

Stabilimento di Dorno
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Lot: 0010516

Certificate of analysis

Product **BEZAFIBRATE MILLED EP8** Code N° **63310** Batch N° **1530000928**

Manufacturing date **JUN 2015** Retest date (where applicable) **MAY 2020**

Analysis Number **P2PF062001** Bulletin **2P1500873**

Test	References	Result	M.U.	Limits
Description	EP	Off-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	0,10	%	≤ 0,50
Assay (NaOH)	EP	99,8	%	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	0,09	%	≤ 0,50
EP Imp. D (bezafibrate ethylester)	EP 2.2.29	<0,05	%	≤ 0,50
EP Imp. E (bezafibrate butylester)	EP 2.2.29	Not possible with our process	%	≤ 0,50
Any unspecified impurity	EP 2.2.29	0,05	%	≤ 0,10
Total impurities	EP 2.2.29	0,22	%	≤ 0,75
Residual solvents: MIBK	Internal Method	306	ppm	≤ 1000
Sulphated Ash	EP 2.4.14	0,04	%	≤ 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	97	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

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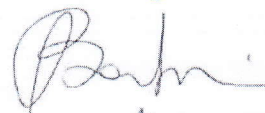
Analysis Number **P2PF062001** Bulletin **2P1500873**

Test	References	Result	M.U.	Limits

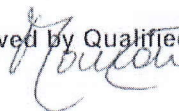
Analysis Date

07/06/2015

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: Stabilimento di Dorno



olon s.p.a.

2/35 / 26/6/15

Result: Solmag Report

User Name: testori

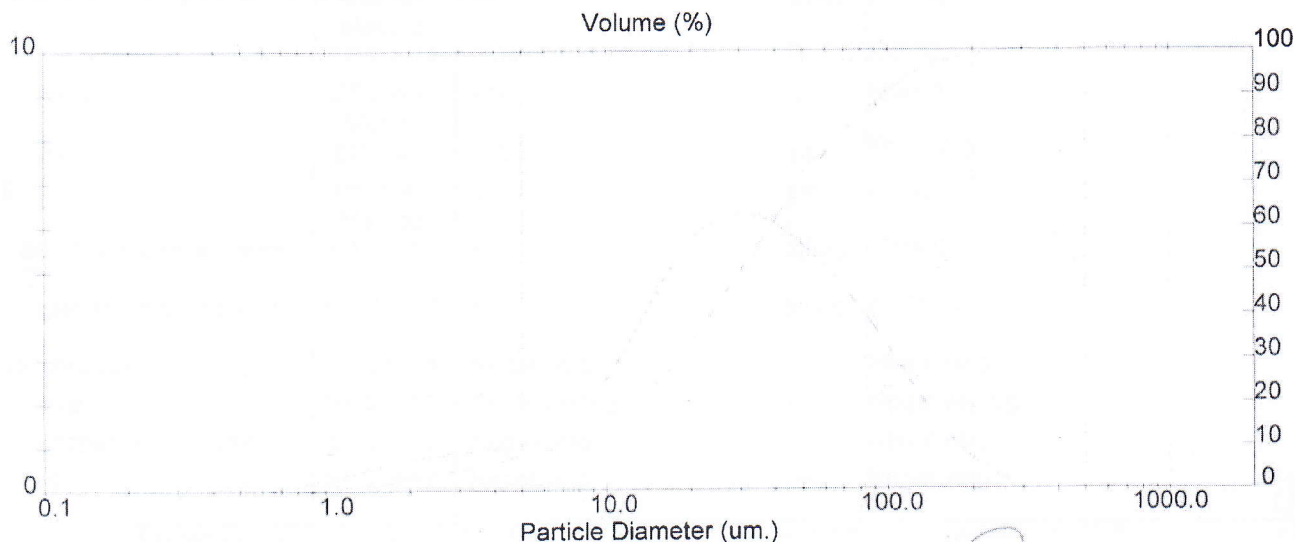
Security Level: 1

Sample Details		
Sample ID: BZM 1530000928	Run Number: 54	Measured:
Sample File: BZM	Record Number: 816	Analysed: Fri 26 Jun 2015 10:39
Sample Path: C:\SIZERMU\DATA\		Result Source: Averaged
Sample Notes:		

System Details		
Sampler:		Measured Beam Obscuration: 12.0 %
Presentation: 4QFD	[Particle R.I. = (1.7290, 0.0100); Dispersant R.I. = 1.3300]	
Analysis Model: Polydisperse		Residual: 0.247 %
Modifications: None		

Result Statistics			
Distribution Type: Volume	Concentration = 0.0210 %Vol	Density = 1.000 g / cub. cm	Specific S.A. = 0.4478 sq. m / g
Mean Diameters:	D (v, 0.1) = 6.65 um	D (v, 0.5) = 30.04 um	D (v, 0.9) = 97.02 um
D [4, 3] = 43.15 um	D [3, 2] = 13.40 um	Span = 3.009E+00	Uniformity = 9.310E-01

Size (um)	Volume Under %	Size (um)	Volume Under %	Size (um)	Volume Under %	Size (um)	Volume Under %
0.335	0.00	1.87	2.28	10.40	15.64	57.97	75.38
0.359	0.00	2.00	2.58	11.14	16.92	62.10	77.67
0.384	0.00	2.14	2.91	11.93	18.34	66.51	79.85
0.411	0.00	2.29	3.25	12.78	19.91	71.25	81.94
0.441	0.00	2.46	3.60	13.69	21.64	76.31	83.93
0.472	0.00	2.63	3.96	14.66	23.52	81.74	85.81
0.506	0.00	2.82	4.34	15.71	25.55	87.56	87.58
0.542	0.00	3.02	4.72	16.83	27.73	93.79	89.23
0.580	0.00	3.23	5.12	18.02	30.04	100.5	90.76
0.621	0.00	3.46	5.52	19.30	32.47	107.6	92.15
0.666	0.01	3.71	5.93	20.68	35.02	115.3	93.41
0.713	0.03	3.97	6.35	22.15	37.66	123.5	94.54
0.764	0.06	4.26	6.77	23.73	40.37	132.2	95.54
0.818	0.11	4.56	7.21	25.41	43.14	141.7	96.40
0.876	0.18	4.88	7.66	27.22	45.94	151.7	97.14
0.938	0.27	5.23	8.13	29.16	48.77	162.5	97.77
1.01	0.38	5.60	8.63	31.23	51.61	174.1	98.29
1.08	0.50	6.00	9.15	33.45	54.44	186.5	98.73
1.15	0.65	6.43	9.71	35.83	57.25	199.7	99.07
1.24	0.82	6.89	10.32	38.38	60.02	213.9	99.35
1.32	1.02	7.38	10.99	41.11	62.75	229.2	99.57
1.42	1.23	7.90	11.73	44.04	65.42	245.5	99.75
1.52	1.46	8.46	12.55	47.17	68.03	262.9	99.86
1.63	1.72	9.06	13.46	50.53	70.56	281.6	99.93
1.74	1.99	9.71	14.49	54.12	73.02	301.7	100.00



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