

NEWCHEM

CERTIFICATE OF ANALYSIS HYDROCORTISONE BUTYRATE MICRONIZED

Batch: **NC3525M**

Manuf. date: **12/2022**

Expiration date: **12/2027**

Tests	Specifications	Results
GENERAL TESTS		
Appearance the powder	White crystalline powder	Complies
Solubility	Complies	Complies
Identification IR	Positive	Positive
Identification UV	Positive	Positive
Specific rotation	+47° - +54° o.d.b.	48°
Clarity of the solution	Clear solution	Complies
Loss on drying	NMT 0.5 %	0,1 %
Free butyric acid	NMT 1.1 mL NaOH 0,01 M	0,2 ml
ASSAY		
HPLC assay	97.0 % - 102.0 % o.d.b.	100,2 %
RESIDUAL SOLVENTS		
Methanol	NMT 3000 ppm	187 ppm
Ethyl acetate	NMT 1500 ppm	N.Q.
Dichloromethane	NMT 150 ppm	N.D.
Pyridine	NMT 20 ppm	N.D.
IMPURITIES		
Impurity B (hydrocortisone)	NMT 0.50%	N.Q.
Impurity D (prednisolone 17 butyrate)	NMT 0.15%	N.Q.
Impurity F (hydrocortisone 21 butyrate)	NMT 0.50%	0,29 %
Any other impurity	NMT 0.10%	N.Q.
Total impurities	NMT 2.0%	0,3 %
MICROBIOLOGIC TESTS		
TYMC	NMT 100 cfu/g	< 10 cfu/g

Complies with cUSP

NEWCHEM declares that: this batch was produced under GMP condition; the documentation relevant to this process has been reviewed by the Quality Unit

Verona

15/02/2023

Page 1 of 2


Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at: Via E. De Amicis 47 - 20123 Milano - Italy Tel. +39 02 581516 ✉ info@newchemspa.it

Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 iscrizione registro imprese MI - codice fiscale e partita IVA/vat 12437910156

Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

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Tests	Specifications	Results
MICROBIOLOGIC TESTS		
TAMC	NMT 100 cfu/g	< 10 cfu/g
Pseudomonas aeruginosa	Absent	Absent
Staphylococcus aureus	Absent	Absent
Enterobacteria and other gram-negative bacteria	NMT 10 Ufc/g	< 10 Cfu/g
Escherichia coli	Absent	Absent
PARTICLE SIZE		
Particle size	100 % < 50 µm	100 %

Complies with cUSP

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Particle Size Distribution Report

MASTERSIZER



Measurement file name: \\nc-srv-fslab\CQ147-malvern\Measurement Data\CQ\ldrocortisone 17 butirrato\NC3525M.mea

Measurement date and time : venerdì 10 febbraio 2023 15:49:52

Analysis date and time : venerdì 10 febbraio 2023 15:49:54

Operator name : enrico.scarpellini

Name of editor : enrico.scarpellini

Operator Notes : Authorship

Sample Name : Idrocortisone 17-butirrato

Sample bulk lot ref : NC3525M

Source type : PF

Instrument serial number : MAL1039317 Instrument kernel version : 4.01 Instrument firmware version : 2.01 Software version : 5.61

Particle name : Fraunhofer

Particle refractive index : 0.000

Particle absorption index : 0

Particle refractive index - blue : 0.000

Particle absorption index - blue : 0

Dispersant name : Water

Dispersant refractive index : 1.330

Analysis sensitivity : Normal

Analysis model : General purpose

Measurement integration time : 10000

Background integration time : 10000

Obscuration range - lower : 5.0

Obscuration range - upper : 20.0

Accessory name : Hydro 2000µP (A)

Pump speed : 2500

Ultrasonic level : 50

Obscuration : 6.54

Residual - weighted : 0.470

Result source : Averaged

Average result records : "30,31,32,33,34"

