

CERTIFICATE OF ANALYSIS

Report n° 325/19
 Packaging 1000 g bag

Manufacturing date: Mar-19
 Expiry date: Mar-21
 Analysis date 27-Mar-19

DOXYBAN		BATCH N°	19030237
TEST	SPECIFICATIONS	RESULTS	
Appearance	Homogeneous Yellow powder	Conform	
Solubility	100 g/L limpid solution	Conform	
pH (0.375 g/L)	between 5.5 ÷ 6.5	6,43	
Doxycycline identification (HPLC)	Correspondance with the reference standard	Positive	
Doxycycline base assay (HPLC)	475 - 525 g/Kg	510,83	g/Kg
Doxycycline related substances assay (HPLC)	Impurity A: ≤2.0%	1,7	%
	Impurity B: ≤2.0%	<0,1	%
	Impurity C: ≤0.5%	n.d.	%
	Impurity D: ≤0.5%	<0,1	%
	Impurity F: ≤0.5%	n.d.	%
	Total Impurities: ≤3.0%	1,9	%
Microbiological quality	TAMC: ≤1000	<750	CFU/g
	TYMC: ≤100	<10	CFU/g
	E. Coli: absent	absent	

Date 20/05/2019

Rejected



Approved



Issued by Quality Control Department: Dr. Simone Mora

Approved by Qualified Person: Dr.ssa Germana Stefanelli