



A. MENARINI
MANUFACTURING LOGISTICS AND SERVICES

CERTIFICATE OF ANALYSIS

Product **BIFRIL 30 mg**
Code **55629U**
Zofenopril calcium 28 coated tablets 30 mg

Batch number **4513A**
Production 28/05/2024
Expiry date 28/05/2027
Manufacturing site: **A, Menarini MLS L'Aquila Italy**

Test	Results	Limits
Appearance	complies	(White, oblong coated tablets, with break marks on both sides)
Hardness	251	(≥ 40 N)
Active ingredient identification	complies	(comparable to standard)
Uniformity of mass	complies	(not more than two tablets exceed ± 7.5 % of the average mass, no tablet exceeds ± 15 % from average mass)
Loss on drying	2.3	(≤ 5 %)
Disintegration time	4	(≤ 10 min.)
Active ingredient assay	29.2	(28.5 – 31.5 mg/tablet)
Dissolution	100 (Min 100-Max 100) ($Q \geq 75\%$, after 45 min.)	
Related substances:		
SQ 26333	0.0	(≤ 0.2 I.I.)
SQ 26874	0.0	(≤ 0.2 I.I.)
Benzoic acid	0.0	(≤ 0.2 I.I.)
Total impurities	0.0	(< 0.3 I.I.)
Microbial contamination: *		(according Ph.Eur. 5.1.4)
TAMC	0	$\leq 10^3$ UFC/g
TYMC	0	$\leq 10^2$ UFC/g
Escherichia Coli	absent	absent in 1 g
Titanium dioxide identification	positive	Positive

* Not routinary test

Specification: In-house Specification TF0145

Approved according to EU GMP

The batch complies with the agreed specification and has been released by a Qualified Person

L'Aquila, **25 NOV. 2024**

Qualified Person
Dr. Giuseppe A. Irrera

A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L. CON SOCIO UNICO - SEDE LEGALE: VIA ROSOLINO PILO 4 - 50131 FIRENZE - TEL. +39 055 56801 - FAX: +39 055 582771

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



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A. MENARINI
MANUFACTURING LOGISTICS AND SERVICES

CERTIFICATE OF BATCH RELEASE

Product: BIFRIL 30MG 28CPR VN CP (Cod. 55629U)
Batch no.: 4513A
Expiry date: 28/05/2027
Number of packs: 2.280
Lot releaser (company): A. Menarini M.L.S. – L'Aquila
Releasing country: Italy
Destination country: VIETNAM

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and [when within the EU] with the requirements of the Marketing Authorization(s) of the destination country/countries

L'Aquila,
Place

25 NOV. 2024

Date

.....
Signature of Qualified Person
Giuseppe Antonio Irrera

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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



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L'Aquila,
Place

25 NOV. 2024
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Date

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Signature of Qualified Person
Giuseppe Antonio Irrera