23

Certificate No.: Сертифікат №:	FP2/23/0085	Page 1 of 1 Сторінка 1 з 1

CERTIFICATE OF BATCH RELEASE
СЕРТИФІКАТ ВИПУСКУ СЕРІЇ

Product name: Назва продукції:	EUROFAST COMBI ЄВРОФАСТ КОМБІ		
Pharmaceutical form: Лікарська форма:	soft capsules, 200 mg/500 mg капсули м'які, 200 мг/500 мг	Manufacturing country: Країна-виробник:	India Індія
Strength/potency: Сила дії/активність:	1 soft capsule contains Ibuprofen 200 mg and Paracetamol 500 mg 1 капсула м'яка містить ібупрофену 200 мг та парацетамолу 500 мг		
Type and size of packaging: Вид і розмір упаковки:	10 capsules in a blister; 1 blister into a carton box with labeling in Ukrainian and English по 10 капсул у блістері; по 1 блістеру в картонній коробці з маркуванням українською та англійською мовами		
Batch No.: Серія №:	GX3003	Batch Size: Розмір серії:	25000 packs упаковок
Mfg. Date: Дата виробництва:	04/2023	Expiry Date: Термін придатності:	03/2025
Registration Certificate: Реєстраційне посвідчення:	UA/19195/01/01	Valid up to: Дійсне до:	04.02.2027
Name of manufacturer: Найменування виробника:	Olive Healthcare Олів Хелскер	License No.: Ліцензія №:	DD/688
Location: Місцезнаходження:	Unit 2, Plot 163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, 396210, India Юніт 2, Плот 163/2, Махатма Ганді Удіог Нагар, Дабхель Віледж, Нані Даман, 396 210, Індія		

Conclusion on confirmation of GMP Certificate No.: Висновок щодо підтвердження сертифікату НВП №:	554/2021/C-1319	dated: від:	01.12.2021
Labelling: Маркування:	Should correspond to the registered labelling. Повинно відповідати зареєстрованому маркуванню.	Complies Відповідає	
Packaging: Пакування:	Should correspond to the requirements of MQC. Повинно відповідати вимогам МКЯ.	Complies Відповідає	
Analysis results: Результати аналізу:	Certificate of analysis No.: Сертифікат аналізу №: FP2/23/0085	dated: від:	12.05.2023

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labeling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specification available in registration dossier. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Цим я засвідчую, що наведена вище інформація є достовірною та точною. Цю серію продукції було вироблено (включаючи пакування/маркування) та контроль її якості на вищезазначеній виробничій дільниці проведено у повній відповідності з вимогам GMP, встановленими місцевим регуляторним органом, а також відповідно до специфікації, що міститься в реєстраційному досьє. Протоколи виробництва, пакування та аналізів було переглянуто та встановлено відповідність GMP.

Name	Mr. Rajan Desai
Position of person authorizing the batch release	Vice President – Quality
Прізвище	Пан Раджан Десай
Посада особи, яка видала дозвіл на випуск серії	Віце-президент – Якість
Signature of person authorizing the batch release	
Підпис особи, яка видала дозвіл на випуск серії	
Date of signature	12.05.2023
Дата підписання	

UNIT-2
Regd. Office : Godrej Coliseum, Somaiya Hospital Road, B-3, 2nd Floor, Sion (East), Mumbai - 400 022. INDIA.
Tel.: +91-22-66288888, Fax : 91-22-2408 4323, Email : customer.care@olivehealthcare.co.in
Fact. : Unit-II, Plot No.163/1&163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, [illegible]-396210. INDIA.
Tel.:0260 - 6622222

Вх. ан №0182
від 26.07.23 Дата

УКРАЇНА * м.Київ * Спільне Українсько-естонське підприємство у формі товариства з обмеженою відповідальністю "Оптіма-Фарм, ЛТД" Ідентифікаційний код 21642228
Україна м. Харків ТОВ "КОНАРК ІНТЕЛМЕД" ДЛЯ СЕРТИФІКАТІВ №25182226

Olive HEALTHCARE

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

OHC/II/FM/4/03-SOP/QA/040

Product Name	**EUROFAST COMBI**		
Generic Name	**Ibuprofen 200 mg with Paracetamol 500 mg soft gelatin capsules**		
Finished Product Code	7122813129A	**Product Code**	7122813129
Batch No.	GX3003	**Page No.**	Page 1 of 4
A.R. No.	FP2/23/0085	**Mfg Date**	APR-2023
Batch size	250,000 capsules	**Expiry date**	MAR-2025
Sample quantity	150 Capsules	**Date of release**	12/05/2023
Sampled by / Date	Hiren 02/05/2023	**Reference STP No.**	FPP/IBP/039-01
Container Closure details	1 x 10's Blister Pack.		

