

NEWCHEM

CERTIFICATE OF ANALYSIS HYDROCORTISONE BUTYRATE MICRONIZED

Batch: **NF0382M**

Manuf. date: **02/2025**

Expiration date: **02/2030**

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.	50 °
Clarity of the solution	Clear solution	Complies
Loss on drying	NMT 0.5 %	0,2 %
Free butyric acid	NMT 1.1 mL NaOH 0,01 M	0,4 ml
ASSAY		
HPLC assay	97.0 % - 102.0 % o.d.b.	100,6 %
RESIDUAL SOLVENTS		
Methanol	NMT 3000 ppm	57 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%	0,18 %
Any other impurity	NMT 0.10%	N.Q.
Total impurities	NMT 2.0%	0,2 %
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

03/04/2025

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Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

Via San Vittore, 39 - 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: info@newchemspa.it PEC: newchemspa@legalmail.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 it n. IT12437910156

Company subject to direction and coordination of Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

Via Roveggia, 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 E-mail: info@newchemspa.it

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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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MICROCHEM

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190312025

CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 5 del 11/03/2025

Informazioni Prodotto	
Cliente	NEWCHEM
Nome Prodotto	IDROCORTISONE BUTIRRATO
Numero di lotto cliente	NF0382
Numero di lotto interno	L25141A1
Data fine produzione	11/03/2025

Strumentazione	
Marca	Malvern
Modello	Mastersizer 3000
Tecnica	LALLS

Metodo di Analisi	
Codice	MGR164IDR031
Mezzo disperdente	ACQUA DEPURATA
Teoria di diffrazione	FRAUNHOFER

Distribuzione Granulometrica	
Specifiche richieste	Risultati
100% < 50 μm	100% < 50 μm
90% < 10 μm	100% < 10 μm

Note
Il lotto sopraindicato e ricevuto dal cliente al solo scopo di essere micronizzato, dal momento dell'arrivo alla fine produzione, è stato processato, analizzato e documentato in base al nostro Sistema Qualità gestito secondo le cGMP.

Allegato stampato analisi

Data	Firma Laboratorio
11-03-2025	Giuseppe Pelton
Data/Firma QC	Data/Firma QP
11/03/2025	18/03/2025
	GRETA SOMMI QUALIFIED PERSON

Mod. MBR4/A7i
Microchem S.R.L. a socio unico
Via Turati 2
29017 Fiorenzuola d'Arda (PC) Italy

MUNIT
WE ARE MICRONIZATION

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contact@microchem.it
www.microchem.it



Riva - CF - Reg. Imp. 01026710333 - R.E.A. PC 122206 - Cap. Soc. € 93.600 i.v.
Soggetta ad attività di direzione e coordinamento di ALGA Holding SA

AP

Result Analysis Report

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1803182006



Measurement Details

Sample Name NEWCHEM IDROCORTISONE BUTIRRATO
Lot number NF0382 (L25141A1)
SOP File Name Idrocortisone butirrato.msop
Instrument Type Mastersizer3000
Instrument Serial No. MAL1275796

Measurement Details

Analysis Date Time 11/03/2025 09:28:44
Measurement Date Time 11/03/2025 09:28:44
Result Source Measurement
Record Number 5
Operator Name sacconi

