Hanmi Fine Chemical Co., Ltd.
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Certificate of Analysis

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

Ref. No. : 20120913-01
Product : Sterile Ceftriaxone Sodium
Formula : $C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3^1/_2H_2O$
M.W. : 661.61

Batch No. : 12CTOHA11099
Mfg. Date : Jul. 30, 2012
Retest Date : Jan. 29, 2014
Quantity : 230kg (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_5 or BY_6	Passed
pH	6.0 ~ 8.0	7.3
Specific optical rotation	$[\alpha]_D^{20}$ = - 155° ~ - 170°	- 163.5°
Related substances		
1) Impurity A	Not more than 1.0%	Not detected
2) Impurity C	Not more than 1.0%	0.07%
3) Impurity E	Not more than 1.0%	<0.03%
4) Any unspecified impurity(max.)	Not more than 0.05%	0.04%
5) Sum of the unspecified impurities	Not assigned	0.04%
6) Total	Not more than 4.0%	0.11%
Residual Acetone	Not more than 0.5%	0.017%
Bacterial endotoxins	Less than 0.08 IU/㎎	Passed
Sterility	Meets the requirements	Passed
Water	8.0% ~ 11.0%	8.4%
Particulate contamination	≥10㎛ Not more than 3,000 particles/g	8
(sub-visible)	≥25㎛ Not more than 300 particles/g	0
Assay	96.0% ~ 102.0%(as anhydrous basis)	99.8%

* Packing and storage conditions : Preserve in tight containers protected from light and store below 25℃.
* 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 Sep. 13, 2012

Issued Date : Sep. 13, 2012

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

Related SOP No. : QC 122