

CERTIFICATE OF ANALYSIS

Report n° 692/2020

Packaging 1000 g bag

Manufacturing date: 23/09/2020

Expiry date: 03/2022

Analysis date 25-Sep-20

DOXIBAN 500 mg/g		BATCH N°	20090635
TEST	SPECIFICATIONS	RESULTS	
Appearance	Yellow, crystalline powder	conform	
Solubility	0,375 g/L of tap water give a limpid solution	conform	
pH (133 mg/L "Hard water High pH)	between 5,0 ÷ 7,5	7,4	
Loss on drying	≤3,5%	0,6	
Doxycycline identification (HPLC)	Correspondance with the reference standard	conform	
Doxycycline base assay (HPLC)	475,00- 525,00 g/Kg	503,80	g/Kg
Doxycycline realted substances assay (HPLC)	Impurity A: ≤2%	1	%
	Impurity B: ≤2%	0	%
	Impurity C: ≤0,5%	0,0	%
	Impurity D: ≤0,5%	0,0	%
	Impurity E: ≤0,5%	0,0	%
	Impurity F: ≤0,5%	0,1	%
	Any other Impurity : ≤0,5%	<0,5	%
Microbiological quality	Total Impurities: ≤3%	1	%
	TAMC: ≤1000	<750	CFU/g
	TYMC: ≤100	<10	CFU/g
	E. Coli: absent	absent	

Date 04/10/2020

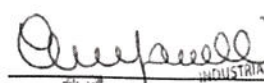
Rejected

☐ Approved



Issued by Quality Control Department: Dr. Simone Mora

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