OPKO CHILE S.A.

ESPECIFICACIONES DE EXCIPIENTES

Gentamicina Sulfato solución oftálmica 0,3%

Subdepartamento Registros y Autorizaciones Sanitarias

Fórmula Cuali-Cuantitativa

Cada 1 mL de Gentamicina Sulfato solución oftálmica 0,3% contiene:

Ingrediente	Cantidad (mg)	Exceso (%)	Cantidad declarada (%)	Función	Especificación
Gentamicina Sulfato* *Equivalente a 3 mg de Gentamicina*	5,29	10	0,3%	Principio Activo (Antibiótico)	BP
Nitrato de fenilmercurio	0,02	-	0,002%	Preservante	BP
Cloruro de sodio	7,0	-	-	Agente de tonicidad	BP
Borax	3,0	-	-	Agente tampón (Buffer)	BP
Ácido bórico	1,0	-	-	Agente tampón (Buffer)	BP
Agua para inyectables	c.s.p. 1 mL	-	-	Vehículo	BP

***4,8 mg de Gentamicina Sulfato son equivalentes a 3 mg de Gentamicina:**

Valor calculado asumiendo los resultados del ensayo de valoración de Gentamicina como un 100% en base seca. Así, la cantidad total de Gentamicina Sulfato puede variar dependiendo del contenido de agua y de la valoración del activo.

Cálculo:

$$\text{Cantidad total de Gentamicina Sulfato} = \frac{(\text{Cantidad de Gentamicina declarada en la etiqueta} \times \text{tamaño de lote} \times 100)}{(\text{Valoración de Gentamicina Sulfato base})} + \text{Exceso}(\%)$$

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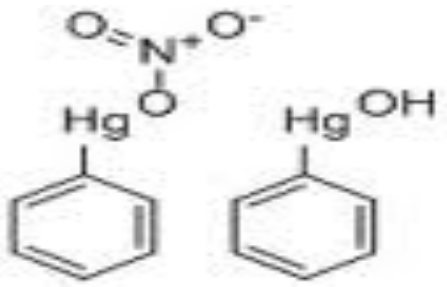
RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **PHENYLMERCURIC NITRATE BP**

SPECIFICATION	AS PER BP	PAGE NO.	1 OF 2
SPECIFICATION NO.	CI/RM/QA/1391/02	SUPERCEDES	CI/RM/QA/1391/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	SEP 2014	REVIEW DATE	SEP 2019

MOLECULAR STRUCTURE :



IUPAC NAME : Mixture of phenylmercuric Nitrate and phenylmercuric hydroxide.

MOLECULAR FORMULA : Phenylmercuric Nitrate: $C_6H_5HgNO_3$
Phenylmercuric hydroxide: C_6H_5HgOH

MOLECULAR WEIGHT : $C_6H_5HgNO_3$: 339.7
C_6H_5HgOH : 294.7

STORAGE : Protected from light.

CATEGORY : Antiseptic, antimicrobial preservative.

SHELF LIFE : Not less than 4 years

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RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **PHENYLMERCURIC NITRATE BP**

SPECIFICATION	AS PER BP	PAGE NO.	2 OF 2
SPECIFICATION NO.	CI/RM/QA/1391/02	SUPERCEDES	CI/RM/QA/1391/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	SEP 2014	REVIEW DATE	SEP 2019

S.N.	TEST		SPECIFICATION
1.	**DESCRIPTION**	:	White or pale yellow powder.
2.	**SOLUBILITY**	:	Very slightly soluble in water and in ethanol (96 %), slightly soluble in hot water. It dissolves in glycerol and in fatty oils.
3.	**IDENTIFICATION**	:	**A.** A white precipitate is formed that darkens slowly on heating. **B.** A white, flocculent precipitate is formed. **C.** The lower layer is orange-yellow. **D.** The upper layer is coloured deep violet.
4.	**APPEARANCE OF SOLUTION**	:	Solution S is colourless.
5.	**INORGANIC MERCURIC COMPOUNDS**	:	Maximum 0.1 %
6.	**LOSS ON DRYING**	:	Maximum 1.0 % w/w.
7.	**ASSAY (BY TITRIMETRY)**	:	NLT 62.5 % and NMT 64.0 % on dried basis.

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RAW MATERIAL STANDARD TESTING PROCEDURE			
ITEM : **SODIUM CHLORIDE BP**			
SPECIFICATION	AS PER BP	PAGE NO.	1 OF 3
SPECIFICATION NO.	CI/RM/QA/120/02	SUPERCEDES	CI/RM/QA/120/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

MOLECULAR STRUCTURE : Not available

IUPAC NAME : Not available

MOLECULAR FORMULA : NaCl

MOLECULAR WEIGHT : 58.44

STORAGE : Store in a well closed container

CATEGORY : Used in treatment of electrolyte deficiency.

