

Diacerein EP8.0

Batch no 20241011 Mf date 0ct 11 2024 Retest 0ct 11 2026

Molecular Structure

Molecular Formula

 $C_{19}H_{12}O_8$

Molecular Weight

368.3

CAS Registry Number

13739-02-1

Dec 09 2024

Tests	<u>Specifications</u>		Results
Appearance	To the or you are the powder		Conforms
Solubility	Practically insoluble in water,		Conforms
	dimethylacetamide, slightly so		
	tetrahydrofuran practically in anhydrous ethanol	soluble in	
Identification	IR		Positive
Loss on drying	≤ 0.5%		0. 14%
Sulfated ash	≤ 0.1%		0. 03%
Chromium, Cr	≤ 10 ppm		1.16 ppm
Impurities B&H	≤ 15 ppm		Conforms
Related substances	Impurity C	≤ 0.2%	0. 12%
	Impurity D	≤ 0.5%	0. 29%
	Impurity E	≤ 0.2%	0. 16%
*	Impurity F	≤ 0.15%	0. 13%
~ *	Individual unspecified impurity	$y \leq 0.1\%$	0. 07%
	Total impurities	≤ 2.0%	1. 05%
Solvents residue	Ethanol ≤ 5000 ppm		3400 ppm
Bulk density	40 ~ 60 g/100 mL		57 g/100 mL
Particle size	100% pass 80 mesh		Conforms
Assay (odb)	98.0 $^{\sim}$ 102.0% of $C_{19}H_{12}O_8$		99.0%

Packaging and storage	In an airtight container, protected from light	
Conclusion	Material complies with EP8.0	

