

**XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD**

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Certificate of Analysis

Product Name	Azithromycin powder		
Manufacture Date:	10th Aug.,2021	Analysis Date:	10th Aug.,2021
Batch NO.:	HNB20210810-1	Test sample:	20gram
Storage:	Store in cool&dry place, in well-closed containers.		
Shelf life:	24 Months when properly stored.		

items	specifications	results
appearance	a white or almost white crystalline powder	conforms
solubility	practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride	conforms
identification	hplc	conforms
crystallinity	meet the requirements	conforms
ph	9.0 ~ 11.0	9.9
related substances	desosaminylazithromycin $\leq 0.3\%$	dl
	n-demethylazithromycin $\leq 0.7\%$	0.1%
	any other single impurity $\leq 1.0\%$	conforms
	total impurities $\leq 3.0\%$	1.5%
residual solvents	acetone $\leq 0.5\%$	0.3%
loss on drying	4.0 % ~ 5.0%	4.5 %
residue on ignition	$\leq 0.3\%$	0.04 %
melting point	50 ° c ~ 60 ° c	50 ° c ~ 60 ° c
sulphate ash	$\leq 0.1\%$	0.05%
heavy metals	≤ 25 ppm	nmt25 ppm
assay(calculated on the anhydrous basis)	945 ug ~ 103 ug of azithromycin per mg	982 ug/ mg
conclusion	this product complied with the standard of enterprise/usp	

QC MANAGER:

王翠月

INSPECTOR:

杨思远

ANALYST:

杨静