SHELF LIFE : Not less than 4 years.

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RAW MATERIAL STANDARD TESTING PROCEDURE			
ITEM : **SODIUM CHLORIDE BP**			
SPECIFICATION	AS PER BP	PAGE NO.	2 OF 3
SPECIFICATION NO.	CI/RM/QA/120/02	SUPERCEDES	CI/RM/QA/120/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

S.N.	TEST		SPECIFICATION
1.	**DESCRIPTION**	:	White or almost white, crystalline powder or colourless crystals or white or almost white pearls.
2.	**SOLUBILITY**	:	Freely soluble in water, practically insoluble in anhydrous ethanol.
3.	**IDENTIFICATION**	:	**A.** It gives the reactions of chlorides: i)The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly. ii)The paper turns violet-red. **B.** It gives the reactions of sodium;i) A dense white precipitate is formed. ii)No precipitate is formed.
4.	**APPEARANCE OF SOLUTION**	:	Solution S is clear and colourless
5.	**ACIDITY OR ALKALINITY**	:	Not more than 0.5 ml of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide is required to change the colour of the indicator.
6.	**BROMIDES**	:	Maximum 100 ppm
7.	**FERROCYANIDES**	:	No blue colour develops within 10 min.
8.	**IODIDES**	:	The substance shows no blue colour.
9.	**NITRITES**	:	The absorbance is not greater than 0.01.

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10.	**PHOSPHATES**	:	Maximum 25 ppm
11.	**SULPHATES**	:	Maximum 200 ppm
12.	**ARSENIC**	:	Maximum 1 ppm
13.	**BARIUM**	:	After 2 hour, any opalescence in the solution is not more intense than that in a mixture of 5 ml of solution S and 7 ml of distilled water.
14.	**IRON**	:	Maximum 2 ppm
15.	**MAGNESIUM AND ALKALINE-EARTH METALS**	:	Maximum 100 ppm
16.	**POTASSIUM**	:	Maximum 500 ppm, if intended for use in the manufacture of parenteral preparations.
17.	**HEAVY METALS**	:	Maximum 5 ppm
18.	**LOSS ON DRYING**	:	Maximum 0.5 % w/w
19.	**BACTERIAL ENDOTOXINS**	:	Less than 5 IU/g, if intended for use in the manufacture of parenteral dosage forms without a further appropriate procedure for removal of bacterial endotoxins.
20.	**ASSAY**	:	99.0% to 100.5% (dried substance)

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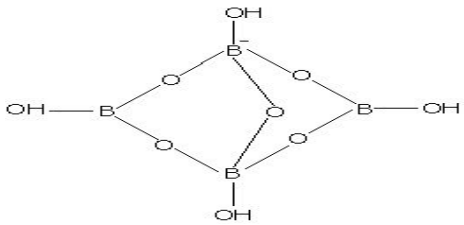
RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **BORAX BP (SODIUM BORATE / SODIUM TETRABORATE)**

SPECIFICATION	AS PER BP 2014	PAGE NO.	1 OF 2
SPECIFICATION NO.	CI/RM/QA/1510/02	SUPERCEDES	CI/RM/QA/1510/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

MOLECULAR STRUCTURE :



IUPAC NAME : Disodium tetraborate decahydrate.

MOLECULAR FORMULA : $Na_2B_4O_7,10H_2O$

MOLECULAR WEIGHT : 381.4

STORAGE : Protected from light.

CATEGORY : Excipient

SHELF LIFE : Not less than 4 years

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RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **BORAX BP (SODIUM BORATE / SODIUM TETRABORATE)**

SPECIFICATION	AS PER BP 2014	PAGE NO.	2 OF 2
SPECIFICATION NO.	CI/RM/QA/1510/02	SUPERCEDES	CI/RM/QA/1510/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

S.N.	TEST		SPECIFICATION
1.	**DESCRIPTION**	:	White or almost white, crystalline powder, colourless crystals or crystalline masses, efflorescent.
2.	**SOLUBILITY**	:	Soluble in water, very soluble in boiling water, freely soluble in glycerol.
3.	**IDENTIFICATION**	:	**A.** The flame has a green border. **B.** On the addition of 5 ml of glycerol (85 per cent) the red colour disappears. **C**. Gives reaction of Sodium; A dense white precipitate is formed.
4.	**APPEARANCE OF SOLUTION**	:	A 4.0 % w/v solution in water is clear and colourless.
5.	**pH**	:	9.0 to 9.6
6.	**SULPHATES**	:	Maximum 50 ppm
7.	**AMMONIUM**	:	Maximum 10 ppm
8.	**ARSENIC**	:	Maximum 5 ppm
9.	**CALCIUM**	:	Maximum 100 ppm
10.	**HEAVY METALS**	:	Maximum 25 ppm
11.	**ASSAY**	:	99.0 % to 103.0 %

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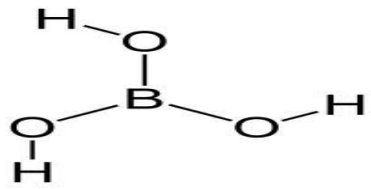
RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **BORIC ACID BP**

SPECIFICATION	AS PER BP	PAGE NO.	1 OF 2
SPECIFICATION NO.	CI/RM/QA/186/02	SUPERCEDES	CI/RM/QA/186/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

MOLECULAR STRUCTURE :



IUPAC NAME : Trihydroxidoboron

MOLECULAR FORMULA : H_3BO_3

MOLECULAR WEIGHT : 61.8

STORAGE : In an airtight container, protected from light.

CATEGORY : Excipient

SHELF LIFE : Not less than 4 years

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RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **BORIC ACID BP**

SPECIFICATION	AS PER BP	PAGE NO.	2 OF 2
SPECIFICATION NO.	CI/RM/QA/186/02	SUPERCEDES	CI/RM/QA/186/01
PLANT	TARAPUR	VERSION NO.	02
EFFECTIVE DATE	JUN 2014	REVIEW DATE	JUN 2019

S.R.	TEST		SPECIFICATION
1.	**DESCRIPTION**	:	White or almost white, crystalline powder, colourless, shiny plates greasy to the touch, or white or almost white crystals.
2.	**SOLUBILITY**	:	Soluble in water and in ethanol (96 per cent), freely soluble in boiling water and in glycerol (85 per cent).
3.	**IDENTIFICATION**	:	**A.** The flame has a green border. **B.** Solution S is acid.
4.	**APPEARANCE OF SOLUTION**	:	A 3.3 % w/v solution in water is clear and colourless.
5.	**pH**	:	3.8 to 4.8
6.	**SOLUBILITY IN ETHANOL (96 PER CENT)**	:	The solution is not more opalescent than reference suspension II and is colourless.
7.	**ORGANIC MATTER**	:	It does not darken on progressive heating to dull redness.
8.	**SULPHATES**	:	Maximum 450 ppm
9.	**HEAVY METALS**	:	Maximum 15 ppm
10.	**ASSAY (BY TITRIMETRY)**	:	99.0 % to 100.5 %

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RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **WATER FOR INJECTIONS BP (IN BULK)**

SPECIFICATION	AS PER BP	PAGE NO.	1 OF 2
SPECIFICATION NO.	CI/RM/QA/1000/04	SUPERCEDES	CI/RM/QA/1000/03
PLANT	TARAPUR	VERSION NO.	04
EFFECTIVE DATE	JAN 2015	REVIEW DATE	JAN 2020

MOLECULAR STRUCTURE : Not Available

IUPAC NAME : Not Available

MOLECULAR FORMULA : H_2O

MOLECULAR WEIGHT : 18.02

STORAGE : Water for injections in bulk is stored and distributed in conditions designed to prevent growth of micro-organisms and to avoid any other contamination.

CATEGORY : Vehicle

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RAW MATERIAL STANDARD TESTING PROCEDURE

ITEM : **WATER FOR INJECTIONS BP (IN BULK)**

SPECIFICATION	AS PER BP	PAGE NO.	2 OF 2
SPECIFICATION NO.	CI/RM/QA/1000/04	SUPERCEDES	CI/RM/QA/1000/03
PLANT	TARAPUR	VERSION NO.	04
EFFECTIVE DATE	JAN 2015	REVIEW DATE	JAN 2020

S.R.	TEST		SPECIFICATION
1.	**DESCRIPTION**	:	Clear and colourless liquid.
2.	**CONDUCTIVITY**	:	Not more than 1.3 μScm^{-1}
3.	**TOTAL ORGANIC CARBON**	:	Maximum: 0.5 mg/l
4.	**NITRATES**	:	Maximum 0.2 ppm
5.	**BACTERIAL ENDOTOXINS**	:	Less than 0.25 IU/ml
6.	**MICROBIAL ENUMERATION TEST**		
	a. TAMC	:	a. 10 CFU/100 ml
	b. TYMC	:	b. 10 CFU/100 ml
	c. Specified Micro-Organisms	:	c. Should be Absent.
	Enterobacteriaceae		
	E.coli		
	Salmonella		
	Stap.Aureus		
	Psud.aeruginosa		

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