

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Clinacin 25mg/ml
Customer: Alphavet/Pharmanovo
Livery: Hungry
Batch No.: B35074/C
Bulk Batch No.: B35074

Man. Date: 02/2019
Expiry Date: 01/2022

Quantity: 1,154 x 22ml

Tests	Specification	Result
1. Appearance	Clear colourless liquid	Complies
2. Condition of Packaging	Packaging Intact	Complies
3. pH	3.0 – 5.5	4.0
4. Assay Active	Clindamycin 25 mg/ml \pm 5% Range: 23.75 – 26.25 mg/ml (95% - 105% LC)	24.76mg/ml
5. Identification	(a) UV by HPLC – The retention time of the major peak of the sample preparation in the assay corresponds to that of the standard solution as obtained in the assay.	Complies
	(b) PDA by HPLC – In the assay method the λ Max of peak apex of the major peak in the sample chromatogram corresponds to that in the standard chromatogram.	Complies
6. Related Substances	Impurity A. Lincomycin \leq 1.0% Impurity B. 7-Epiclindamycin \leq 4.0% Impurity C. Clindamycin B \leq 2.0% Unknown impurity \leq 1.0% Total impurities \leq 6.0%	0.165% 0.172% 0.563% <LOQ 0.900%
7. Uniformity of Mass of delivered doses from multi dose containers	No more than 2 of the individual masses deviate from the average mass by more than 10% and none deviate by more than 20%	Complies
8. Microbial Purity (Ph Eur)	Total aerobic microbial count: NMT 10 ³ cfu/ml Total combined yeasts/moulds count: NMT 10 ² cfu/ml <i>Escherichia coli</i> : Absent per 1ml	Complies Complies Complies

The above mentioned batch has been manufactured, packed and tested in accordance with EU GMP guidelines and in compliance with current Marketing Authorisation No. 3889/1/17 Nebih Ati and it is released for sale.

Checked By: Donna Hall Date: 23/05/19
Quality Assurance (Signature)

Approved By: P. R. B. Date: 27/05/19
Qualified Person (Signature)

Sainath Raddy
Qualified Person (Print Name)