



Not to be used in sterile parenteral and sterile non-parenteral products

Certificate of analysis

Product	TAMOXIFEN CITRATE USP/EP (CURRENT EDITION)	Code N°	40020	Batch N°	1720002790
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Manufacturing date **OCT 2017** Retest date (where applicable) **SEP 2022**

Analysis Number **R1PF102502** Bulletin **1P1790812**

Test	References	Result	M.U.	Limits
Description	EP	White crystalline powder	--	White to almost white crystalline powder
IR	EP/USP	Complies to Standard	--	Complies to Standard
UV	EP/USP	Complies to Standard	--	Complies to Standard
Loss on drying	USP	0,15	%	≤ 0,5
Sulphated Ash	EP/USP	0,06	%	≤ 0,1
Heavy metals	USP	<10	ppm	≤10
Iron (Fe)	USP	<50	ppm	≤50
EP Impurity A (E-Isomer)	EP	<0,20	%	≤ 0,30
EP impurity F	EP	<0,05	%	≤ 0,2
Other related substances	EP	<0,10	%	≤ 0,10
Total impurities		<0,30	%	≤ 0,50
Each single impurity	USP	0,03	%	≤ 0,10
Total impurities	USP	0,07	%	≤ 1,0
Assay (HClO4)	EP/USP	99,5	% dried	99,0 - 101,0
OVI (USP): Not used		Not tested	--	Not tested
Toluene	Internal method	<50	ppm	≤ 890
Ethyl acetate	Internal method	<50	ppm	≤ 1000
Acetone	Internal method	110	ppm	≤ 1500

Analysis Date

11/28/2017

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 Q7).
Manufacturing site of the Active Pharmaceutical Ingredient: Stabilimento di Mulazzano

Result Analysis Report

Sample Name:
Tamoxifen - Average

Sample Source & type:
Factory = Mulazzano

Sample bulk lot ref:
40020 1720002790

SOP Name:
Tamoxifen

Measured by:
gerratana

Result Source:
Averaged

Measured:
martedì 31 ottobre 2017 16.23.00

Analysed:
martedì 31 ottobre 2017 16.23.02

Particle Name:
Tamoxifen

Particle RI:
1.450

Dispersant Name:
water saturated

Accessory Name:
Hydro 2000MU (A)

Absorption:
0

Dispersant RI:
1.330

Analysis model:
General purpose

Size range:
0.020 to 2000.000 μm

Weighted Residual:
0.753 %

Sensitivity:
Normal

Obscuration:
21.82 %

Result Emulation:
Off

Concentration:
0.1033 %Vol

Span:
2.905

Uniformity:
0.898

Result units:
Volume

Specific Surface Area:
0.182 m^2/g

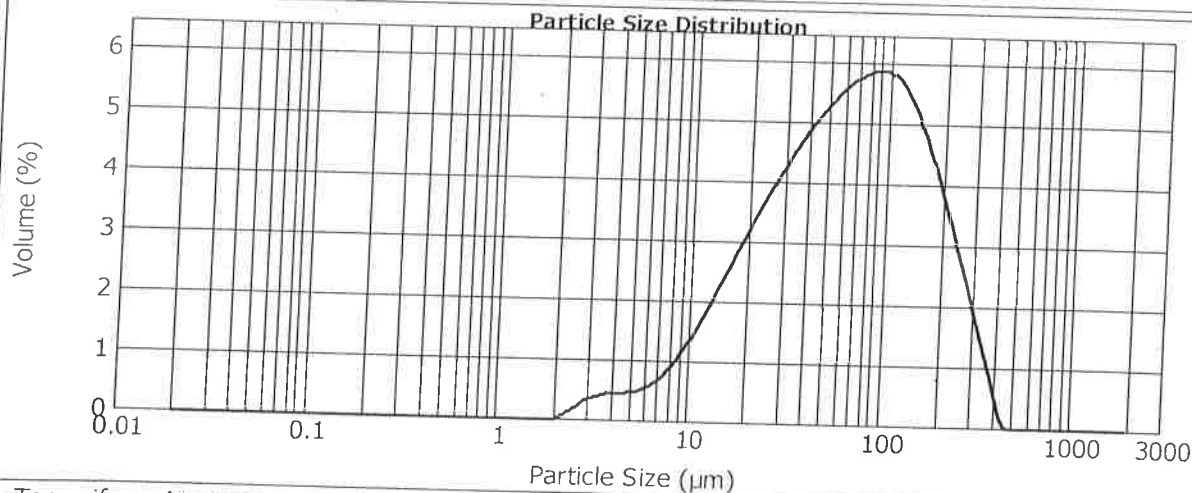
Surface Weighted Mean D[3,2]:
33.024 μm

Vol. Weighted Mean D[4,3]:
89.372 μm

d(0.1): 15.033 μm

d(0.5): 64.465 μm

d(0.9): 202.292 μm



Tamoxifen - Average, martedì 31 ottobre 2017 16.23.00

Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.178	0.00	1.262	0.00	6.400	2.54	17.000	12.05	39.905	33.48	200.000	89.72
0.200	0.00	1.416	0.00	7.096	2.96	17.300	12.36	44.774	37.22	224.404	92.40
0.224	0.00	1.589	0.00	7.962	3.53	17.400	12.47	50.238	41.11	251.785	94.68
0.252	0.00	1.783	0.00	8.934	4.24	17.825	12.91	56.368	45.14	282.508	96.55
0.283	0.00	2.000	0.00	9.300	4.53	18.000	13.09	63.246	49.30	316.979	98.03
0.317	0.00	2.244	0.01	9.500	4.69	19.000	14.14	70.963	53.57	355.656	99.08
0.356	0.00	2.518	0.09	10.000	5.11	19.200	14.34	75.000	55.65	399.052	99.77
0.399	0.00	2.825	0.24	10.024	5.13	19.300	14.45	79.621	57.93	400.000	99.78
0.448	0.00	3.170	0.48	11.247	6.23	19.400	14.55	89.337	62.33	447.744	100.00
0.502	0.00	3.557	0.76	12.619	7.55	20.000	15.17	99.990	66.65	502.377	100.00
0.564	0.00	3.991	1.07	14.159	9.10	21.000	16.20	100.237	66.75	563.677	100.00
0.632	0.00	4.477	1.40	14.200	9.14	22.440	17.66	112.468	71.11	632.456	100.00
0.710	0.00	5.000	1.73	14.300	9.24	25.000	20.22	126.191	75.35	709.627	100.00
0.796	0.00	5.024	1.74	14.400	9.35	25.179	20.40	141.589	79.39	796.214	100.00
0.893	0.00	5.637	2.10	14.500	9.45	28.251	23.35	158.866	83.17	800.000	100.00
1.002	0.00	6.000	2.31	15.000	9.97	31.698	26.53	178.250	86.63	893.367	100.00
1.125	0.00	6.325	2.49	15.887	10.89	35.566	29.91	180.000	86.91		

Operator notes:

9 31/10/17

31/10/17