

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Diosmin

Batch No.: DR20140428	Quantity: 1000.kg
Manufacture Date: 2014.04.28	Expiry Date: 2016.04.27

TESTS:

Items	Specification	Results
CHARACTERS -Appearance -Solubility	Greyish-yellow or light yellow hygroscopic powder. Practically insoluble in water,soluble In dimethyl sulphoxide,practically insoluble in alcohol.It dissolves in dilute solutions of alkali hydroxides.	Greyish— yellow hygroscopic powder. Conforms
IDENTIFICATION A.Infrared absorption spectrophotometry (2.2.24) B.Examine the chromatograms obtained in the Assay	Comparison: diosmin CRS The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution(a).	Conforms Conforms
TESTS -Iodine(2.2.36)&(2.5.10) -Related substances(HPLC)(2.2.29) -impurity A:acetoisovanillone -impurity B:hesperidin -impurity C:isorhoifin -impurity E:linarin -impurity F:diosmetin -any other impurity -total of other impurities and impurity A -total -Heavy metals(2.4.8) -Water(2.5.12) -Sulphated ash(2.4.14)	≤0.1% ≤1.0% ≤5.0% ≤3.0% ≤3.0% ≤3.0% ≤1.0% ≤1.0% ≤10.0% ≤20ppm ≤6.0% ≤0.20%	Conforms 0.09% 2.22% 1.26% 1.12% 0.83% Conforms Conforms 7.07% <20ppm 1.99% 0.1%
ASSAY(HPLC),anhydrous substance(2.2.29)	90.0%-102.0%	92.53%
Particle size	95%< 45um	Conforms
RESIDUAL SOLVENTS(2.4.24) -Methanol -Ethanol -Pyridine	≤3000ppm ≤5000ppm ≤200ppm	<3000ppm <5000ppm <200ppm

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MICROBIOLOGICAL TESTS(2.6.12) &(2.6.13) -Total Plate Count -Yeasts and Molds -Salmonella -E.Coliform -Saureus -Absence of PS Aerugions	<1000/g <100/g Negative in 1g Negative in 1g Negative in 1g Negative in 1g	<1000/g <100/g Negative in 1g Negative in 1g Negative in 1g Negative in 1g
Conclusion: The results conform to EP7.0.		

Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhui

