



河北东风药业有限公司

HEBEI DONGFENG PHARMACEUTICAL CO., LTD.

地址:中国河北邯郸市永年区广源西街365号  
NO.365, GUANGYUAN WEST STREET, YONGNIAN DISTRICT, HEBEI CITY, HEBEI, P.R.CHINA  
TEL:+86 310 6806299 电话:+86 310 6805222  
FAX:86 310 6806299 POST CODE:057150

CERTIFICATE OF ANALYSIS

PRODUCT NAME: AZITHROMYCIN DIHYDRATE		REPORT NO.: A20173
BATCH NO.: A20200621	NET WEIGHT: 25kg/DRUM	DATE OF MANUF: 2020.06.19
BATCH SIZE: 425kg	NO.OF PACKAGE: 17DRUMS	REPORT DATE: 2020.06.26
ACCORDING TO: USP43		DATE OF EXPIRY: 2024.06.18
TEST	SPECIFICATION	RESULT
1. Characters	White or almost white crystallinity powder	Complies
2. Identification	a) Infrared Absorption b) HPLC	Complies Complies
3. Specific rotation	-45° ~ -49°	Complies
4. Crystallinity	Meets the requirements	-46°
5.pH	9.0~11.0	Complies
6. Water	4.0~5.0%	9.9
7.Organic impurities	Azithromycin N-oxide ≤0.5%	4.5%
	3'-(N,N-Didemethyl)- 3'-N-formylazithromycin ≤0.5%	Not found
	Erythromycin A iminoether ≤0.5%	Not found
	3'-(N,N-Didemethyl)azithromycin (aminoazithromycin) ≤0.5%	Not found
	Azithromycin Related Compound F ≤0.5%	Not found
	Desosaminylazithromycin ≤0.3%	Not found
	3'-N-{{4-(Acetylamino)phenyl}sulfonyl}-3' , 3' -didemethylazithromycin ≤0.15%	Not found
	N-Demethylazithromycin ≤0.7%	Not found
	Erythromycin A oxime ≤0.5%	Not found
	Azithromycin C(3'' -O- demethylazithromycin) ≤0.5%	0.11%
	3'-De (dimethylamino) - 3'-oxoazithromycin ≤0.5%	Not found
	3'-N-{{4-(Acetylamino)phenyl}sulfonyl}-3' -demethylazithromycin ≤0.5%	Not found
	Azaerythromycin A ≤0.5%	0.02%
	Azithromycin impurity P ≤0.2%	0.08%
	2-Desethyl-2-propylazithromycin ≤0.5%	0.09%
	3'-N-Demethyl- 3'-N-[ (4-methylphenyl) sulfonyl] azithromycin ≤0.5%	Not found
	3-Deoxyazithromycin (azithromycin B) ≤1.0%	0.25%
	Any individual unidentified impurity ≤0.2%	Complies
	Total impurities ≤3.0%	1.2%
8.Residue on ignition	≤0.3%	0.07%
9. Assay	945~1030μg/mg (C <sub>18</sub> H <sub>22</sub> N <sub>2</sub> O <sub>12</sub> ) Calculated on the anhydrous basis	985μg/mg
10.Bulk density		0.57g/ml
Tapped Density		0.76g/ml

Packaging and Storage: Preserve in tight containers .

CONCLUSION: THIS PRODUCT FULFILLS USP 43.

APPROVED BY

Mr. Liu Jian Long

Director of Quality Control Centre

Signature Date: 2020年06月26日



扫描全能王 创建



河北东风药业有限公司

HEBEI DONGFENG PHARMACEUTICAL CO., LTD.

地址:中国河北邯郸市永年区广源西街365号 NO.365, GUANGYUAN WEST STREET, YONGNIAN DISTRICT, HEBEI PROVINCE, CHINA TEL:+86 310 6805222 FAX:86 310 6806299 POST CODE:057150

CERTIFICATE OF ANALYSIS

PRODUCT NAME: AZITHROMYCIN DIHYDRATE		REPORT NO.: A20174
BATCH NO.: A20200622	NET WEIGHT: 25kg/DRUM	DATE OF MANUF: 2020.06.20
BATCH SIZE: 425kg	NO.OF PACKAGE: 17DRUMS	REPORT DATE: 2020.06.28
ACCORDING TO: USP43		DATE OF EXPIRY: 2024.06.19
<b>TEST</b>	<b>SPECIFICATION</b>	<b>RESULT</b>
1. Characters	White or almost white crystallinity powder	Complies
2. Identification	a) Infrared Absorption	Complies
	b) HPLC	Complies
3. Specific rotation	-45° ~ -49°	-46°
4. Crystallinity	Meets the requirements	Complies
5.pH	9.0~11.0	10.0
6. Water	4.0~5.0%	4.6%
7.Organic impurities	Azithromycin N-oxide ≤0.5%	Not found
	3'-(N,N-Didemethyl)- 3'-N-formylazithromycin≤0.5%	Not found
	Erythromycin A iminoether≤0.5%	Not found
	3'-(N,N-Didemethyl)azithromycin (aminoazithromycin) ≤0.5%	Not found
	Azithromycin Related Compound F≤0.5%	Not found
	Desosaminylazithromycin≤0.3%	Not found
	3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3' , 3'-didemethylazithromycin≤0.15%	Not found
	N-Demethylazithromycin≤0.7%	Not found
	Erythromycin A oxime≤0.5%	Not found
	Azithromycin C(3' -O- demethylazithromycin) ≤0.5%	0.08%
	3'-De (dimethylamino) - 3'-oxoazithromycin≤0.5%	Not found
	3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3'-demethylazithromycin≤0.5%	Not found
	Azaerythromycin A≤0.5%	Not found
	Azithromycin impurity P≤0.2%	0.06%
	2-Desethyl-2-propylazithromycin≤0.5%	0.10%
	3'-N-Demethyl- 3'-N-[ (4-methylphenyl) sulfonyl] azithromycin ≤0.5%	Not found
	3-Deoxyazithromycin (azithromycin B) ≤1.0%	0.26%
	Any individual unidentified impurity≤0.2%	Complies
	Total impurities≤3.0%	1.0%
8.Residue on ignition	≤0.3%	0.1%
9. Assay	945~1030μg/mg (C <sub>38</sub> H <sub>72</sub> N <sub>2</sub> O <sub>12</sub> ) Calculated on the anhydrous basis	982μg/mg
10.Bulk density		0.53g/ml
Tapped Density		0.71g/ml
<b>Packaging and Storage:</b> Preserve in tight containers .		
<b>CONCLUSION: THIS PRODUCT FULFILLS USP 43.</b>		
APPROVED BY		
		Mr. Liu Jian Long
		Director of Quality Control Centre
		Signature Date: 2020年06月28日



扫描全能王 创建