



Certificate of Analysis

Product name **BEZAFIBRATE MILLED EP9**

Product Code **63310**
Batch Number **1930000602**
Order **1191129**
Quantity **100,000 KG**
Manufacturing date **17/04/2019**
Re-test date **19/02/2024**
Certificate Nr. **100000003822**
Batch Size **1.250,000 KG**
Ref. Order **PO 2019 - I /176**

Test References Specification M.L. Result

Appearance	EP monograph	Crystalline powder	White to almost white	Complies	Crystalline powder	Almost white	Complies
Colour	EP monograph	White to almost white	Complies	Complies	Complies	Complies	Complies
Solubility	EP monograph	White to almost white	Complies	Complies	Complies	Complies	Complies
DMF, sparingly soluble in acetone and insoluble in water, freely soluble in EtOH 96%, soluble in diluted alkali	EP monograph	White to almost white	Complies	Complies	Complies	Complies	Complies
IR identification	EP 2.2.24	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard
TLC identification	EP 2.2.27	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard
HPLC identification	Internal Method	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard	Complies with standard
Melting point identification	EP 2.2.14	181 - 185	Clear	NMT BY5	Clear	NMT BY7	183
Appearance of solution	EP 2.2.1	Clear	NMT BY5	Clear	NMT BY7	Clear	183
Colour of solution	EP 2.2.2 Method II	NMT BY5	Clear	NMT BY7	Clear	NMT BY7	183
Loss on drying	EP 2.2.32	<= 0,50	98,0 - 102,0	%	100,4	%	0,11
Assay (NaOH)	EP monograph	98,0 - 102,0	%	100,4	%	0,11	0,08
EP Imp. A (4-chlorobenzoyl tyramine)	EP 2.2.29 (HPLC)	<= 0,50	%	0,11	%	< Disregard limit (0,05)	0,08
EP Imp. B (4-chlorobenzoic acid)	EP 2.2.29 (HPLC)	<= 0,50	%	0,11	%	< Disregard limit (0,05)	0,08
EP Imp. C (bezafibrate methylester)	EP 2.2.29 (HPLC)	<= 0,50	%	0,11	%	< Disregard limit (0,05)	0,08
EP Imp. D (bezafibrate ethylester)	EP 2.2.29 (HPLC)	<= 0,50	%	0,11	%	< Disregard limit (0,05)	0,08
EP Imp. E (bezafibrate butylester)	EP 2.2.29 (HPLC)	<= 0,50	%	0,11	%	< Disregard limit (0,05)	0,08
Any unspecified impurity	EP 2.2.29 (HPLC)	<= 0,10	%	0,11	%	< Disregard limit (0,05)	0,08
Total impurities	EP 2.2.29 (HPLC)	<= 0,75	%	0,11	%	< Disregard limit (0,05)	0,08
Residual solvents: MIBK	Internal Method (GC)	<= 1000	ppm	347	ppm	0,19	347
Sulphated ash	EP 2.4.14	<= 0,10	%	0,03	%	< 10 ppm	0,03
Heavy metals	EP 2.4.8 Method C	NMT 10 ppm	%	0,03	%	< 300 ppm	0,03
Chlorides	EP 2.4.4	NMT 300 ppm	%	0,03	%	< 10 ppm	0,03
Total aerobic microbial count (TAMC)	EP 2.6.12	<= 1000	CFU/g	0,03	CFU/g	< LOQ (25)	0,03
Total yeast and mould counts (TYMC)	EP 2.6.12	<= 100	CFU/g	0,03	CFU/g	< LOQ (25)	0,03
Escherichia coli	EP 2.6.13	Absent/g	Absent/g	0,03	Absent/g	Absent/g	0,03
Salmonella	EP 2.6.13	Absent/10g	Absent/10g	0,03	Absent/10g	Absent/10g	0,03
Pseudomonas aeruginosa	EP 2.6.13	Absent/g	Absent/g	0,03	Absent/g	Absent/g	0,03
Staphylococcus aureus	EP 2.6.13	Absent/g	Absent/g	0,03	Absent/g	Absent/g	0,03

Alessandra Barbieri

QC Manager

Approved June 20, 2019

Qualified Person

Released June 21, 2019

Approved June 21, 2019

Emission June 21, 2019

Capitale Sociale € 40.000.000 I.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - 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. 00651030181

Modello: 63310_S / 1



Certificate of Analysis

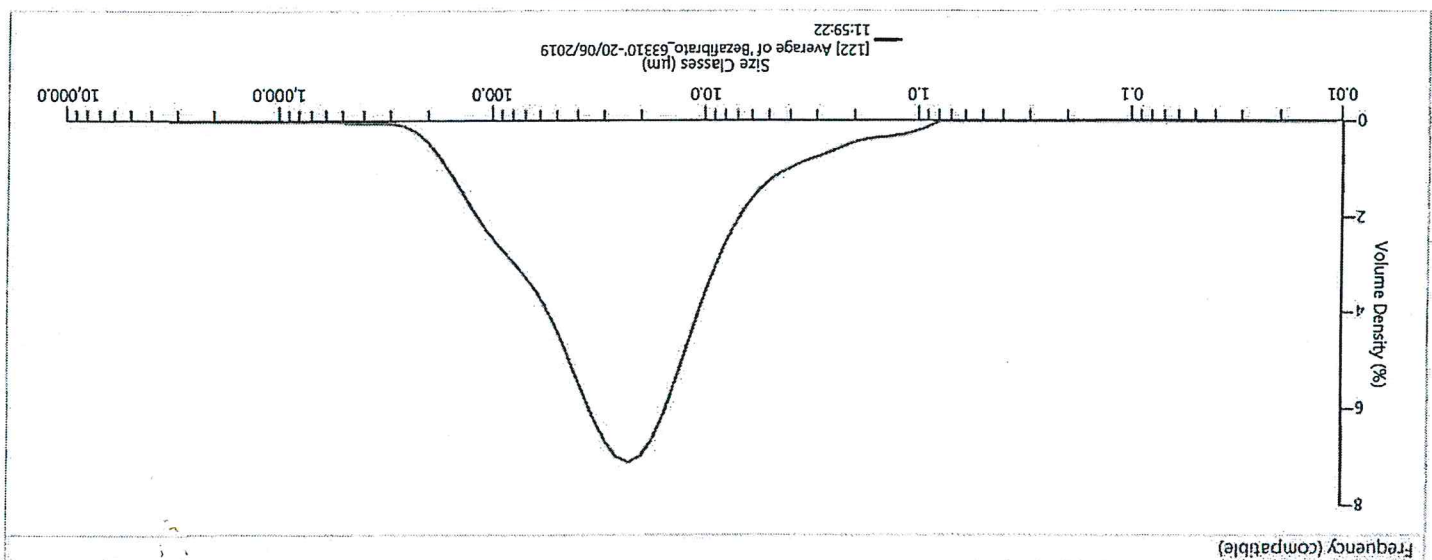
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Quantity	100,000 KG				
References		Specification	M.U.	Result	

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: Olon S.p.A - Dorno

Alessandra Barbieri
QC Manager
Approved June 20, 2019

Claudia Maurogiovanni
Qualified Person
Released June 21, 2019
Approved June 21, 2019
Emission June 21, 2019

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Analysis	Result
Particle Name Bezaflibrato	Concentration 0,0223 %
Particle Refractive Index 1,729	Span 3,194
Particle Absorption Index 0,010	Uniformity 0,976
Dispersant Name Water	Specific Surface Area 433,7 m ² /kg
Dispersant Refractive Index 1,330	D [3;2] 13,8 µm
Scattering Model Mie	D [4;3] 36,6 µm
Analysis Model General Purpose	Dv (10) 7,08 µm
Weighted Residual 0,30 %	Dv (50) 24,0 µm
Laser Obscuration 13,05 %	Dv (90) 83,8 µm
	Dv (95) 115 µm

Measurement Details		Measurement Details	
Operator Name	cazzato	Sample Name	Average of 'Beza fibrato_63310'
Lotto	1930000602	SOP File Name	Beza fibrato_Macinato_BZM.msop
Analysis Date Time	20/06/2019 11:59:22	Measurement Date Time	20/06/2019 11:59:22
Result Source		Averaged	



BZM_2019

Signature	Record Number	Sample Name	Signature State	Signatory	Signature Date
	122	Average of 'Bezafibrate_63310'	Unsigned		

BZM 63310

OLON S.p.A. Dorno (PV)

