



Le: 0050418

Certificate of analysis

Product **BEZAFIBRATE MILLED EP9** Code N° **63310** Batch N° **1830000183**

Manufacturing date **FEB 2018** Retest date (where applicable) **DEC 2022**

Analysis Number **S2PF020202** Bulletin **2P1800155**

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	182	°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	0,09	%	≤ 0,50
Assay (NaOH)	EP	99,8	%	98,0 ÷ 102,0
EP Imp. A (4 chlorobenzoyl tyramine)	EP 2.2.29	0,08	%	≤ 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	0,15	%	≤ 0,75
Residual solvents: MIBK	Internal Method	355	ppm	≤ 1000
Sulphated Ash	EP 2.4.14	0,03	%	≤ 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	78	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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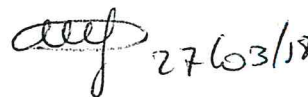
Analysis Date

03/26/2018

QC Manager



Reviewed by Qualified Person

 27/03/18

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

BZM 63310

16/03/18
C3

OLON S.p.A. Dorno (PV)



Measurement Details

Operator Name piccolo
Sample Name Average of 'Bezafibrato_63310'
Lotto 1830000183
SOP File Name Bezafibrato Macinato_BZM.msop

Measurement Details

Analysis Date Time 16/03/2018 16:39:46
Measurement Date Time 16/03/2018 16:39:46
Result Source Averaged

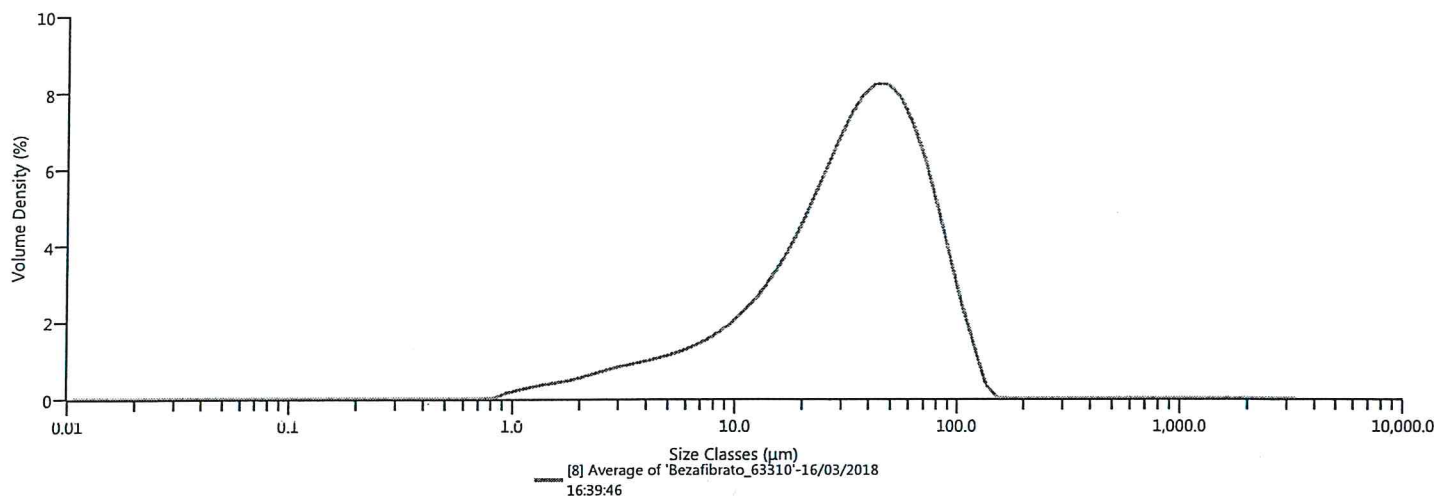
Analysis

Particle Name Bezafibrato
Particle Refractive Index 1,729
Particle Absorption Index 0,010
Dispersant Name Water
Dispersant Refractive Index 1,330
Scattering Model Mie
Analysis Model General Purpose
Weighted Residual 0,36 %
Laser Obscuration 11,37 %

Result

Concentration 0,0210 %
Span 2,041
Uniformity 0,622
Specific Surface Area 394,0 m²/kg
D [3;2] 15,2 µm
D [4;3] 39,3 µm
Dv (10) 7,19 µm
Dv (50) 34,6 µm
Dv (90) 77,8 µm
Dv (95) 92,1 µm

Frequency (compatible)



Result

Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In
0,0100	0,00	0,0597	0,00	0,357	0,00	2,13	0,53	12,7	2,41	76,0	4,20	454	0,00
0,0114	0,00	0,0679	0,00	0,405	0,00	2,42	0,61	14,5	2,80	86,4	3,11	516	0,00
0,0129	0,00	0,0771	0,00	0,460	0,00	2,75	0,68	16,4	3,27	98,1	2,06	586	0,00
0,0147	0,00	0,0876	0,00	0,523	0,00	3,12	0,74	18,7	3,81	111	1,15	666	0,00
0,0167	0,00	0,0995	0,00	0,594	0,00	3,55	0,80	21,2	4,40	127	0,25	756	0,00
0,0189	0,00	0,113	0,00	0,675	0,00	4,03	0,86	24,1	5,03	144	0,00	859	0,00
0,0215	0,00	0,128	0,00	0,767	0,00	4,58	0,93	27,4	5,65	163	0,00	976	0,00
0,0244	0,00	0,146	0,00	0,872	0,12	5,21	1,01	31,1	6,21	186	0,00	1110	0,00
0,0278	0,00	0,166	0,00	0,991	0,19	5,92	1,11	35,3	6,64	211	0,00	1260	0,00
0,0315	0,00	0,188	0,00	1,13	0,26	6,72	1,24	40,1	6,88	240	0,00	1430	0,00
0,0358	0,00	0,214	0,00	1,28	0,31	7,64	1,39	45,6	6,88	272	0,00	1630	0,00
0,0407	0,00	0,243	0,00	1,45	0,35	8,68	1,58	51,8	6,59	310	0,00	1850	0,00
0,0463	0,00	0,276	0,00	1,65	0,39	9,86	1,80	58,9	6,02	352	0,00	2100	0,00
0,0526	0,00	0,314	0,00	1,88	0,45	11,2	2,08	66,9	5,20	400	0,00	2390	0,00



BZM 63310

OLON S.p.A. Dorno (PV)



Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
8	Average of 'Bezafibrato_63310'	Unsigned		

