头孢呋辛酯

无定形，原料药（喷雾干燥法）

Cefuroxime axetil, amorphous，APIs (spray drying)

执行标准：CP2015/EP/USP/IP

CAS：64544-07-6

Packaging: 10kg/carton

产品特点

- 2000 年国内首家取得批文并投产

  The first manufacturer won the approval and went into production in 2000

- 3 年有效期，稳定性好

  Three-year validity period, good stability

- 第二代口服头孢菌素，安全、疗效好、见效快。
- The second-generation oral cephalosporins with safety and good efficacy

质量性能 Quality Performance

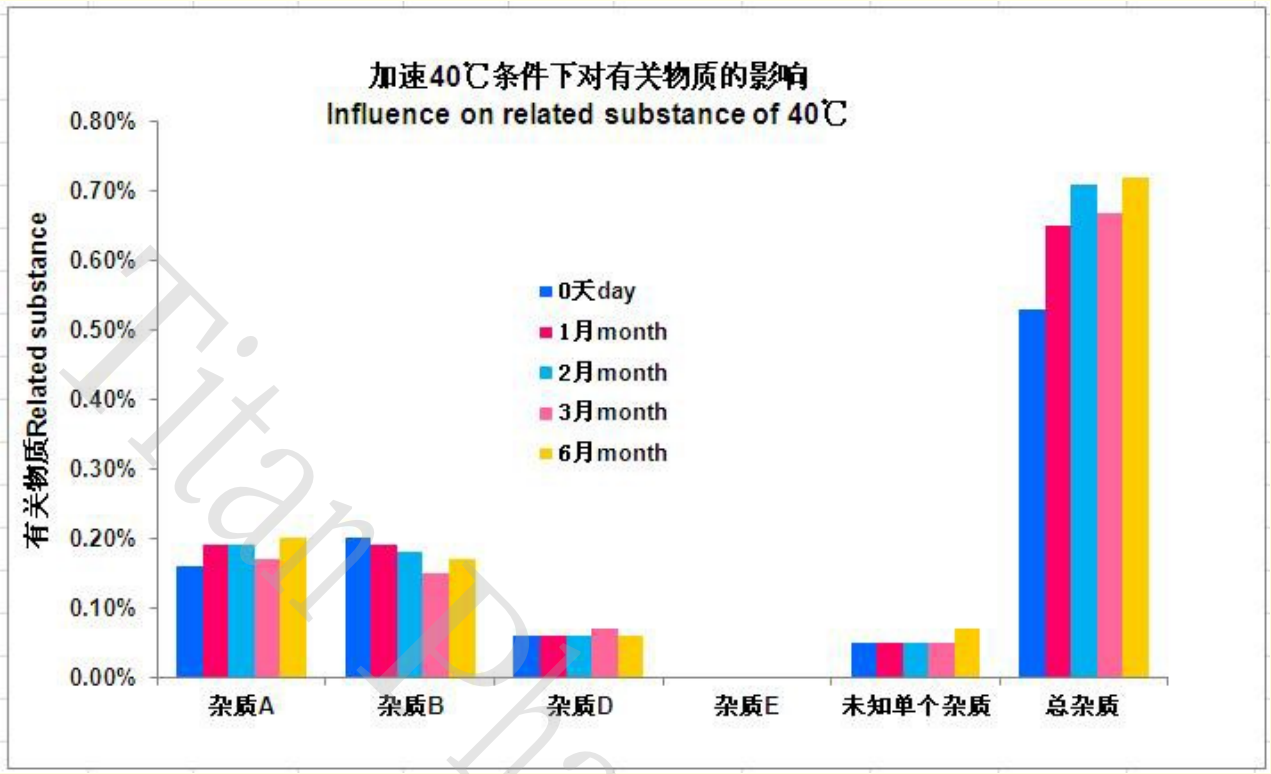
加速试验条件：温度 40±2℃，RH 75±5%，**检验标准：**EP8.0

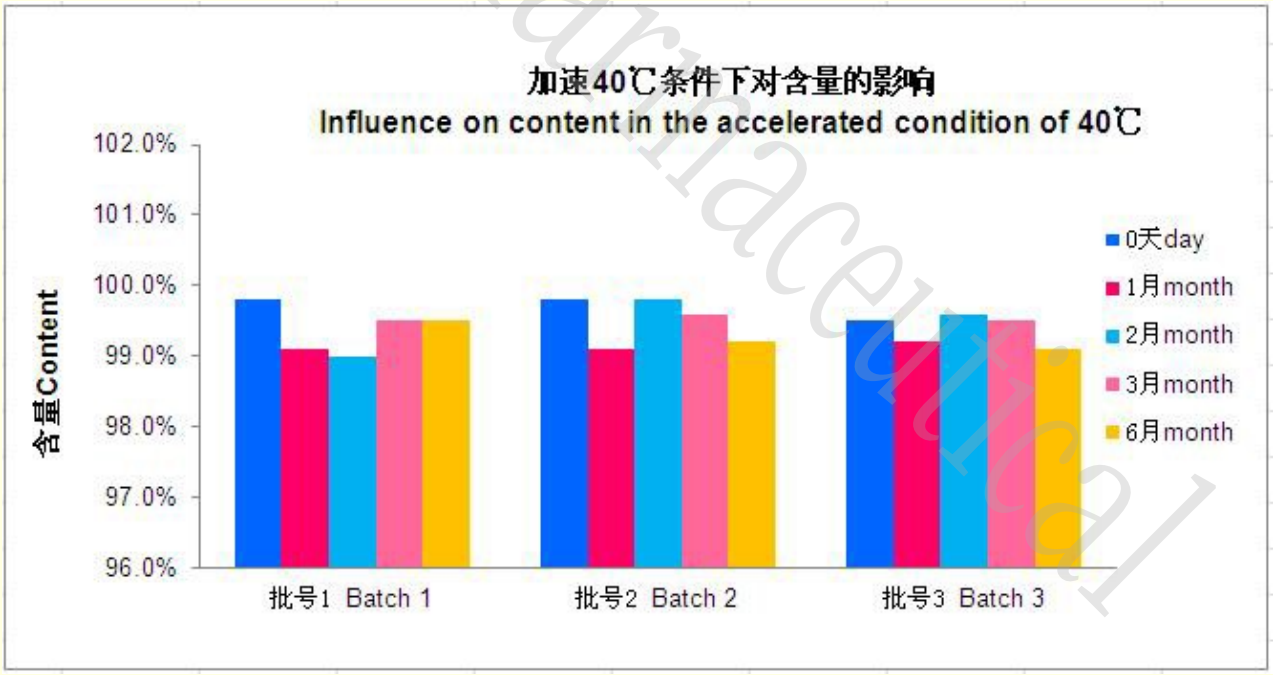
Condition of accelerated testing: 40±2℃, RH75±5%.

Quality Standard: EP8.0 立国

制药 2011 年生产乩随机三批

Three batches of sample produced by Titan Pharmaceutical in 2011





长期试验条件：温度 25±2℃，RH 60 ±10%，**检验标准：**EP8.0

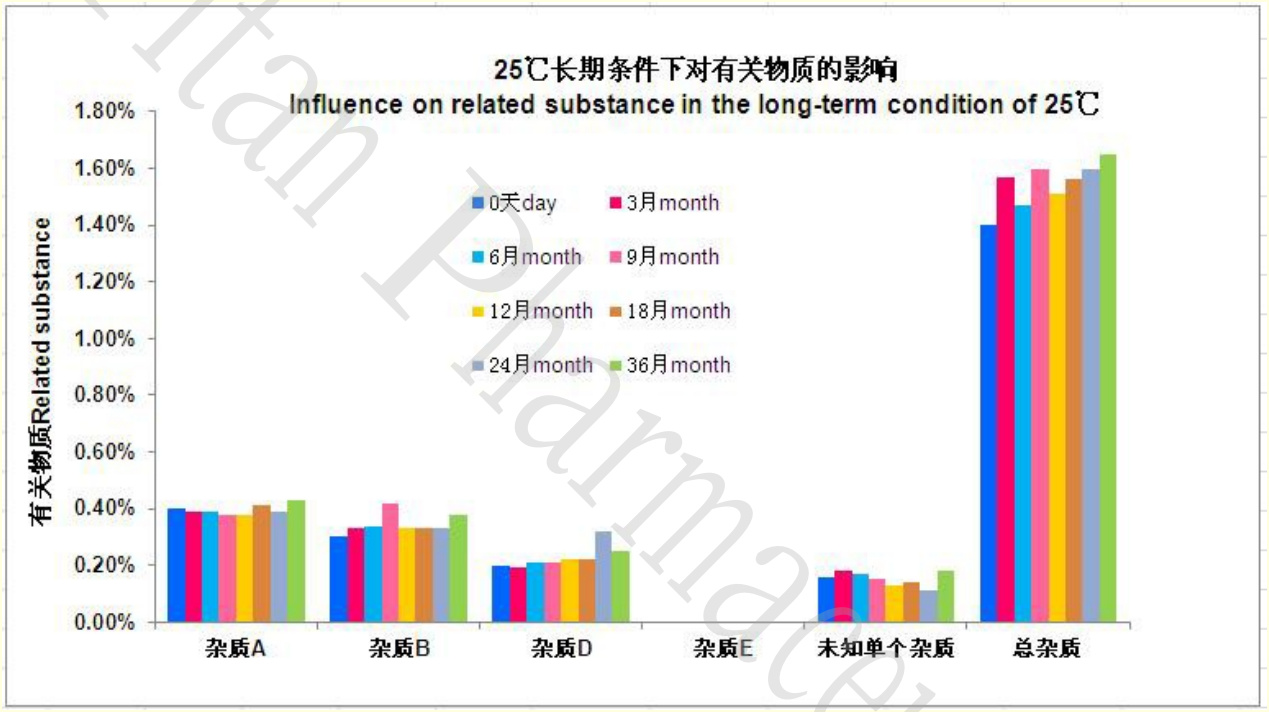
立国制药 2011 年生产的随机三批

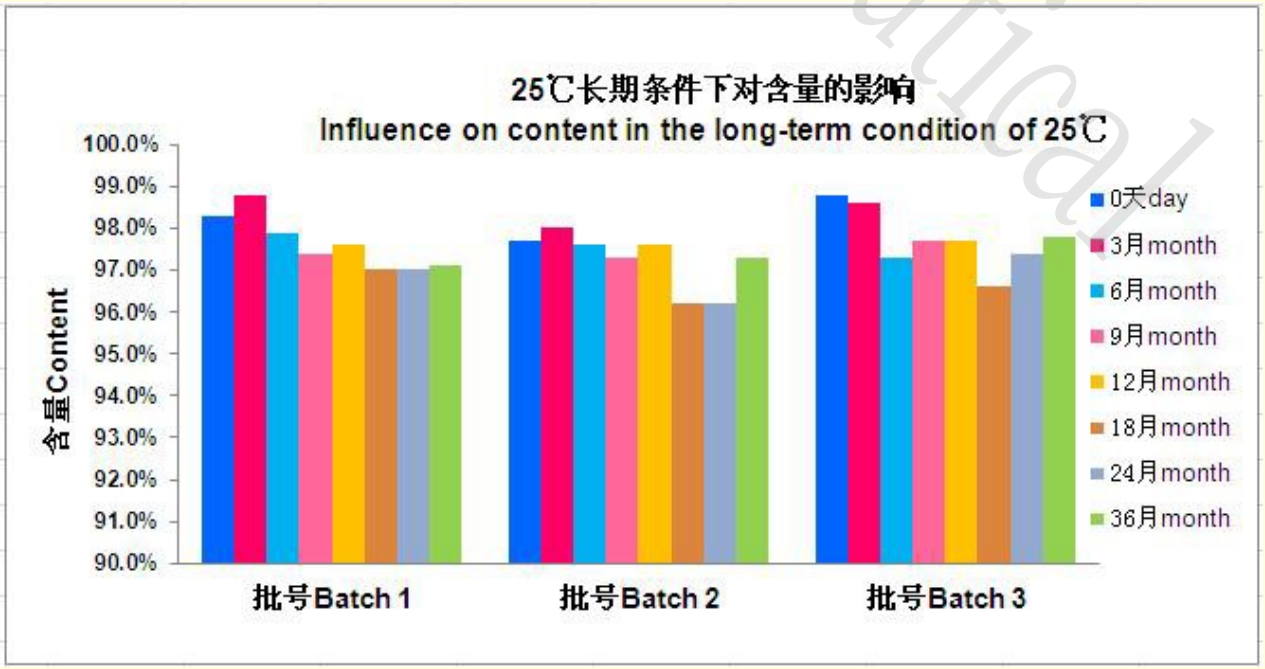
Three batches of sample produced by Titan Pharmaceutical in 2011

Condition of long-term testing: 25±2℃, RH 60% ± 10%,

Quality standard: EP 8.0.

Influence on content in the long-term condition of 25℃





质量标准（国内） Specification (Domestic)

检验项目	药典标准 （中国药典2015年版）	企业放行标准
性状		
性状	白色或类白色粉末	白色或类白色粉末
吸收系数	390 – 420 (276 nm)	390 – 420 (276 nm)
鉴别		
头孢呋辛酯	本品与头孢呋辛酯对照品HPLC主峰保留时间一致	本品与头孢呋辛酯对照品HPLC主峰保留时间一致
头孢呋辛酯	本品红外光吸收图谱与中国药典红外光谱集923图一致	本品红外光吸收图谱与中国药典红外光谱集923图一致
检查		
结晶性	无消光位和双折射	无消光位和双折射
异构体	0.48~0.55	0.48~0.55
有关物质	E异构体：≤1.0%	E异构体：≤0.5%
	Δ^3异构体：≤1.5%	Δ^3异构体：≤0.5%
	单个杂质：≤0.5%	单个杂质：≤0.25%
	总杂质：≤3.0%	总杂质：≤1.5%
水分	≤1.5%	≤1.5%
炽灼残渣	≤0.2%	≤0.2%
重金属	不超过百万分之二十	不超过百万分之二十
残留溶剂	二氯甲烷：≤0.06%	二氯甲烷：≤0.05%
	N,N -二甲基乙酰胺：≤0.109%	N,N -二甲基乙酰胺：≤0.08%
	乙酸乙酯：≤0.5%	乙酸乙酯：≤0.4%
	异丙醇：≤0.5%	异丙醇：≤0.4%
	环已烷：≤0.388%	环已烷：≤0.3%
	丙酮：≤0.5%	丙酮：≤0.45%
微生物限度	需氧菌总数：≤10^3cfu/g	需氧菌总数：≤10^3cfu/g
	霉菌和酵母菌总数：≤10^2cfu/g	霉菌和酵母菌总数：≤10^2cfu/g
	大肠埃希菌：不得检出	大肠埃希菌：不得检出
含量测定		
头孢呋辛含量	不少于75.0 % (按无水物计)	不少于80.5 % (按无水物计)

质量标准（EP8.0） Specification (EP8.0)

检验项目 Parameter	标准 Specification	药典参照 Pharmacopoeia reference
性状 Characters		
外观 Appearance	白色或类白色粉末 White or almost white powder	--
鉴别 Identification		
头孢呋辛酯 Cefuroxime axetil	本品与头孢呋辛酯对照品红外光吸收图谱一致 IR-spectra of the substance is comparable with the Ph. Eur. reference spectrum of cefuroxime axetil.	Ph. Eur.2.2.24
头孢呋辛酯 Cefuroxime axetil	本品与头孢呋辛酯对照品HPLC主峰保留时间一致 The principal peaks in the chromatogram obtained with the test solution are similar in retention time and size to that obtained with reference solution (d).	Ph. Eur.2.2.29
检查 Tests		
有关物质 Related substances	A杂质（Δ^3-异构体）：不超过1.5% Impurity A(Δ^3-isomer): n.m.t 1.5%	Ph. Eur.2.2.29
	B杂质（E-异构体）：不超过1.0% Impurity B(E-isomer): n.m.t 1.0%	
	D杂质（头孢呋辛酸）：不超过0.5% Impurity D(Cefuroxime acid): n.m.t 0.5%	
	E杂质（DCC内酯）：不超过0.5% Impurity E(DCC lactone): n.m.t 0.5%	
	未知单个杂质：不超过0.10% Individual non-specified impurity : n.m.t 0.10%	
	总杂质：不超过3.0% Total impurities: n.m.t 3.0%	
异构体 Diastereoisomer ratio	0.48~0.55	Ph. Eur.2.2.29
水分 Water	不超过1.5% n.m.t 1.5%	Ph. Eur.2.5.12
结晶性 Crystalline	无消光位和双折射 Amorphous nature	Ph. Eur.5.11
残留溶剂 Residual solvents	丙酮：不超过5000 ppm Acetone: n.m.t 5000 ppm	Ph. Eur.2.2.28 Ph. Eur.2.4.24
	异丙醇：不超过5000 ppm Isopropanol: n.m.t 5000 ppm	
	乙酸乙酯：不超过5000 ppm Ethyl acetate: n.m.t 5000 ppm	
	N, N-二甲基乙酰胺：不超过1090 ppm Dimethylacetamide: n.m.t 1090 ppm	
含量测定 Assay		
头孢呋辛酯含量 Content of Cefuroxime axetil	96.0%~102.0% (按无水物计) (Anhydrous substance)	Ph. Eur.2.2.29