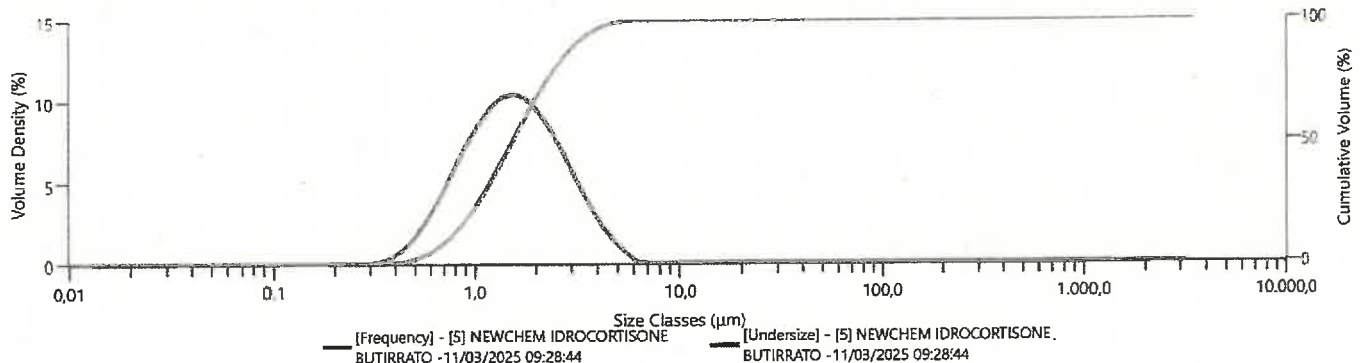
Analysis

Particle Name FRAUNHOFER
Particle Refractive Index 0,000
Particle Absorption Index 0,000
Particle Refractive Index Blue 0,000
Particle Absorption Index Blue 0,000
Dispersant Name Water
Dispersant Refractive Index 1,330
Scattering Model Fraunhofer
Analysis Model General Purpose
Background Measurement Time 12,00 s
Sample Measurement Time 5,00 s
Manual Stirrer Speed 2000
Accessory Name Manual Accessory
Are particles non-spherical? Yes

Result

Weighted Residual 0,48 %
Laser Obscuration 24,16 %
Dv (10) 0,739 µm
Dv (50) 1,528 µm
Dv (90) 3,117 µm
D [4;3] 1,759 µm
Span 1,557
Dv (70) 2,071 µm
Dv (75) 2,256 µm
Dv (85) 2,744 µm
Dv (95) 3,732 µm
Dv (98) 4,440 µm
Dv (99) 4,908 µm
Dv (99,9) 5,774 µm
Dv (100) 5,911 µm

Frequency (compatible) and Undersize



Result

Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under
0,010	0,00	0,750	10,48	2,600	82,40	9,500	100,00	20,000	100,00	56,000	100,00	115,000	100,00
0,020	0,00	0,800	12,90	2,800	85,80	10,000	100,00	22,000	100,00	60,000	100,00	120,000	100,00
0,030	0,00	0,900	17,96	3,000	88,51	10,500	100,00	24,000	100,00	65,000	100,00	130,000	100,00
0,050	0,00	1,000	23,23	3,300	91,74	11,000	100,00	25,000	100,00	70,000	100,00	135,000	100,00
0,060	0,00	1,100	28,66	3,500	93,50	12,000	100,00	28,900	100,00	72,000	100,00	140,000	100,00
0,080	0,00	1,200	34,01	3,800	95,38	13,000	100,00	30,000	100,00	74,000	100,00	149,000	100,00
0,090	0,00	1,400	44,09	4,000	96,48	14,000	100,00	32,500	100,00	75,600	100,00	150,000	100,00
0,099	0,00	1,500	48,75	4,500	98,19	14,500	100,00	35,000	100,00	80,000	100,00	160,000	100,00
0,100	0,00	1,500	48,75	4,500	98,19	14,500	100,00	35,000	100,00	80,000	100,00	160,000	100,00
0,200	0,00	1,700	57,25	5,000	99,15	15,000	100,00	35,500	100,00	85,000	100,00	180,000	100,00
0,240	0,00	1,800	61,06	5,500	99,70	16,000	100,00	38,000	100,00	90,000	100,00	190,000	100,00
0,330	0,19	1,900	64,62	6,000	100,00	16,500	100,00	40,000	100,00	95,000	100,00	200,000	100,00
0,450	0,85	2,000	67,82	7,000	100,00	17,000	100,00	45,000	100,00	96,000	100,00		
0,500	1,75	2,200	73,58	7,500	100,00	18,000	100,00	48,000	100,00	100,000	100,00		
0,550	2,97	2,300	76,08	8,000	100,00	18,500	100,00	50,000	100,00	103,000	100,00		
0,600	4,41	2,500	80,51	9,800	100,00	19,000	100,00	55,000	100,00	110,000	100,00		

Operator Notes ANALISI FINALE (2 GOCCE TWEEN 80 + 30" US)



Malvern Instruments Ltd.
www.malvern.com

Mastersizer - v3.81
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L25141A1 Idrocortisone Butirrato

AP

Created: 18/03/2024
Printed: 11/03/2025 09:47

Result Analysis Report



Signature				
Record Number	Sample Name	Signature State	Signatory	Signature Date
5	NEWCHEM IDROCORTISONE BUTIRRATO	Signed	MICROCHEM\sacconi	11/03/2025 09:29:17 +01:00
		Locked	MICROCHEM\testi	11/03/2025 09:47:37 +01:00

