



Certificate of analysis

Product **BEZAFIBRATE MILLED EP8** Code N° **63310** Batch N° **1630000419**

Manufacturing date **MAR 2016** Retest date (where applicable) **FEB 2021**

Analysis Number **Q2PF033101** Bulletin **2C1600089** Farmaceutica Paraguaya SA

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	0,13	%	≤ 0,50
Assay (NaOH)	EP	99,6	%	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	0,06	%	≤ 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	0,06	%	≤ 0,10
Total impurities	EP 2.2.29	0,20	%	≤ 0,75
Residual solvents: MIBK	Internal Method	273	ppm	≤ 1000
Sulphated Ash	EP 2.4.14	0,02	%	≤ 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	80	µm	< 100
Colour of solution	Internal Method	0,018	ABS	≤ 0,070
Extraneous particles	Internal Method	<6	ppm	NMT 6
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

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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

Analysis Date

04/22/2016

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

Result: Analysis Report

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piccio

User Name: piccio

Security Level: 2

Sample Details		
Sample ID: BZM 1630000419	Run Number: 6	Measured:
Sample File: BZM	Record Number: 968	Analysed: Thu 21 Apr 2016 9.43
Sample Path: C:\SIZERMU\DATA\		Result Source: Averaged
Sample Notes:		

System Details		Measured Beam Obscuration: 11.1 %
Sampler:		
Presentation: 4QFD	[Particle R.I. = (1.7290, 0.0100); Dispersant R.I. = 1.3300]	
Analysis Model: Polydisperse		Residual: 0.417 %
Modifications: None		

Result Statistics			
Distribution Type: Volume	Concentration = 0.0113 %Vol	Density = 1.000 g / cub. cm	Specific S.A. = 0.7079 sq. m / g
Mean Diameters:	D (v, 0.1) = 3.22 um	D (v, 0.5) = 18.73 um	D (v, 0.9) = 80.22 um
D [4, 3] = 33.05 um	D [3, 2] = 8.48 um	Span = 4.111E+00	Uniformity = 1.293E+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	4.54	12.21	34.65
0.36	0.00	0.42	0.00	12.21	5.12	14.22	39.77
0.42	0.00	0.49	0.00	14.22	5.57	16.57	45.34
0.49	0.00	0.58	0.00	16.57	5.82	19.31	51.16
0.58	0.00	0.67	0.00	19.31	5.81	22.49	56.97
0.67	0.09	0.78	0.09	22.49	5.59	26.20	62.56
0.78	0.26	0.91	0.35	26.20	5.22	30.53	67.78
0.91	0.47	1.06	0.82	30.53	4.76	35.56	72.54
1.06	0.69	1.24	1.51	35.56	4.27	41.43	76.81
1.24	0.91	1.44	2.42	41.43	3.78	48.27	80.59
1.44	1.11	1.68	3.53	48.27	3.30	56.23	83.90
1.68	1.28	1.95	4.81	56.23	2.87	65.51	86.77
1.95	1.44	2.28	6.25	65.51	2.49	76.32	89.26
2.28	1.58	2.65	7.83	76.32	2.17	88.91	91.43
2.65	1.70	3.09	9.53	88.91	1.89	103.53	93.32
3.09	1.80	3.60	11.33	103.53	1.63	120.67	94.95
3.60	1.90	4.19	13.23	120.67	1.39	140.58	96.33
4.19	2.04	4.88	15.27	140.58	1.17	163.77	97.50
4.88	2.22	5.69	17.49	163.77	0.96	190.80	98.46
5.69	2.49	6.63	19.98	190.80	0.75	222.28	99.20
6.63	2.86	7.72	22.85	222.28	0.52	258.95	99.73
7.72	3.34	9.00	26.19	258.95	0.27	301.68	100.00
9.00	3.92	10.48	30.11				

