



A. MENARINI
MANUFACTURING LOGISTICS AND SERVICES

CERTIFICATE OF ANALYSIS

Product : **FASTUM GEL 30 G**
Code no. : 75661G
Batch no. : 4262A
Manufacturing date : 09 24
Expiry date : 08 2028
Date of analysis : September 23, 2024
Country : Singapore

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Characteristics	gel of mucilaginous consistency, colourless or almost transparent, with an aromatic odour	conforms
Average weight	≥ 30 g	31 g
pH	$5.9 \div 6.4$	6.2
Ketoprofene identification	positive	positive
Ketoprofene assay	2.375 – 2.625 g/100 g	2.516 g/100g
<u>Related substances*</u>		
3-acetylbenzophenone	≤ 0.2 %	not tested
2-(3-carboxyphenyl) propionic acid	≤ 0.2 %	not tested
ketoprofen ethyl ester	≤ 0.2 %	not tested
Other single impurity	≤ 0.2 %	not tested
Total impurities (except KEE)	≤ 1.0 %	not tested
<u>Microbial contamination*</u>		
- TAMC	$\leq 10^2$ CFU/g	not tested
- TYMC	$\leq 10^1$ CFU/g	not tested
- Pseudomonas aeruginosa	absent on 1 g	not tested
- Staphylococcus aureus	absent on 1 g	not tested

* Not routinary test

APPROVED

Qualified Person
Dr. Luca Nannelli

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PEC: manufacturing@legalmail.it - CAPITALE SOCIALE €42.650.000 I.V. - C. F. / P. IVA E REG. IMPRESE 05006670482

STABILIMENTI DI PRODUZIONE: VIA SETTE SANTI 3, 50131 FIRENZE - VIA DI SCANDICCI 37, 50143 FIRENZE - VIA CAMPO DI PILE 67100 L'AQUILA

SOCIETA' SOGGETTA ALL'ATTIVITA' DI DIREZIONE E COORDINAMENTO DI A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE S.R.L. - VIA SETTE SANTI 3 - 50131 FIRENZE - P. IVA 00395270481