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**CERTIFICATE OF ANALYSIS**

PRODUCT: TROXERUTIN EP9
MANUFACTURING DATE: May 14th, 2017
EXPIRY DATE: May 13th, 2019

BATCH No. C002K170601
BATCH SIZE: 1000 kg

SPECIFICATION: EP9

NATURE OF TEST	QUALITY STANDARD	TEST RESULT
CHARACTERISTICS:		
- Appearance	Yellowish-green crystalline powder, hygroscopic	Conforms
- Solubility	Free Soluble in water; slightly soluble in ethanol; practical insoluble in methylene chloride.	Conforms
IDENTIFICATION:		
A. IR	Identical with that of the reference (comparison: troxerutin CRS)	Conforms
B: Examine the chromatogram	obtained in the test for composition	Conforms
PURITY TEST:		
- Composition		
- principal peak Trihydroxyethylrutin	$\geq 80 \%$	87.7%
- Any other peak than principal peak	Each peak $\leq 5.0 \%$, except 1 peak can be $\leq 10.0 \%$	Conforms
- Result reported:		
Monohydroxyethylrutin(RRT about 0.8)	Meets the a.m.requirements	0.05%
Dihydroxyethylrutin(RRT about 1.1)	Meets the a.m.requirements	5.0%
Tetrahydroxyethylrutin(RRT about 0.5)	Meets the a.m.requirements	1.3%
Maximum other peak detected	$\leq 5.0 \%$	2.3%
- Loss on drying	$\leq 5.0 \%$	1.4%
- Sulphated ashes	$\leq 0.4 \%$	0.1%
- GC		
Ethylene oxide	$\leq 1 \text{ ppm}$	not detected
RESIDUAL SOLVENTS:		
- Methanol	$\leq 3000 \text{ ppm}$	69ppm
- Triethylamine	$\leq 100 \text{ ppm}$	5ppm
DOSAGE:		
- Assay(UV, according to dried substance)	95.0 %-105.0 %	100.0%
MICROBIOLOGICAL TEST:		
-Total plate count /1g	≤ 1000	<10
-Yeast & mould /1g	≤ 100	10cfu/g
-E. Coli /1g	Absence	Absence
CONCLUSION: THE TEST RESULTS CONFORM TO CURRENT EP MONOGRAPH/EP9.		