



四川青益纯医药科技有限公司
SICHUAN BENEPURE PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name	Diosmin	Code	BPBE-610-A
Botanical Source	Citrus Aurantium L.	Used Part	Immature fruit
Batch No.	H060561017A	Mfg. Date	May 11, 2017
Packing	25kg/Drum	Retest Date	May 10, 2019
Quantity	1000kg	Report Date	May 18, 2017
Specification	EP8.3 Micronized		

ITEM	SPECIFICATION	RESULT
Assay(HPLC, on anhydrous basis)	90.0%-102.0%	93.37%
Appearance	Greyish-yellow or light yellow, hygroscopic powder	Complies
Identification	A) IR:Compliesdiosmin CRS B) HPLC:Complies to the test solution	Complies
Solubility	Practically insoluble in water, soluble in dimethyl sulfoxide, practically insoluble in ethanol (96%), it dissolves in dilute solution of alkali hydroxides	Complies
Particle Size	95% below 5 microns	Complies
Water	≤6.0%	3.15%
Sulphated Ash	≤0.2%	0.14%
Heavy Metals	≤20ppm	Complies
Iodine	≤0.1%	Complies
Related Substances		
Impurity A(Acetoisovanillone)	≤0.5%	Undetected
Impurity B(Hesperidin)	≤4.0%	1.08%
Impurity C(Isorhoifolin)	≤3.0%	1.87%
Impurity D(6-iododiosmin)	≤0.6%	0.21%
Impurity E (Linarin)	≤3.0%	1.88%
Impurity F(Diosmitin)	≤2.0%	1.01%
Unspecified Impurities(each)	≤0.4%	Undetected

Benepure—Natural Ingredients Specialist.

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Total Impurities	≤8.5%	6.05%
Residual Solvents		
Methanol	≤3000ppm	Complies
Ethanol	≤5000ppm	Complies
Pyridine	≤200ppm	Complies
Total Plate Count	≤1000cfu/g	Complies
-Yeast & Mold	≤100cfu/g	Complies
-E.Coli	Negative	Negative
-Salmonella	Negative	Negative
Conclusion	Conforms to EP 8.3.	
Storage	Preserve in tight containers, protected from strong light and high heat. Store in dry cool place.	

Analyst:

QC Manager:

QA: