SALES SPECIFICATION

CERTIFICATE OF ANALYSIS

Product Name	**ATOPINE SULPHATE BP/USP**	
Items	**Specifications**	**Results**
Appearance	Crystalline powder or white granular	White granular
Identification	A: IR B: Sulphate	Complies
Loss on drying	<4.0%	2.5%
Residual on ignition	<0.2%	0.10%
Specific Rotation	-0.60°~+0.50°	-0.005°
MP	≤187°C	189.5°~192°C
Assay:	98.5%~101.0%	99.0%
Conclusion	**It conforms to USP34**	

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SALES SPECIFICATION

BESIFLOXACIN HYDROCHLORIDE (MICRONISED AND STERILE)

Items	Specifications	Results
Appearance	White to yellow crystal powder	Confirms
Solubility	Very slightly spoilable in menthol and ethanol	Confirms
Identification	IR,HPLCM, UV	Confirms
Total impurities	≤1.0%	0.8%
Single impurity	≤.5%	0.4%
Heavy metals	≤20ppm	Confirms
Residue on ignition	≤0.2%	0.10%
Loss on drying	≤1.0%	0.52%
Particle Size	d(0.9) <10micron	Confirms
Acidity	1.8~3.0	2.2
Microbial Limit (Bacte-ria)	Total Count NMT 100 cfu/g	Confirms
Yeasts & Moulds)	Meets the requirements	Confirms
Sterility	8.0%~8.5%	8.2%
Chlorine content	≥99.0%	99.55%

Conclusion **It conform to the factory's standard**

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SALES SPECIFICATION

Product Name **BRINZOLAMIDE (MICRONISED AND STERILE)**

Items	Specifications	Results
Description	White or almost white micronized fine powder	Complies
Identification	UV/ IR	Complies
Solubility	Insoluble in water, slightly soluble in alcohol and in methanol	Complies
Appearance of Solution	Clear and colorless	Complies
Melting point	NLT125 °C	131.0132.4°C
Specific optical rotation	+14.5°-+17.0°	+15.75°
Heavy Metals	20ppm Max	Complies
Loss on drying	0.5% Max	0.03%
Residue on lenition	0.1% Max	0.02%
Related substances		
Impurity A	≤0.5%	ND
Impurity B	≤0.3%	ND
Purity	≥99.0%	99.90%
Total Impurities	≤1.0%	0.1%
Assay	98.0%~102.0%	99.2%
Residual Solvents		
Accetonitrile	≤410ppm	N.D
Terahydrofuran	≤720ppm	N.D
1,2-dimethoxyethane	≤100ppm	N.D
Tert-butylmethl ether	≤5000ppm	N.D
Ethyl accetate	≤5000ppm	ND
Isopropanol	≤5000ppm	317PPM
Particle Size	95% ≤5micron 100%≤10micron	95% 100%

Conclusion **The material complies to the specification given by USP 32.**

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SALES SPECIFICATION

Moxifloxacin Hcl (Injectable Grade)

Sl.No	Test	Specifications	Results
1	Appearance	Light yellow or yellow powder or crystal , slightly hygroscopic	Yellow crystal slightly hygroscopic
2	Solubility	Sparingly soluble in Water and Slightly Soluble in ethanol (96%) Practically insoluble in Acetone	Sparingly soluble in Water and Slightly Soluble in ethanol (96%) Practically insoluble in Acetone.
3	Identification by A) Optical Rotation and On anhydrous basis. b) Infrared absorption c) Reaction of Chloride	a)Between -125 to138 b) The IR spectrum of the test sample Should be concordant with that of working Standard. c) Should respond to the test for Chlorides	a)-132.35 b) The IR spectrum of the test sample Should be concordant with that of working Standard. c) compiles
4	Appearance of solution	The solution is not more Opalescent than reference suspension II(2.2.2) not more intensely colored than reference Solution GY2(2.2.2Method II)	The solution is not more Opalescent than reference suspension II(2.2.2) not more intensely colored than reference Solution GY2(2.2.2Method II)
5	pH	Between 3.9 and 4.6	4.40
6	Related substance (By HPLC) A)Impurities A, B,C,D,E B)Unspecified Impurity C)Total Impurity	A)Not more than 0.10 B)Not more than 0.10 c)Not more than 0.30	Impurities –A=0.08 Not Detected Not Detected Not Detected B)0.03 c)0.12
7	Water content by KFR(%W/W)	Not more than 4.5	3.12
8	Sulphate ash(%W/W)	Not more than 0.1	0.08
9	Assay By HPLC (On anhydrous basis.)(%w/w)	Not more than 98.0and not more than 102.0	99.1
10	Microbial limits a) Total plate count (CFU/g) b) Yeast and mould (CFU/g) c) E.coli/g d) Staphylococcus Aurus/g e) Salmonella/g f) Endotoxin (Eu/mg)	Not more than 1000 Not more than 100 Should be absent Should be absent Should be absent	Not more than 1000 Not more than 100 absent absent absent

Remark: The product Confirms as per the above Specification.

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SALES SPECIFICATION

Product Name	**FLUROMETHOLONE (Micronise)**	
Items	**Specifications**	**Results**
Appearance	White or almost white crystalline powder	Confirms
Identification	A, B, C	Complies
Loss on drying	≤1.0%	0.48%
Specific optical rotation	+52°- +60°	+53.6°
Residual Solvent	Tetrahydrofuran ≤720ppm Acetone ≤5000ppm Methanol ≤3000ppm Dichloromethane ≤600ppm	Confirms Conforms Confirms 0.03%
Residual on ignition	≤0.2%	0.06%
Assay	97.0%~103.0%	98.3%
Particle Size	96. 54% ≤10micron	Complies
Conclusion	**Confirm to USP37**	

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SALES SPECIFICATION

Tobramycin

Items	Specifications	Results
Appearance	White or almost white crystalline powder	Confirms
Identification	A: Confirms with reference R.F (TLC) B: Confirms with reference standard retention time (HPLC)	Complies
Water	≤8.0%	3.5%
PH	9.0-11.0	10.0
Residual on ignition	≤1.0%	0.0%
Heavy metals	≤0.003%	≤0.003%
TLC Chromatographic Purity	>1.0%	≤1.0%
Assay	≤ 900ug/mg(on anhydrous Basis)	938ug/mg
Bacteria Endotoxin	<2EU/mg	<2EU/mg
Solution clear degree and color	Clear, not more than 3 bugle yellow or Flavour-green	Clear <2# Yellow
Residual Solvents	Ethanol not more than 2000ppm	1050ppm
Microbiological purity	Not more than 1000 aerobic bacteria per 1g Not more than 100 fungi per 1g Absence of Escherichia Coli per 1g	<10CFU/g <10CFU/g Undetected
Conclusion	**Conform with the specification of USP and the specification of NNR**	

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SALES SPECIFICATION

TROPICAMIDE

Items	Specifications	Results
Appearance	White crystalline Powder	Complies
Identification	A, B, C, D, E	Complies
Optical rotation	-0.1 ~ 0.1	Complies
Solution	Clear and colorless	Complies
M. P	96-100 C degree	96.5—98.0
Loss on drying	≤0.5%	0.05%
Chloride	<0.1%	Complies
Heavy Metal	<0.002%	Complies
Residue on ignition	<0.05%	<0.05%
Related substance	Single impurity tropic acid <0.5% N-Ethyl 4-Picolyl Methylene Amine <0.2%	Negative Nagative
Assay	99.0% - 101.0%	99.50%
Conclusion	**Conform with USP32**	

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