A. MENARINI
MANUFACTURING LOGISTICS AND SERVICES

Batch Certification (MRA)

Product	:	**FASTUM GEL**
Importing Country:	:	**Vietnam**
Marketing Authorization Number	:	VN-12132-11
Strenght/Potency:	:	Ketoprofen 25 mg/g
Dosage form:	:	gel
Package size and type:	:	30 g (Tube)
Lot/Batch number	:	4247A
Manufacturing date	:	July 2024
Expiry date	:	July 2029
Name and address of Manufacturing site and Quality Control site	:	A.Menarini M.L.S.- Via Sette Santi ,3 Firenze (Italy)
Number Certificates of GMP Compliance	:	aM-54/2024
Results of analysis	:	see attached CoA
Comments/Remarks	:	----------

Certification statement

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP

A. Menarini Manufacturing Logistics and Services s.r.l.Via Sette Santi ,3 Firenze
Qualified Person

Dr. Luca Nannelli

Signature:

Release Date: 10/10/2024

A. MENARINI
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CERTIFICATE OF ANALYSIS

Product	: **FASTUM GEL**
Code no.	: 556826
Batch no.	: 4247A
Manufacturing date	: 17/07/24
Expiry date	: 17/07/29
Date of analysis	: September 23, 2024
Manufacturer	: A. Menarini Manufacturing Logistics and Services S.r.l.
Manufacturer Legal address	: Via Sette Santi n.3, 50131 Firenze (Italy)
Manufacturer Specification no.	: TF0375
Country	: Vietnam

TEST	SPECIFICATION	RESULTS
Characteristics	gel of mucilaginous consistency, colourless or almost transparent, with an aromatic odour	complies
Average weight	≥ 30 g	31 g
pH	5.9 ÷ 6.4	6.1
Identifications (HPLC- UV)		
- Ketoprofen	positive	positive
Assay		
Ketoprofen (HPLC)	95- 105 % of declared	100 %
Related substance*		
3-acetylbenzophenone	≤ 0.2 %	not tested
2-(3-carboxyphenyl) propionic acid	≤ 0.2 %	not tested
ketoprofene ethyl ester (KEE)	≤ 0.2 %	not tested
Other single impurity	≤ 0.2 %	not tested
Total impurities (except KEE)	≤ 1 %	not tested
Microbial contamination*		
- TAMC	≤ 10^2 cfu/g	not tested
- TYMC	≤ 10^1 cfu/g	not tested
- pseudomonas aeruginosa	absent on 1 g	not tested
- staphylococcus aureus	absent on 1 g	not tested

*not routinary tests

"I hereby certify that the manufacture and control of this batch was carried out in compliance with the GMP. Documentation and retention samples are stored in conformity to the law in force and are available for any request or inspection". The batch has been released by a Qualified Person.

APPROVED
Qualified Person
Dr. Luca Nannelli