Sr. No.	Test Parameters	Specification	Result	Procedure Ref. No
1.	Description	Oval shaped, soft gelatin capsule, one side white opaque and another side light brown opaque colored, containing off white to white colored suspension.	Oval shaped, soft gelatin capsule, one side white opaque and another side light brown opaque colored, containing off white colored suspension..	FPP/IBP/039-01 (1) In-house
2.	Identification Test			
2.1	For Ibuprofen i) By RT comparison (HPLC)	The Retention time of the major peak of Ibuprofen in the sample solution correspond to those of Standard solution, as obtain as Assay.	The Retention time of the major peak of Ibuprofen in the sample solution correspond to those of Standard solution, as obtain as Assay.	FPP/IBP/039-01 (2.1) In-house
	ii) By PDA (HPLC)	The UV absorption spectra of the Ibuprofen in the sample solution and that of standard solution exhibit maxima and minima at the same wavelength as obtained in Assay.	The UV absorption spectra of the Ibuprofen in the sample solution and that of standard solution exhibit maxima and minima at the same wavelength as obtained in Assay.	FPP/IBP/039-01 (2.1) In-house
2.2	For Paracetamol i) By RT comparison (HPLC)	The Retention time of the major peak of Paracetamol in the sample solution correspond to those of Standard solution, as obtained in Assay.	The Retention time of the major peak of Paracetamol in the sample solution correspond to those of Standard solution, as obtained in Assay.	FPP/IBP/039-01 (2.2) In-house

	Prepared by	Checked by	Approved by
Signature	mehul	Sanjay	
Name	MEHUL RANA	SANJAY PATEL	KAMLESH SHARMA
Title	SR.EXECUTIVE Q.C.	DY.MANAGER Q.C.	AGM Q.C.
Date	12/05/2023	12/05/2023	12/05/2023

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Olive HEALTHCARE

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

OHC/II/FM/4/03-SOP/QA/040

Product Name	**EUROFAST COMBI**		
Generic Name	**Ibuprofen 200 mg with Paracetamol 500 mg soft gelatin capsules**		
Finished Product Code	7122813129A	**Product Code**	7122813129
Batch No.	GX3003	**Page No.**	Page 2 of 4
A.R. No.	FP2/23/0085	**Mfg Date**	APR-2023
Batch size	250,000 capsules	**Expiry date**	MAR-2025
Sample quantity	150 Capsules	**Date of release**	12/05/2023
Sampled by / Date	Hiren 02/05/2023	**Reference STP No.**	FPP/IBP/039-01
Container Closure details	1 x 10's Blister Pack.		

Sr. No.	Test Parameters	Specification	Result	Procedure Ref. No
	ii) By PDA (HPLC)	The UV absorption spectra of the Paracetamol in the sample solution and that of standard solution exhibit maxima and minima at the same wavelength as obtained in Assay.	The UV absorption spectra of the Paracetamol in the sample solution and that of standard solution exhibit maxima and minima at the same wavelength as obtained in Assay.	FPP/IBP/039-01 (2.2) In-house
3.	Uniformity of Dosage Units (HPLC) (By Content uniformity for Ibuprofen and Paracetamol)	The acceptance value of the first 10 dosage units is less than or equal to *L1* If the acceptance value is greater than *L1* test the next 20 dosage unit and calculate the acceptance value. The requirement are met if the final acceptance value of dosage units is less than or equal to *L1* and no individual content of the dosage unit is less than (1-*L2* x 0.01)*M* or more than (1+*L2* x 0.01)*M* in calculation of the acceptance value. *L1* is 15.0 and *L2* is 25.0.	1)Ibuprofen : L1 : 0.6 2) Paracetamol : L1 : 0.8	FPP/IBP/039-01 (3) Ph. Eur. 2.9.40
4.	Dissolution: by HPLC Ibuprofen :	NLT 75% (Q) in 30 Minutes	Ibuprofen : Min : 93 % Max : 102 % Mean : 100 %	FPP/IBP/039-01 (4) In-house

	Prepared by	Checked by	Approved by
Signature	mehul		
Name	MEHUL RANA	SANJAY PATEL	KAMLESH SHARMA
Title	SR.EXECUTIVE Q.C.	DY.MANAGER Q.C.	AGM Q.C.
Date	12/05/2023	12/05/2023	12/05/2023

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CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

OHC/II/FM/4/03-SOP/QA/040

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Generic Name	Ibuprofen 200 mg with Paracetamol 500 mg soft gelatin capsules		
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Batch No.	GX3003	Page No.	Page 3 of 4
A.R. No.	FP2/23/0085	Mfg Date	APR-2023
Batch size	250,000 capsules	Expiry date	MAR-2025
Sample quantity	150 Capsules	Date of release	12/05/2023
Sampled by / Date	Hiren 02/05/2023	Reference STP No.	FPP/IBP/039-01
Container Closure details	1 x 10's Blister Pack.		

