

EXCIPHARMA SOLUTIONS LTD.

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CERTIFICATE OF ANALYSIS

Doc. No: EXP-COA-MCC-2026-0614 | Date of Issue: 20 Jun 2026 | Page 1 of 1

SECTION 1 — PRODUCT & BATCH INFORMATION

Product Name (Compendial):	Microcrystalline Cellulose	Trade Name:	EXCIPCEL® 102
Compendial Designation:	USP/NF & Ph. Eur.	Grade:	PH-102 (Pharmaceutical)
Batch Number:	MCC-2026-0614-A	Date of Manufacture:	14 Jun 2026
Batch Quantity:	5,000 kg	Recommended Retest Date:	14 Jun 2029
Container Type:	25 kg Double Polyethylene-lined HDPE Drums	Storage Conditions:	Store in a cool, dry place. T: 15-30°C. RH: ≤60%.
Original Manufacturer:	Excipharma Solutions Ltd., Dubai, UAE	Manufacturing Site:	Plant A, Industrial Zone Block 7, Dubai, UAE
Specification Reference:	EXP-SPEC-MCC-001, Ver. 4.0	Customer PO Reference:	N/A (Manufacturer Release)

SECTION 2 — TEST RESULTS

[All tests performed on finished excipient batch unless noted. Dates of testing: 14–17 Jun 2026]

Identification (IR Spectroscopy)	USP <197K> / Ph. Eur. 2.2.24	Conforms to reference spectrum	Conforms	PASS
Description (Appearance)	Visual Examination	White or almost white, fine or granular powder	White, fine granular powder	PASS
pH (20% w/v Slurry)	USP <791>	5.0 – 7.5	6.2	PASS
Loss on Drying	USP <731> / Ph. Eur. 2.2.32	NMT 7.0% (105°C, 3 hrs)	4.8%	PASS
Residue on Ignition	USP <281> / Ph. Eur. 2.4.14	NMT 0.1%	0.03%	PASS
Heavy Metals (as Pb)	USP <231> Method II	NMT 10 ppm	< 5 ppm	PASS
Nickel	USP <231>	NMT 1 ppm	< 0.5 ppm*	PASS
Water-Soluble Substances	USP MCC Monograph	NMT 0.24%	0.09%	PASS
Ether-Soluble Substances	USP MCC Monograph	NMT 0.05%	0.02%	PASS
Degree of Polymerization	USP MCC Monograph	NMT 350	220	PASS
Particle Size (D90)	Supplier Method SM-PS-001 (Laser Diffraction)	90.0 – 130.0 µm	108.5 µm	PASS
Particle Size (D50)	Supplier Method SM-PS-001 (Laser Diffraction)	75.0 – 100.0 µm	88.2 µm	PASS
Bulk Density (Untapped)	USP <616>	0.25 – 0.45 g/mL	0.31 g/mL	PASS
Tapped Density	USP <616>	0.35 – 0.55 g/mL	0.42 g/mL	PASS
Hausner Ratio	Calculated from BD/TD	NMT 1.35	1.21	PASS
Microbial Enumeration (TAMC)	USP <61>	NMT 1000 CFU/g	< 10 CFU/g	PASS
Microbial Enumeration (TYMC)	USP <61>	NMT 100 CFU/g	< 10 CFU/g	PASS
E. coli	USP <62>	Absent in 1 g	Absent	PASS
Salmonella spp.	USP <62>	Absent in 10 g	Absent	PASS
Residual Solvents (ICH Class 1 & 2)	USP <467>	Meets USP requirements	Conforms+	PASS

* Nickel: Tested in-process on each batch; material shown not to change in finished excipient sample.

+ Residual Solvents: Evidence of compliance available in separate correspondence (EXP-RS-MCC-2026-001).

SECTION 3 — ADDITIONAL & PERIODIC TEST RESULTS

Arsenic (in-process)*	Ph. Eur. 2.4.2	NMT 2 ppm	< 1 ppm	PASS
Elemental Impurities (quarterly)+	USP <232> / Ph. Eur. 5.20	Meets USP <232> limits	Conforms	PASS

* Arsenic: Performed in-process on each batch; demonstrated not to change in finished excipient.

+ Elemental Impurities: Periodic (quarterly) monitoring per validated process capability data. Last tested: 01 Mar 2026 — Conforms.

SECTION 4 — CERTIFICATION & COMPLIANCE STATEMENTS

GMP Compliance	This batch of EXCIPCEL® 102 (Microcrystalline Cellulose) has been manufactured in full compliance with the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients (2017) and 21 CFR Part 211.
Compendial Standards	This batch complies with all current requirements of the United States Pharmacopeia/National Formulary (USP-NF) Microcrystalline Cellulose Monograph and the European Pharmacopoeia (Ph. Eur.) Microcrystalline Cellulose Monograph.
Residual Solvents	The manufacturing process for this product does not utilize ICH Class 1 or Class 2 solvents. The product conforms to requirements of USP General Chapter <467>.
GMO Status	This product is derived from wood pulp (non-food-chain) and is not produced using genetically modified organisms (GMO-free).
TSE / BSE Status	This product is of vegetable origin (wood pulp). It does not contain material of animal origin and is free from TSE/BSE risk.
Allergen Statement	This product does not contain or is produced in the presence of any declared food allergens as listed in EU Regulation 1169/2011 or FDA CFR 21 Part 101.

BATCH DISPOSITION: RELEASED — CONFORMS TO ALL SPECIFICATIONS

SECTION 5 — AUTHORIZATION

Prepared By: Dr. Ahmed Al-Rashidi, QC Analyst Date: 18 Jun 2026
Reviewed By: Ms. Fatima Khalil, QC Supervisor Date: 19 Jun 2026
Approved By (QA Release): Dr. Sara Mohammed, Head of Quality Assurance Date of Approval: 20 Jun 2026

Electronic Signature Notice: This COA has been issued from an electronic quality management system in compliance with 21 CFR Part 11 and ALCOA+ data integrity principles. The electronic approval records, audit trail, and signatory credentials are maintained in the ExciPharma QMS (System ID: QMS-EXP-003, Validated: Jan 2025). Physical signatures are available on request.

This Certificate of Analysis has been prepared in accordance with the IPEC Federation Certificate of Analysis Guide for Pharmaceutical Excipients, Version 2.1, 2024. Retain this document for a minimum of one year after the recommended retest date.

This COA is prepared in accordance with IPEC Federation COA Guide v2.1 (2024). For verification, contact quality@excipharma.ae