

Certificate of Compliance



Latina S.r.l.

Product: PATHOZONE 10MLX10SYR H

Lot number: 43502202

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Inspiring Partner for Efficient Solutions

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Product PATHOZONE 10MLX10SYR H

Lot number 43502202

Manufacturing date 04/2014

Expiration date 09/2015

Test	Specifications	Results	Methods
Appearance	White/Whitish homog.oily Susp.	PASS	A 28.01
Specific Gravity	0.90 - 0.94	0.92	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 GTP 025
Id.Cefoperazone	Meets Test (HPLC)	PASS	C 89.02
Assay Cefoperaz	262.5-287.5 mg/10ml HPLC	266.4 mg/10 ml	
Impurit. Total	Max 6%	1 %	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)	4.48 mg/10 ml	USP <551>
Water	0.3% max	0.2 %	W 1.0
Particle Size	Avg 15-25 u	18 u	93 GTP 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 30, 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: IT06385930960

An enterprise of the
Haupt Pharma Group

Diszpó: PN-ZA14001204 Vevő: Alpha-Vet 8000

File név: PN00008037 Egyedi sorszám: PN0000073479 10 másolat

Szállító: Zoetis Hungary Kft.

Oldal/Lap 2 / 1 Anyaglap: PN0299/14

Az eredetiről készült hiteles másolat.

Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

Nyomatás dátuma: 2014.12.11

CertEx v3.03a

