are carried out.						



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TEST	SPECIFICATIONS	METHOD	SOP (Internal Code)
Description	White or almost white, crystalline powder	Eur. Ph. * No. 0798	ERCROS-4045
Identification IR	Positive	Eur. Ph. No. 0798 / 2.2.24 // USP <197 M>	ERCROS-4045
Identification Na	Negative	Eur. Ph. * No. 0798 / 2.3.1	ERCROS-4045
Solubility	Practically insoluble in water. Freely soluble in ethanol (96 %)	Eur. Ph. * No. 0798	ERCROS-4045
Optical Rotation (a.s.)	-7° to -12°	In-house method (Polarimetry)	ERCROS-4045
Water	1.4 % - 2.0 %	Eur. Ph.* No. 0798 / 2.5.12 // USP <921>	ERCROS-4045
Sulfated Ash	Not more than 0.2 %	Eur. Ph. * No. 0798 / 2.4.14 // USP <281>	ERCROS-4045
Assay (a.s.)	97.5 % - 101.0 %	Eur. Ph. * No. 0798	ERCROS-4045
Microbiological examination	TAMC: NMT 10 ³ cfu/g TYMC: NMT 10 ² cfu/g	Eur. Ph.* 2.6.12 // USP <61>	ERCROS-4741
Related substances (HPLC)			
Impurity A	Not more than 0.3 %	Eur. Ph. * No. 0798 / 2.2.29	ERCROS-4154
Impurity B	Not more than 0.4 %		
Impurity C	Not more than 0.2 %		
Impurity D	Not more than 0.2 %		
Impurity E	Not more than 0.10 %		
Impurity F	Not more than 0.2 %		
Impurity G	Not more than 0.7 %		
Impurity H	Not more than 0.10 %		
Impurity I	Not more than 0.2%		
Impurity J	Not more than 0.10 %		
Impurity K	Not more than 0.2 %		
Impurity L	Not more than 0.5 %		
Impurity M	Not more than 1.0 %		
Impurity N	Not more than 0.2 %		
Impurity O	Not more than 0.10 %		
Unspecified impurities	Not more than 0.10 %		
Total sum of impurities	Not more than 2.0 %		
Residual solvents (GC)			
Ethanol	Not more than 100 ppm	In-house method (GC)	ERCROS-4162
Methanol	Not more than 200 ppm		
Xylene **	Not more than 125 ppm		
TEST	SPECIFICATIONS	METHOD	SOP (Internal Code)
Particle size distribution	Powder: d10 under 2 µm d50 under 5 µm d90 under 21 µm Micronized: d10 under 2 µm d50 under 3 µm d90 under 7 µm	In-house method (Malvern method)	ERCROS - 4045

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 BMR	N/A
Butylated Hydroxy Anisole		☐	☐	☐	-
		☐	☐	☐	☐
White Soft Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
Cetyl Alcohol		☐	☐	☐	-
		☐	☐	☐	☐
Potassium Sorbate		☐	☐	☐	-
		☐	☐	☐	☐
Polysorbate 60		☐	☐	☐	-
		☐	☐	☐	☐
Glycerol		☐	☐	☐	-
		☐	☐	☐	☐
Liquid Paraffin		☐	☐	☐	-
		☐	☐	☐	☐
Hydrochloric Acid		☐	☐	☐	-
		☐	☐	☐	☐
Low Oxygen Nitrogen		☐	☐	☐	-
		☐	☐	☐	☐
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	☐ 343A revision 13			
	Strength	Market	Packaging Repertoire Sheet code and version		
	15g tube	ES	☐ 293B revision 22		
	30g tube	ES	☐ 293C revision 20		
Comments					
Batch Manufacturing Record and Critical Controls review					
Critical Process Parameters and In-Process Controls are indicated with <u>bold, italic and underlined</u> format and classified in column CPP/IPC format.					