Concentration : 0.0032 % Vol

Span : 2.236

Uniformity : 0.702

Beam length : 1.35

Size range: 0.020 to 2000.000 µm

Result transform type : Volume

Specific surface area : 3.13 m²/g

D [3, 2] - Surface weighted mean : 1.917 µm

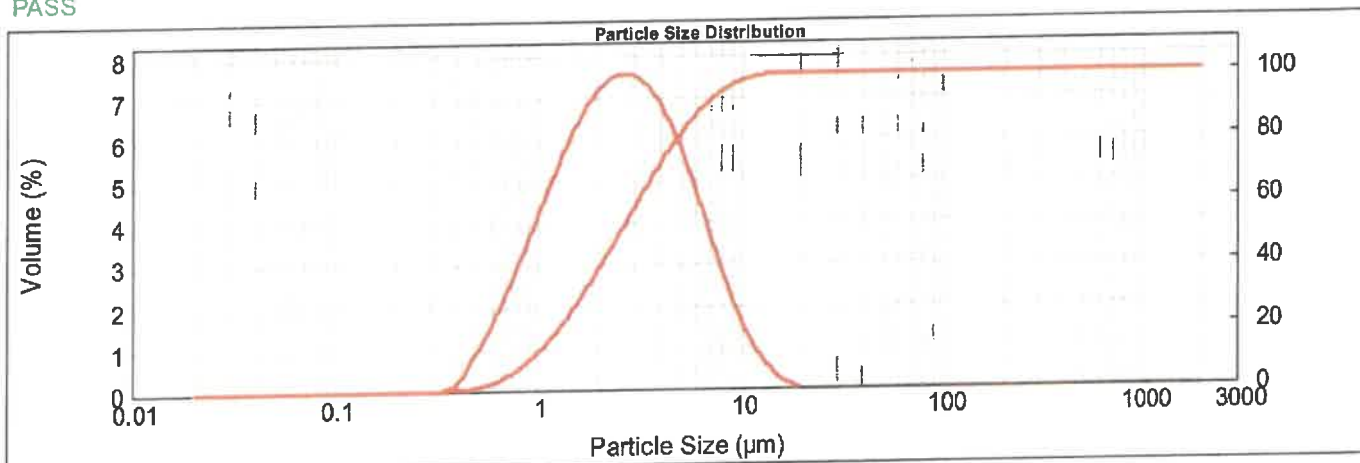
D [4, 3] - Volume weighted mean : 3.262 µm

D(1.00) : 18.15 µm
PASS

D(0.90) : 6.59 µm

D(0.50) : 2.53 µm

D(0.10) : 0.93 µm
PASS



Idrocortisone 17-butirrato, venerdì 10 febbraio 2023 15:49:52

Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %
1.000	11.94	15.000	99.79	29.000	100.00	43.000	100.00	57.000	100.00	71.000	100.00	85.000	100.00
2.000	38.56	16.000	99.88	30.000	100.00	44.000	100.00	58.000	100.00	72.000	100.00	86.000	100.00
3.000	58.35	17.000	99.95	31.000	100.00	45.000	100.00	59.000	100.00	73.000	100.00	87.000	100.00
4.000	71.90	18.000	99.99	32.000	100.00	46.000	100.00	60.000	100.00	74.000	100.00	88.000	100.00
5.000	81.10	19.000	100.00	33.000	100.00	47.000	100.00	61.000	100.00	75.000	100.00	89.000	100.00
6.000	87.32	20.000	100.00	34.000	100.00	48.000	100.00	62.000	100.00	76.000	100.00	90.000	100.00
7.000	91.52	21.000	100.00	35.000	100.00	49.000	100.00	63.000	100.00	77.000	100.00	95.000	100.00
8.000	94.34	22.000	100.00	36.000	100.00	50.000	100.00	64.000	100.00	78.000	100.00	100.000	100.00
9.000	96.24	23.000	100.00	37.000	100.00	51.000	100.00	65.000	100.00	79.000	100.00	110.000	100.00
10.000	97.53	24.000	100.00	38.000	100.00	52.000	100.00	66.000	100.00	80.000	100.00	120.000	100.00
11.000	98.39	25.000	100.00	39.000	100.00	53.000	100.00	67.000	100.00	81.000	100.00	130.000	100.00
12.000	98.97	26.000	100.00	40.000	100.00	54.000	100.00	68.000	100.00	82.000	100.00	140.000	100.00
13.000	99.35	27.000	100.00	41.000	100.00	55.000	100.00	69.000	100.00	83.000	100.00	150.000	100.00
14.000	99.62	28.000	100.00	42.000	100.00	56.000	100.00	70.000	100.00	84.000	100.00	200.000	100.00

13 FEB. 2023

10/02/23 es