



ZAMBON SPA

Registered office:

Via Lillo del Duca, 10 - 20091

Bresso(MI)-Italy

Phone +39 02 665 241

Fax: +39 02 66 501 492

Share Capital € 5,649,880,00 fully paid up

Milan Court Register of Companies

registration No. 1814364

Taxpayer Identification No. and VAT

registration No. IT 05341830965

Single-member company

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Pharmaceutical Plant:

Via della Chimica 9 - 36100

Vicenza(VI)-Italy

Phone +39 0444 968.911 - Fax: +39 0444

348.049

Batch	20190101	Inspection Lot	890000014734
Material	D161583 NEBIVITAE 5MG 28 COMPRIMIDOS	CL V	
Prod.Date	29.01.2019	Expir.Date	01-2022
Order		Date appr.	07.03.2019
Quantity	8.899 PCS		

Characteristic	Specification	Results
APPEARANCE	round convex tablets, white coloured, with cross midline fracture line	Compliant
IDENT. NEBIVOLOL (HPLC)	positive	Compliant
IDENT. NEBIVOLOL (UV)	positive	Compliant
DISINTEGRATION TIME, within	<= 15 min.	4
SUBDIVISION OF TABLET (Ph.Eur.)	conforms	Compliant
WATER (K. F.)	<= 8,00 %	3,60
DISSOLUTION (after 30 min, 6 tabl.)	conforms (Q=75%, time=30min.)	Compliant
DISSOLUTION: AVERAGE - % of decl.	>= 80,0 %	97,6
DISSOLUTION: MIN. VALUE -% of decl.	>= 80,0 %	94,0
DISSOLUTION: MAX. VALUE -% of decl.	>= 80,0 %	100,5
NEBIVOLOL/tablet (HPLC)	4,75 - 5,25 mg	5,00
% OF DECLARED	95,0 - 105,0 %	100,0
IMPURITY (HPLC) RRT 0,76	<= 0,20 %	0,00
EACH UNKNOWN IMPURITY (HPLC)	<= 0,20 %	0,00
TOTAL IMPURITIES (HPLC)	<= 1,00 %	0,00
NEBIVOLOL PEAK 1 (HPLC)	48,5 - 51,5 %	50,9
NEBIVOLOL PEAK 2 (HPLC)	48,5 - 51,5 %	49,1
UNIFORMITY OF DOSAGE UNITS: C.U.	conforms to Ph. Eur.	Compliant
CHEMICAL CONTROL LAB. REF.		241601
RETAINED SAMPLE CONTROL	conforms	Compliant
TOTAL AEROBIC MICROBIAL COUNT/g	<= 1000 cfu	0
TOTAL MOULDS AND YEASTS/g	<= 100 cfu	0
Escherichia coli/1 g	absent	Compliant
BIOLOGICAL CONTROL LAB. REF.		52428

Batch meets the specifications

Print Date 13.03.2019

Quality Control Head

Note:

Marco Cristini
Quality Control Head
13 MAR 2019



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Pharmaceutical Plant:
Via della Chimica 9 - 36100
Vicenza (VI) - Italy
Phone +39 0444 968.911 - Fax: +39 0444
348.049

Batch	20190101A	Inspection Lot	040000197941
Material	D161583 NEBIVITAE 5MG 28 COMPRIMIDOS	CL V	
Prod.Date	29.01.2019	Expir.Date	01-2022
Order	20040772	Date appr.	04.04.2019
Quantity	3.365 PCS		

Characteristic	Specification	Results
APPEARANCE	round convex tablets, white coloured, with cross midline fracture line	Compliant
IDENT. NEBIVOLOL (HPLC)	positive	Compliant
IDENT. NEBIVOLOL (UV)	positive	Compliant
DISINTEGRATION TIME, within	<= 15 min.	4
SUBDIVISION OF TABLET (Ph.Eur.)	conforms	Compliant
WATER (K. F.)	<= 8,00 %	3,60
DISSOLUTION (after 30 min, 6 tabl.)	conforms (Q=75%, time=30min.)	Compliant
DISSOLUTION: AVERAGE - % of decl.	>= 80,0 %	97,6
DISSOLUTION: MIN. VALUE -% of decl.	>= 80,0 %	94,0
DISSOLUTION: MAX. VALUE -% of decl.	>= 80,0 %	100,5
NEBIVOLOL/tablet (HPLC)	4,75 - 5,25 mg	5,00
% OF DECLARED	95,0 - 105,0 %	100,0
IMPURITY (HPLC) RRT 0,76	<= 0,20 %	0,00
EACH UNKNOWN IMPURITY (HPLC)	<= 0,20 %	0,00
TOTAL IMPURITIES (HPLC)	<= 1,00 %	0,00
NEBIVOLOL PEAK 1 (HPLC)	48,5 - 51,5 %	50,9
NEBIVOLOL PEAK 2 (HPLC)	48,5 - 51,5 %	49,1
UNIFORMITY OF DOSAGE UNITS: C.U.	conforms to Ph. Eur.	Compliant
CHEMICAL CONTROL LAB. REF.		241601
RETAINED SAMPLE CONTROL	conforms	Compliant
TOTAL AEROBIC MICROBIAL COUNT/g	<= 1000 cfu	0
TOTAL MOULDS AND YEASTS/g	<= 100 cfu	0
Escherichia coli/1 g	absent	Compliant
BIOLOGICAL CONTROL LAB. REF.		52617

Batch meets the specifications

Print Date 05.04.2019

Quality Control Head

Note:

Marco Cristini
Quality Control Head
05 APR. 2019