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Step	Page	Parameter /Process	Specification	IPC/ CPP	Compliance	
					C	NC
Batch Record	1/40	Ref. MFR No.	343	NA	☐	☐
		Batch size	☐ 60 kg	NA	☐	☐
			☐ 600 kg			
		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	22/40	<u>Temperature of heating</u>	<u>70-80°C</u>	IPC CPP	☐	☐
	22/40	<u>Intermittent stirring</u>	<u>Stirring speed Limit: 855 - 945 rpm</u>	IPC	☐	☐
	22/40	<u>Clarity of the solution</u>	<u>Solution should be clear and homogeneous</u>	IPC CPP	☐	☐
Step II – Water Phase Vessel	24/40	<u>Stirring speed while addition of Glycerol</u>	<u>Stirring speed Limit: 855 - 945 rpm</u>	IPC	☐	☐
	24/40	<u>Heating of water phase</u>	<u>Temperature: 71-73°C</u>	IPC CPP	☐	☐
	24/40	<u>Addition and dissolving of Potassium Sorbate</u>	<u>Stirring speed Limit: 855 - 945 rpm</u>	IPC	☐	☐
	24/40	<u>Clarity of the solution</u>	<u>Solution should be clear</u>	IPC CPP	☐	☐
	25/40	<u>Adjusting pH of water phase</u>	<u>Limit: 4.8-5.2</u>	IPC CPP	☐	☐
	25/40		<u>Temperature: 71-73°C</u>	IPC	☐	☐
Step III Mixing Vessel	27/40	<u>Pre-heat of the mixing vessel</u>	<u>Temperature: 35-40°C</u>	IPC	☐	☐
	27/40	<u>Transfer of the wax phase into mixing vessel</u>	<u>Temperature: 71-73°C</u>	IPC	☐	☐
			<u>Stirring speed Limit: 20±2 rpm</u>	IPC	☐	☐
			<u>Vacuum: at least 300 mmHg</u>	IPC	☐	☐
			<u>Temperature: 71-73°C</u>	IPC	☐	☐



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	27/40	<u>Transfer approx. 150 kg of water phase into the mixing vessel</u>	<u>Stirring speed Limit: 20±2 rpm</u>	IPC	☐	☐
	28/40		<u>Continue stirring at 20±2 rpm</u>	IPC	☐	☐
	28/40		<u>Time: 5 minutes</u>	IPC	☐	☐
	28/40		<u>Temperature: 71-73°C</u>	IPC	☐	☐
	28/40	<u>Formation of W/O</u>	<u>Check the W/O emulsion type by putting a drop of emulsion in a few 'ml' of purified water in a stopper test tube wherein doesn't get dispersed upon shaking for 1 or 2 minutes.</u>	CPP	☐	☐
	28/40	<u>Transfer remaining quantity of water phase</u>	<u>Temperature: 71-73°C</u>	IPC	☐	☐
			<u>Stirring speed limit: 20 rpm</u>	IPC	☐	☐
			<u>Vacuum: at least 300 mmHg</u>	IPC	☐	☐
	28/40	<u>Rinsing of the water vessel</u>	<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
			<u>Vacuum: at least 300 mmHg</u>	IPC	☐	☐
	29/40	<u>Continue stirring</u>	<u>Stirring speed limit: 20 ± 2 rpm</u>	IPC	☐	☐
			<u>Check phase inversion from W/O to O/W wherein few drops of emulsion easily dispersed upon shaking when added to water taken in a test-tube</u>	CPP	☐	☐
			<u>Stirring time: 10 minutes</u>	IPC	☐	☐
			<u>A uniform dispersion is obtained</u>	IPC	☐	☐
	29/40	<u>Homogenization of emulsion</u>	<u>Homogenization speed: 2700 ±100 rpm</u>	IPC	☐	☐
			<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
			<u>Time: 20 minutes</u>	IPC	☐	☐



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			<u>Vacuum: at least 300 mmHg</u>	IPC	☐	☐
	30/40	<u>Addition of Fusidic Acid</u>	<u>Temperature limit: 71-73°C</u>	IPC CPP	☐	☐
	30/40	<u>Applying vacuum to wet the Fusidic Acid</u>	<u>Vacuum: 150 to 200 mmHg</u>	IPC CPP	☐	☐
			<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
	30/40	<u>Homogenization of batch</u>	<u>Homogenization speed: 2700 ±100 rpm</u>	IPC	☐	☐
			<u>Vacuum: at least 300 mmHg</u>	IPC	☐	☐
			<u>Time: 30 minutes</u>	IPC CPP	☐	☐
			<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
	CoA 2/2		<u>90% of Fusidic Acid particles must be <10µ & distributed homogeneously</u>	IPC CPP	☐	☐
	31/40	<u>Cooling of the product</u>	<u>Temperature limit: 40-42°C</u>	IPC	☐	☐
			<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
	32/40	<u>Cooling of the product further with chilled water</u>	<u>Temperature limit: 28-32°C</u>	IPC CPP	☐	☐
	32/40		<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
	33/40	<u>Making the weight of the batch to 600kg</u>	<u>Qty. of water added:</u>	IPC CPP	☐	☐
			<u>Stirring speed: 20 ±2 rpm</u>	IPC	☐	☐
			<u>Time: 15 minutes</u>	IPC	☐	☐
	33/40	<u>Check pH of 10% dispersion of cream</u>	<u>Limit: 4.5-6.0</u>	IPC CPP	☐	☐



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Batch Packaging Record							
In Process Controls							
Step	Page	Parameter/ Process	Specification			Compliance	
						C	NC
Filling and Packaging	17/57	Filling and packaging	Target fill weight	15g tube	15.40 g	☐	☐
				30g tube	30.60 g		
	18/57 - 27/57		Individual fill weight	15g tube	15.10 – 15.70 g	☐	☐
				30g tube	30.30 – 30.90 g		
	Along BPR		Uniform Crimping and Legible Coding Overprinting of inner cartons clearly legible, no smudging.				☐
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		
ES	☐	15 g per tube	23671	24007	23732		
ES	☐	30 g per tube	23668	24006	23732		
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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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	☐	☐
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
	☐ ES	ACIDO FUSIDICO ISDIN 20 mg/g CREMA
Importing Country	☐ SPAIN (ES)	
Marketing Authorization Number	Market	Marketing Authorization number
	☐ ES	74064
Strength	☐ 20 mg/g	
Dosage form	Cream	
Packaging size and packaging type	☐ 15 g per tube	
	☐ 30 g per tube	
Batch number of Finished Product		
Date of manufacture		
Expiry date of product		
Quantity Released		
Deviations		



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CERTIFICATE OF ANALYSIS (COA) ISSUED BY THE MANUFACTURER	
CoA reference number	
Quality Spec. number	EERP123/04
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	
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) > Picking Farma (Spain) > QC and reference/retention samples: Kymos ☐ If other, explain:		
	Dataloggers	Shipment from Encube to Picking Farma	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				



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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 Picking Farma					☐ C ☐ NC	☐	
	Picking Farma to Kymos (QC samples)			☐	15g	56	☐ C ☐ NC	☐
				☐	30g	32	☐ C ☐ NC	☐
	Picking Farma to Kymos (reference and retention samples)			☐	15g	45	☐ C ☐ NC	☐
				☐	30g	40	☐ C ☐ NC	☐
Incoming inspection of goods into warehouse		Reception number: ☐ Compliant. ☐ Not compliant, justify:						
Reference and retention samples location		Kymos or subcontracted warehouse by 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:								
BATCH RELEASE CERTIFICATE (LIMS Batch Release Certificate)								
Product Trade Name	Market	Strength	Name on the Marketing Authorization					
	☐ ES	20mg/g	ACIDO FUSIDICO ISDIN 20 mg/g CREMA					
Destination country/ies	☐ Spain (ES)							
Marketing Authorization Number	Market	Strength	Marketing Authorization number					
	☐ ES	20mg/g	74064					
Strength/Potency	☐ Each gram contains 20 mg Fusidic Acid							
Dosage form	Cream							
Type and size of packaging	☐ 15 g per tube							
	☐ 30 g per tube							
Batch number								



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Quantity Released (packs)		Package size & type	Released by Encube	QC testing in Kymos	Ref./Ret. samples in Kymos	Other	Quantity Released						
		☐ 15g		- 56 vials	- 45 vials	-	=						
		☐ 30g		- 32 vials	- 40 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	ISDIN S.A.										
		Address	Provençals, 33 - Barcelona - 08019 - España										
		Auth. No	74064										
		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	Importer, 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



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CHANGE CONTROLS				
☐ No change control recorded.				
☐ Change controls:				
Code	Regulatory Impact	Short Description	Status	
	☐ Yes / ☐ No			
	☐ Yes / ☐ No			
	☐ Yes / ☐ No			
BATCH TESTING 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