



Hanmi Fine Chemical Co., Ltd.

1248-8, Chongwang-Dong, Shihung-City, Kyonggi-Do, KOREA

Tel : +82(31)499-2541, Fax : +82(31)499-2540

## Certificate of Analysis

We hereby confirm that the goods are according to Ph. Eur.

Ref. No. : 20120919-11

Product : Sterile Ceftriaxone Sodium

Formula :  $C_{18}H_{16}N_6Na_2O_7S_3 \cdot 3\frac{1}{2}H_2O$

M.W. : 661.61

Batch No. : 12CTOHA11108

Mfg. Date : Sep. 03, 2012

Retest Date : Mar. 02, 2014

Quantity : 60kg (Net)

### PHYSICAL & CHEMICAL PROPERTIES

TEST	SPECIFICATION	RESULT
Characters		
- Appearance	Almost white or yellowish crystalline powder	Almost white crystalline powder
- Solubility	Freely soluble in water, sparingly soluble in methanol, very slightly soluble in anhydrous ethanol	Passed
Identification		
- IR	To be concordant with standard spectrum	Confirmed
- Sodium	To be formed a white precipitate	Confirmed
Appearance of solution		
- Clarity of solution	The same as clarity of water or not more pronounced than clarity of reference suspension I	Passed
- Color of solution	Not more intensely colored than reference solution Y <sub>s</sub> or BY <sub>s</sub>	Passed
pH	6.0 ~ 8.0	7.4
Specific optical rotation	$[\alpha]_D^{20} = -155^\circ \sim -170^\circ$	-162.2°
Related substances		
1) Impurity A	Not more than 1.0%	Not detected
2) Impurity C	Not more than 1.0%	0.04%
3) Impurity E	Not more than 1.0%	0.03%
4) Any unspecified impurity(max.)	Not more than 0.05%	<0.03%
5) Sum of the unspecified impurities	Not assigned	<0.03%
6) Total	Not more than 4.0%	0.07%
Residual Acetone	Not more than 0.5%	0.013%
Bacterial endotoxins	Less than 0.08 IU/mg	Passed
Sterility	Meets the requirements	Passed
Water	8.0% ~ 11.0%	8.4%
Particulate contamination	$\geq 10/\mu$ Not more than 3,000 particles/g	12
(sub-visible)	$\geq 25/\mu$ Not more than 300 particles/g	1
Assay	96.0% ~ 102.0% (as anhydrous basis)	99.9%

\* Packing and storage conditions : Preserve in tight containers protected from light and store below 25°C.

\* Impurity B (Ceftriaxone Lactone) and Impurity D (AT-MT) are not detected actually in Hanmi Ceftriaxone Sodium at all.

\* Hanmi does not use N,N-dimethylaniline(N,N-DMA) and 2-ethylhexanoic acid(2-EHA) in the manufacturing process.

So, tests of N,N-DMA and 2-EHA are not carried out.

\* Reporting level of impurity : above 0.03%

Signature

*Luthio Son* Sep. 19, 2012

Luthio Son (E-mail : ssk119@hanmifc.co.kr) / QC Manager

Issued Date : Sep. 19, 2012

Related SOP No. : QC 122