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Olon S.p.A.
Sede Legale
Strada Rivoltana km 6/7
Rodano (MI)

Lote 0110517



Certificate of analysis

Product **BEZAFIBRATE MILLED EP9** Code N° **63310** Batch N° **1630001386**

Manufacturing date **OCT 2016** Retest date (where applicable) **JUL 2021**

Analysis Number **Q2PF100702** Bulletin **2P1601355**

Test	References	Result	M.U.	Limits
Description	EP	White cryst. powder	--	White to off-wh. cr. powder
Solubility	EP	Complies	--	Insol. in water, freely sol. in DMF, sparingly sol. in acetone and in EtOH 96%, sol. in dil. alkali
IR	EP 2.2.24	Complies with standard	--	Complies with standard
TLC	EP 2.2.27	Complies with standard	--	Complies with standard
HPLC	Internal Method	Complies with standard	--	Complies with standard
Melting point	EP 2.2.14	183	°C	181 ÷ 185
Appearance of solution	EP 2.2.1, EP 2.2.2 Meth. II	Clear, n.m.t. BY7	--	Clear, n.m.t. BY5
Loss on drying	EP 2.2.32	0,14	%	≤ 0,50
Assay (NaOH)	EP	100,0	%	98,0 + 102,0
EP Imp. A (4 chlorobenzoyl tyramine)	EP 2.2.29	0,07	%	≤ 0,50
EP Imp. B (4 chlorobenzoic acid)	EP 2.2.29	<0,05	%	≤ 0,50
EP Imp. C (bezafibrate methylester)	EP 2.2.29	0,05	%	≤ 0,50
EP Imp. D (bezafibrate ethylester)	EP 2.2.29	<0,05	%	≤ 0,50
EP Imp. E (bezafibrate buthylester)	EP 2.2.29	Not possible with our process	%	≤ 0,50
Any unspecified impurity	EP 2.2.29	0,07	%	≤ 0,10
Total impurities	EP 2.2.29	0,20	%	≤ 0,75
Residual solvents: MIBK	Internal Method	351	ppm	≤ 1000
Sulphated Ash	EP 2.4.14	0,01	%	≤ 0,10
Heavy metals	EP 2.4.8 Met. C	<10	ppm	NMT 10
Chlorides	EP 2.4.4	<300	ppm	NMT 300
d(0,9)	Internal Method	94	µm	< 100
Total aerobic microbial count (TAMC)	EP 2.6.12	<25	cfu/g	≤ 1000
Total yeast and mould counts (TYMC)	EP 2.6.12	<25	cfu/g	≤ 100
Escherichia coli	EP 2.6.13	Negative/g	--	Negative/g
Salmonella	EP 2.6.13	Negative/10g	--	Negative/10g
Pseudomonas aeruginosa	EP 2.6.13	Negative/g	--	Negative/g
S.Aureus	EP 2.6.13	Negative/g	--	Negative/g

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivoltana km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00851030181

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Analysis Date

11/23/2016

Reissued on

04/21/2017

QC Manager



Reviewed by Qualified Person

Notes:

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A).
Manufacturing site of the Active Pharmaceutical Ingredient: Stabilmanto di Dorno

Handwritten signature
24/04/17

Result: Analysis Report

User Name: piccolo

2135

761816

Security Level: 2

Sample Details		
Sample ID: BZM 1630001386	Run Number: 3	Measured:
Sample File: BZM	Record Number: 1120	Analysed: Wed 26 Oct 2016 11.35
Sample Path: C:\SIZER\MU\DATA\		Result Source: Averaged
Sample Notes:		

System Details		Measured Beam Obscuration: 10.9 %
Sampler:		
Presentation: 4QFD	[Particle R.I. = (1.7290, 0.0100); Dispersant R.I. = 1.3300]	
Analysis Model: Polydisperse		Residual: 0.321 %
Modifications: None		

Result Statistics			
Distribution Type: Volume	Concentration = 0.0138 %Vol	Density = 1.000 g / cub. cm	Specific S.A. = 0.6487 sq. m / g
Mean Diameters:	D (v, 0.1) = 3.55 um	D (v, 0.5) = 21.52 um	D (v, 0.9) = 94.34 um
D [4, 3] = 37.77 um	D [3, 2] = 9.25 um	Span = 4.218E+00	Uniformity = 1.295E+00

Size Low (um)	In %	Size High (um)	Under%	Size Low (um)	In %	Size High (um)	Under%
0.31	0.00	0.36	0.00	10.48	4.07	12.21	31.44
0.36	0.00	0.42	0.00	12.21	4.57	14.22	36.00
0.42	0.00	0.49	0.00	14.22	4.98	16.57	40.98
0.49	0.00	0.58	0.00	16.57	5.23	19.31	46.21
0.58	0.00	0.67	0.00	19.31	5.31	22.49	51.53
0.67	0.09	0.78	0.09	22.49	5.24	26.20	56.77
0.78	0.24	0.91	0.34	26.20	5.07	30.53	61.84
0.91	0.42	1.06	0.76	30.53	4.84	35.56	66.69
1.06	0.61	1.24	1.37	35.56	4.57	41.43	71.26
1.24	0.80	1.44	2.17	41.43	4.26	48.27	75.52
1.44	0.98	1.68	3.15	48.27	3.91	56.23	79.43
1.68	1.13	1.95	4.28	56.23	3.54	65.51	82.97
1.95	1.29	2.28	5.57	65.51	3.18	76.32	86.15
2.28	1.42	2.65	6.98	76.32	2.84	88.91	88.99
2.65	1.53	3.09	8.52	88.91	2.50	103.58	91.49
3.09	1.64	3.60	10.15	103.58	2.17	120.67	93.65
3.60	1.75	4.19	11.90	120.67	1.84	140.58	95.49
4.19	1.89	4.88	13.79	140.58	1.51	163.77	97.00
4.88	2.06	5.69	15.85	163.77	1.20	190.80	98.20
5.69	2.31	6.63	18.16	190.80	0.90	222.28	99.10
6.63	2.63	7.72	20.79	222.28	0.60	258.95	99.70
7.72	3.05	9.00	23.83	258.95	0.30	301.68	100.00
9.00	3.54	10.48	27.37				

