

连云港超博国际贸易有限公司

LIANYUNGANG ZOBO INTERNATIONAL TRADE CO., LTD.

ADD: A-R2205 LONGHE BUILDING CANGWU ROAD, LIANYUNGANG,
JIANGSU, CHINA

Certificate of Analysis

Product Name	Diosmin	Order No.	
Batch No.		Quantity	350kgs/14drums
Manufacturing date	NOV 12,2018	Expiry Date	OCT,2021
Producer: Chengdu Okay Pharmaceutical Co.,Ltd			
Items	EP 8.0		Results
Appearance(Visual)	Greyish-yellow or light yellow hygroscopic powder		Complies
Identification[a,b] IR/HPLC	Must positive		positive
Solubility(Visual)	Practically insoluble in water , soluble in dimethyl sulphoxide, practically insoluble in alcohol. It dissolves in dilute solutions of alkali hydroxides.		Complies
Residual solvent			
-Methanol	3000ppm max		<150ppm
-Ethanol	5000ppm max		<250ppm
-Pyridine	200ppm max		<200ppm
Iodine	0.1%max		<0.1%
Related substance (Impurity by HPLC)			
A:acetoisovanillone	0.5%max		0.11%
B:hesperidin	4.0%max		1.11%
C:isorhoifolin	3.0%max		1.71%
D:6-iododiosmin	0.6%max		0.51%
E:linarin	3.0%max		1.89%
F:diosmetin	2.0%max		0.51%
Unspecified impurities	0.4%max		0.34%
Total	8.5%max		6.52%
Sulfated ash	0.2 % max		0.16%
Water	6.0%max		3.16%
Particle size	100%pass through 5 microns 80%pass through 2 microns		Complies
Assay by HPLC(On dry basis)	90.0 % - 102.0 %		92.17%
Microbiological test:			
Total plate count	1000 cfu/g max		10 cfu/g
Mildew&Yeast	100cfu/g max		<10 cfu/g
E.Coli	Negative		Negative
Salmonella	Negative		Negative
Coliforms	10 cfu/g max		<10 cfu/g

Conclusion: Conform with EP'9.0.

