



**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

**Certificate of Analysis**

<b>Product:</b>	BIFRIL 30MG 28CPR VN CP		
<b>Dosage:</b>	30 mg	<b>Pharmaceutical Form:</b>	Film-Coated Tablet
<b>Pack Size:</b>	28	<b>Pack Size Unit:</b>	pieces
<b>Packing Type:</b>	Blister		
<b>Internal Product Code n.:</b>	55629U		
<b>Batch no.:</b>	4519A	<b>Analysis Number:</b>	88091
<b>Number of packages/Quantity:</b>	2760 pieces	<b>Storage Conditions:</b>	do not store above 30°C
<b>Manufacturing date:</b>	Jul-2024	<b>Expiry Date:</b>	Jul-2027
<b>Date of Analysis:</b>	02-Oct-2024	<b>Date of Batch Release:</b>	02-Oct-2024
<b>Importing Country:</b>	Viet Nam	<b>Country manufacturer:</b>	Italy
<b>Name of manufacturer:</b>	N/A		
<b>Marketing authorization n.:</b>	VN3-34-18		
<b>Normative Documentation:</b>	N/A		

LIMS Lot Num: 88091

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Print date: 16-Oct-2024 11:07

Certificate of Analysis

Report Number 48294

LW\_ORA\_PHARMA\_PRD

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

**API Name:** ZOFENOPRIL CALCIUM PISA  
**API Manufacturer Site Information:** Luscochimica SpA  
Via Livornese 897  
56122 Pisa -La vettola Italy - Via Livornese 897  
56122 Pisa -La vettola Italy  
**API Manufacturer batch number:** ZFN C3030

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**API Name:** ZOFENOPRIL CALCIUM PISA  
**API Manufacturer Site Information:** Luscochimica SpA  
Via Livornese 897  
56122 Pisa -La vettola Italy - Via Livornese 897  
56122 Pisa -La vettola Italy  
**API Manufacturer batch number:** ZFN C3028

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**SF Name:** ZOFENOPRIL 30MG NC PISA  
**SF Manufacturer Site Information:** N/A  
**SF Manufacturer batch number:** N/A

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Print date: 16-Oct-2024 11:07

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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  
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**A. MENARINI**  
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Test	Specification	Results (with UOM)	Testing Frequency
Appearance	white, oblong tablets, scored on both sides sides.	Complies	
HPLC Identity			
Identity HPLC	complies	Complies	
UV Identity			
Identity UV	complies	Positive	
Identity Titanium dioxide			
Titanium dioxide Identity	complies	Complies	
Hardness	NLT 40 N	180 N	
Average weight	200-216 (208 ± 8 mg)	206 mg	
Uniformity of weight	No tablet can deviate from average weight by more than ± 15%, no more than 2 tablets can deviate from average weight by more than ± 7.5%	Complies	
Uniformity of dosing units			
Uniformity of dosage unities (mass variation)	complies to Ph. Eur.2.9.40	2.1	
Uniformity of dosage unities (mass variation)	complies to Ph. Eur.2.9.40	2.1	
Weight loss on drying	NMT 5%	2.0 %	
Disaggregation	NMT 10 minutes	3 min	
Assay	Between 28.5 and 31.5 mg/cpr (95-105%)	30.0 mg/tablet	
Dissolution test			
Dissolution A01	NMT 75% (Q) at 45 minutes	100 %	
Related Compounds			
SQ 26.333 (I.I.)	NMT 0.2%	0.00 %	
SQ 26.874 (I.I.)	NMT 0.2%	0.00 %	
Benzoic acid	NMT 0.2%	0.00 %	
Total degradation products	NMT 0.2%	0.00 %	
Single unidentified impurity	NMT 0.2%	0.00 %	
Total unidentified impurities	NMT 0.3%	0.00 %	

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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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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

Test	Specification	Results (with UOM)	Testing Frequency
<b>Microbiological requirements</b>			
E. Coli	Absent on 1g	Absent	
TAMC	NMT 1000 CFU/g	0 CFU/g	
TYMC	NMT 100 CFU/g	0 CFU/g	
TAMC	NMT 1000 CFU/g		
TYMC	NMT 100 CFU/g		
E. Coli	Absent on 1g		

Testing Frequency Explanation:

- Ax, test added every "x" lots
- Ry, test removed every "y" lots
- Iz, test performed every "z" days from last analyzed lot

LIMS Lot Num: 88091

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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

Manufacturing Site: Via Campo di Pile - 67100 L'Aquila (Italy)

**Final Status:** Released

E-signature for CoA

**QC Manager Signature:**

Name - Antonella Giuditta Giorgi

Date - 02-Oct-2024 16:07:40 (GMT +1)

**Disposition Signature:**

Name - Irrera Giuseppe A.

