

# Certificate of Compliance



Latina S.r.l.

Product: PATHOZONE 10MLX10SYR H

Lot number: 43501802

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Inspiring Partner for Efficient Solutions

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**Product** PATHOZONE 10MLX10SYR H

**Lot number** 43501802

**Manufacturing date** 03/2014  
**Expiration date** 08/2015

Test	Specifications	Results	Methods
Appearance	White/Whitish homog.oily Susp.	PASS	A 28.01
SpecificGravity	0.90 - 0.94	0.91	EP 2.2.5
Extract.Amount	Meets Test	PASS	EP 2.9.28
Impurities	Unknown: Max 1%	0 %	GTP1196
Oversize	Max 100 um	PASS	93 GIP 025
Id.Cefoperazone	Meets Test (HPLC)	PASS	C 89.02
Assay Cefoperaz	262.5-287.5 mg/10ml HPLC	272.2 mg/10 ml	
Impurit. Total	Max 6%	0 %	GTP1196
Impurities	T 1551 F: Max 3%	0 %	
Impurities	T 1551 B: Max 1%	0 %	
Impurities	T 1551 E: Max 2%	0 %	
Assay Alphanoc.	90-110% of LC (4.6 mg/10ml)	4.58 mg/10 ml	USP <551>
Water	0.3% max	0.2 %	W 1.0
Particle Size	Avg 15-25 u	20 u	93 GIP 025
Sterility	Meets Test	PASS	EP 2.6.1

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.  
This certificate was created by a validated system and is valid without manual signature.

**Batch Released**

**Date : Jun 13, 2014**

Haupt Pharma Latina S.r.l. was formerly known as Pfizer Italia S.r.l.

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Commercial Register Latina 174220  
VAT: IT06385830980

An enterprise of the  
Haupt Pharma Group

Diszpó: PN-ZA14001040 Vevő: Alpha-Vet 8000  
Szállító: Zoetis Hungary Kft.  
Az eredetiről készült hiteles másolat.

File név: PN00007974 Egyedi sorszám: PN0000072980 1 másolat  
Oldal/Lap 2 / 1 Anyaglap: PN0319/14  
Nyomtatás dátuma: 2014.11.06

**CertEx v3.03**

