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CERTIFICATE OF ANALYSIS

PRODUCT: TROXERUTIN EP7

MANUFACTURING DATE: January 08, 2012

EXPIRY DATE: January 07, 2015

BATCH No.: C002E120105

BATCH SIZE: 1,000 kg

SPECIFICATION: C002E

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	$\geq 80 \%$	87.7 %
Trihydroxyethylrutin	Each peak $\leq 5.0 \%$, except	Conforms
- Any other peak than principal peak	1 peak can be $\leq 10.0 \%$	
- Result reported:		
Monohydroxyethylrutin(RRT about 0.8)	Meets the a.m.requirements	0.2 %
Dihydroxyethylrutin(RRT about 1.1)	Meets the a.m.requirements	5.2 %
Tetrahydroxyethylrutin(RRT about 0.5)	Meets the a.m.requirements	1.0 %
Maximum other peak detected	$\leq 5.0 \%$	2.1 %
- Loss on drying	$\leq 5.0 \%$	0.9 %
- Sulphated ashes	$\leq 0.4 \%$	0.05 %
- Heavy metals	$\leq 20 \text{ ppm}$	< 20 ppm
- GC		
Ethylene oxide	$\leq 1 \text{ ppm}$	Not detected
RESIDUAL SOLVENTS:		
- Methanol	$\leq 3000 \text{ ppm}$	115 ppm
- Etanol	$\leq 5000 \text{ ppm}$	5 ppm
- Ethyl acetate	$\leq 5000 \text{ ppm}$	1 ppm
- Pyridine	$\leq 200 \text{ ppm}$	2 ppm
DOSAGE:		
- Assay(UV, according to dried substance)	95.0 %-105.0 %	99.3 %
CONCLUSION: THE TEST RESULTS CONFORM TO C002E.		
MICROBIOLOGICAL TEST:		
-Total plate count /1g	≤ 1000	<10
-Yeast & mould /1g	≤ 100	<10
-E. Coli /1g	Absence	Absence
CONCLUSION: THE TEST RESULTS CONFORM TO MICROBIOLOGICAL REQUIREMENTS.		