Date - 02-Oct-2024 18:23:27 (GMT +1)

Plant Director/Qualified Person

**Issuer Signature:**

Name - Massimo Renzetti

Date - 16-Oct-2024 11:07:46 (GMT +1)

Quality Control & Release Officer

**Date Format Explanation:** dd-MMM-yyyy

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**A. MENARINI**  
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<b>Dosage:</b>	30 mg	<b>Pharmaceutical Form:</b>	Film-Coated Tablet
<b>Pack Size:</b>	28	<b>Pack Size Unit:</b>	pieces
<b>Packing Type:</b>	Blister		
<b>Internal Product Code n.:</b>	55629U		
<b>Batch no.:</b>	4519A	<b>Analysis Number:</b>	88091
<b>Number of packages/Quantity:</b>	2760 pieces	<b>Storage Conditions:</b>	do not store above 30°C
<b>Manufacturing date:</b>	Jul-2024	<b>Expiry Date:</b>	Jul-2027
<b>Date of Analysis:</b>	02-Oct-2024	<b>Date of Batch Release:</b>	02-Oct-2024
<b>Importing Country:</b>	Viet Nam	<b>Country manufacturer:</b>	Italy
<b>Name of manufacturer:</b>	N/A		
<b>Marketing authorization n.:</b>	VN3-34-18		
<b>Normative Documentation:</b>	N/A		

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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

**API Name:** ZOFENOPRIL CALCIUM PISA  
**API Manufacturer Site Information:** Lusochimica SpA  
Via Livornese 897  
56122 Pisa -La vettola Italy - Via Livornese 897  
56122 Pisa -La vettola Italy  
**API Manufacturer batch number:** ZFN C3030

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**API Name:** ZOFENOPRIL CALCIUM PISA  
**API Manufacturer Site Information:** Lusochimica SpA  
Via Livornese 897  
56122 Pisa -La vettola Italy - Via Livornese 897  
56122 Pisa -La vettola Italy  
**API Manufacturer batch number:** ZFN C3028

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**SF Name:** ZOFENOPRIL 30MG NC PISA  
**SF Manufacturer Site Information:** N/A  
**SF Manufacturer batch number:** N/A

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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

Test	Specification	Results (with UOM)	Testing Frequency
Appearance	white, oblong tablets, scored on both sides sides.	Complies	
HPLC Identity			
Identity HPLC	complies	Complies	
UV Identity			
Identity UV	complies	Positive	
Identity Titanium dioxide			
Titanium dioxide Identity	complies	Complies	
Hardness	NLT 40 N	180 N	
Average weight	200-216 (208 ± 8 mg)	206 mg	
Uniformity of weight	No tablet can deviate from average weight by more than ± 15%, no more than 2 tablets can deviate from average weight by more than ± 7.5%	Complies	
Uniformity of dosing units			
Uniformity of dosage units (mass variation)	complies to Ph. Eur.2.9.40	2.1	
Uniformity of dosage units (mass variation)	complies to Ph. Eur.2.9.40	2.1	
Weight loss on drying	NMT 5%	2.0 %	
Disaggregation	NMT 10 minutes	3 min	
Assay	Between 28.5 and 31.5 mg/cpr (95-105%)	30.0 mg/tablet	
Dissolution test			
Dissolution A01	NMT 75% (Q) at 45 minutes	100 %	
Related Compounds			
SQ 26.333 (I.I.)	NMT 0.2%	0.00 %	
SQ 26.874 (I.I.)	NMT 0.2%	0.00 %	
Benzoic acid	NMT 0.2%	0.00 %	
Total degradation products	NMT 0.2%	0.00 %	
Single unidentified impurity	NMT 0.2%	0.00 %	
Total unidentified impurities	NMT 0.3%	0.00 %	

LIMS Lot Num: 88091

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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

Test	Specification	Results (with UOM)	Testing Frequency
<b>Microbiological requirements</b>			
E. Coli	Absent on 1g	Absent	
TAMC	NMT 1000 CFU/g	0 CFU/g	
TYMC	NMT 100 CFU/g	0 CFU/g	
TAMC	NMT 1000 CFU/g		
TYMC	NMT 100 CFU/g		
E. Coli	Absent on 1g		

Testing Frequency Explanation:

- Ax, test added every "x" lots
- Ry, test removed every "y" lots
- Iz, test performed every "z" days from last analyzed lot

LIMS Lot Num: 88091

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**A. MENARINI**  
MANUFACTURING LOGISTICS AND SERVICES

Manufacturing Site: Via Campo di Pile - 67100 L'Aquila (Italy)

**Final Status:** Released

E-signature for CoA

<b>QC Manager Signature:</b>	Name - Antonella Giuditta Giorgi	Date - 02-Oct-2024 16:07:40 (GMT +1)
<b>Disposition Signature:</b>	Name - Irrera Giuseppe A.	Date - 02-Oct-2024 18:23:27 (GMT +1)
<b>Issuer Signature:</b>	Plant Director/Qualified Person Name - Massimo Renzetti	Date - 16-Oct-2024 11:07:46 (GMT +1)
	Quality Control & Release Officer	

**Date Format Explanation:** dd-MMM-yyyy

LIMS Lot Num: 88091

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