



Oxytetracycline Dihydrate, BP

BP 2022 — Injectable Grade | Quality Assurance Release Certificate

BATCH & PRODUCT INFORMATION

Product Name	Oxytetracycline Dihydrate, BP
Catalogue Number	ASA-3017
AuSaMicS Batch / Lot No.	OX24127
Net Weight (this pack)	1 kg
CAS Number	6153-64-6
Molecular Formula	C ₂₂ H ₂₄ N ₂ O ₉ · 2H ₂ O
Molecular Weight	496.46 g/mol
Manufacturing Date	May 2024
Re-Test	May 2027
Source / Parent Batch Reference	13682046-OB (A.R. No. OB/24/046/13682) — original manufacturer's release batch, tested 05-Jul-2024, repackaged by AuSaMicS Pty Ltd under controlled conditions
Storage Condition	2–8 °C, protected from light

CERTIFICATE OF ANALYSIS

Results below are carried forward from the originating manufacturer's Certificate of Analysis for parent batch 13682046-OB (tested 05-Jul-2024 against BP 2022 specifications) and verified by AuSaMicS Pty Ltd upon receipt and prior to repackaging into the batch identified above. All parameters comply with British Pharmacopoeia 2022 requirements for Oxytetracycline Dihydrate.

Test	Specification	Result	Observation
Characters	A yellow, crystalline powder, slightly hygroscopic	A yellow, crystalline powder, slightly hygroscopic	Complies
Solubility	Very slightly soluble in water; soluble in dilute acid and alkaline solution	Complies	Complies
Identification (A, B, C & D)	Complies	Complies	Complies
pH	4.5 to 7.5	5.29	Complies
Light absorbing — Impurities (anhydrous substance)	At 430 nm NMT 0.25 / At 490 nm NMT 0.20	0.126 / 0.026	Complies
Related substances (HPLC) — Impurity A	NMT 0.7%	Complies	Complies
Related substances (HPLC) — Impurity B	NMT 1.0%	Complies	Complies
Related substances (HPLC) — Impurity C	NMT 2.0%	Complies	Complies

Test	Specification	Result	Observation
Related substances (HPLC) — Impurity D	NMT 0.2%	Complies	Complies
Related substances (HPLC) — Impurity E	NMT 0.2%	Complies	Complies
Related substances (HPLC) — Any other impurity	NMT 0.1%	Complies	Complies
Related substances (HPLC) — Total impurities	NMT 3.5%	Complies	Complies
Water	6.0% to 9.0%	7.59%	Complies
Sulphated ash	NMT 0.2%	0.059%	Complies
Assay (C22H24N2O9, anhydrous substance)	NLT 94.5% and NMT 102.0%	99.82%	Complies
Bacterial endotoxin	NMT 0.4 EU/mg of Oxytetracycline	Complies	Complies

Remark: The product complies with British Pharmacopoeia (BP) 2022 specifications for Oxytetracycline Dihydrate, Injectable Grade.

APPROVAL

Prepared By	AuSaMicS Pty Ltd — Technical/QA Department
Checked By	AuSaMicS Pty Ltd — Technical/QA Department
Approved By	Hassan Salimi — Technical Director, AuSaMicS Pty Ltd
Release Date	May 2024

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