Sr. No.	Test Parameters	Specification	Result	Procedure Ref. No
5.	Dissolution: by HPLC Paracetamol:	NLT 75% (Q) in 45 Minutes	Paracetamol: Min: 85 % Max: 101 % Mean : 97 %	FPP/IBP/039-01 (5) In-house
6.	Related substances for Ibuprofen (HPLC) 1. Impurity-B 2. Ibuprofen 1- monoglyceride impurity 3. Individual Unspecified Impurities 4. Total Impurities (Other than Impurity-B and Ibuprofen 1- monoglyceride)	 1.NMT 0.3% 2.NMT 1.0% 3.NMT 0.3% 4.NMT 0.7%	 1. Not Detected 2. BDL (Less than 0.05%) 3. 0.06% 4. 0.11%	FPP/IBP/039-01 (6) In-house, British Pharmacopoeia.
7.	Related substances: (HPLC) For Paracetamol 1. 4-Aminophenol (Imp-K) 2. 4-Chloracetanilide(Imp-J) 3. Any unknown individual Impurity 4. Total Impurities (Excluding Imp-J)	 1. NMT 0.10 % 2. NMT 10 ppm 3. NMT 0.25 % 4. NMT 0.50 %	 1. BDL (Less than 0.05%) 2. Not Detected 3. 0.01 % 4. 0.03 %	FPP/IBP/039-01 (7) In-house, ICH

	Prepared by	Checked by	Approved by
Signature	mehul		
Name	MEHUL RANA	SANJAY PATEL	KAMLESH SHARMA
Title	SR.EXECUTIVE Q.C.	DY.MANAGER Q.C.	AGM Q.C.
Date	12/05/2023	12/05/2023	12/05/2023

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Generic Name	**Ibuprofen 200 mg with Paracetamol 500 mg soft gelatin capsules**		
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A.R. No.	FP2/23/0085	**Mfg Date**	APR-2023
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Sample quantity	150 Capsules	**Date of release**	12/05/2023
Sampled by / Date	Hiren 02/05/2023	**Reference STP No.**	FPP/IBP/039-01
Container Closure details	1 x 10's Blister Pack.		

Sr. No.	Test Parameters	Specification	Result	Procedure Ref. No
8.	Assay By HPLC: (Each soft gelatin capsule contains)			
	Ibuprofen Ph. Eur.	NLT 190.0 mg and NMT 210.0 mg NLT 95.0% and NMT 105.0%	199.73 mg 99.9 %	FPP/IBP/039-01 (8) In-house
	Paracetamol Ph. Eur.	NLT 475.0 mg and NMT 525.0 mg NLT 95.0% and NMT 105.0%.	498.08 mg 99.6 %	
9.	Loss on drying	NMT 12.5 % m/m	10.58 % m/m	FPP/IBP/039-01 (9) Ph.Eur 2.2.32
10.	Microbial enumeration: i. Total aerobic microbial count (TAMC). ii. Total combined yeasts/mold count (TYMC) iii. Specified microorganisms: a. Escherichia coli	 i. Not more than 10^3 cfu/g ii. Not more than 10^2 cfu/g a. Must be Absent/1g	 <10 cfu/g < 10 cfu/g Absent/g	FPP/IBP/039-01 (10) Ph.Eur 2.6.12 and Ph.Eur 2.6.13

Conclusion: The sample of above batch **complies**/~~does not comply~~ as per specification no. FPS/IBP/049-02 & stands "Approved/Rejected".

Abbreviation:

NMT : Not More Than
NLT : Not Less Than
HPLC: High Performance Liquid Chromatography
UV: Ultraviolet
PDA : Photometric Diode Array
RT : Retention time
% : Percentage
cfu: Colony forming unit
Ppm : Parts per million
m/m : Mass by mass
g : Gram
mg: milligram

	Prepared by	Checked by	Approved by
Signature			
Name	MEHUL RANA	SANJAY PATEL	KAMLESH SHARMA
Title	SR.EXECUTIVE Q.C.	DY.MANAGER Q.C.	AGM Q.C.
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