

No.: BPBE-610-B-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Diosmin	Code	BPBE-610-B
Botanical Source	Citrus Aurantium L.	Used Part	Immature fruit
Batch No.	H050861020B	Mfg. Date	Aug. 12, 2020
Packing	25kg/Drum	Retest Date	Aug. 11, 2024
Quantity	1000kg	Report Date	Aug. 18, 2020
Specification	EP8.3		

ITEM	SPECIFICATION	RESULT
Appearance	Greyish-yellow or light yellow, hygroscopic powder	Complies
Solubility	Practically insoluble in water, soluble in dimethyl sulfoxide, practically insoluble in ethanol (96%), it dissolves in dilute solution of alkali hydroxides	Complies
Identification	A) IR: Complies diosmin CRS B) HPLC: Complies to the reference solution	Complies
Iodine	≤0.1%	Complies
Related Substances		
Impurity A(Acetoisovanillone)	≤0.5%	0.03%
Impurity B(Hesperidin)	≤4.0%	1.45%
Impurity C(Isorhoifolin)	≤3.0%	2.02%
Impurity D(6-iododiosmin)	≤0.6%	0.16%
Impurity E (Linarin)	≤3.0%	1.41%
Impurity F(Diosmetin)	≤2.0%	0.74%
Unspecified Impurities(each)	≤0.4%	0.35%
Total Impurities	≤8.5%	6.16%
Heavy Metals	≤20ppm	Complies
Water	≤6.0%	2.34%
Sulphated Ash	≤0.2%	0.09%
Particle Size	NLT95% pass 80 mesh	Complies
Assay (HPLC, Anhydrous substance)	90.0%~102.0%	90.74%
Residual Solvents		
Methanol	≤3000ppm	Undetected
Ethanol	≤5000ppm	Undetected
Pyridine	≤200ppm	94ppm
Total Plate Count	≤1000cfu/g	50cfu/g
-Yeast & Mold	≤100cfu/g	<10cfu/g
-E.Coli	Negative	Negative
-Salmonella	Negative	Negative
Conclusion	Comply with EP8.3.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: