



Certificate of Analysis

Product name	Flumazenil		
Batch No.	RY160203	CAS No.	78755-81-4
Mfg. Date	24 th ,Feb,2016	Exp. Date	23th,Feb,2018
Standard	USP32	Quantity	189g

Tests	Specifications	Result
Appearance	White or off white crystalline powder	Complies
Identification		
IR	The sample's IR spectrum is according with spectrum of Flumazenil	Complies
HPLC	The retention time of the major peak for flumazenil in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay	complies
Related substance		
Flumazenil related compound A	≤0.2%	Not detected
7-fluoro-4-methyl-3,4-dihydro-2,5H-1,4-benzodiazepine-2,5-dione	≤0.2%	Not detected
Ethyl-5,6-dihydro-5-methyl-6-oxo-4H-imidazo- 【1,5-a】【1,4】 benzodiazepine-3-carboxylate	≤0.2%	Not detected
Flumazenil related compound B	≤0.2%	Not detected
Ethyl-8-chloro-5,6-dihydro-5-methyl-6-oxo-4H-imidazo- 【1,5-a】【1,4】	≤0.2%	Not detected

benzodiazepine-3-carboxylate		
Any individual unknown impurity	≤0.1%	<0.1%
Total impurity	≤0.5%	<0.1%
Bacterial endotoxins	≤25.0EU/mg	complies
Microbial limits		
Bacterial:	≤50CFU/g	<10CFU/G
Mildew and microzyme:	≤50CFU/g	<10CFU/G
Escherichia coli	absence	absence
Loss on Drying	≤0.5%	<0.1%
Melting point	198°C-202°C	199°C-200°C
Residue on ignition	≤0.1%	<0.1%
Heavy metals	≤20ppm	Complies
Assay(on dried basis)	98.0%~102.0%	99.4%
Conclusion : Conforms to USP32 standard		

Tested by: Alice

Checked by: Penny

Approved by: Michelle