

OPKO CHILE S.A.

ESPECIFICACIONES DE EXCIPIENTES

Gentamicina Sulfato solución oftálmica 0,3%

Subdepartamento Registros y Autorizaciones Sanitarias

Fórmula Cualitativa

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

Ingrediente	Cantidad (mg)	Exceso (%)	Cantidad declarada (%)	Función	Especificación
Gentamicina Sulfato* <i>Equivalente a 3 mg de Gentamicina</i>	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:

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



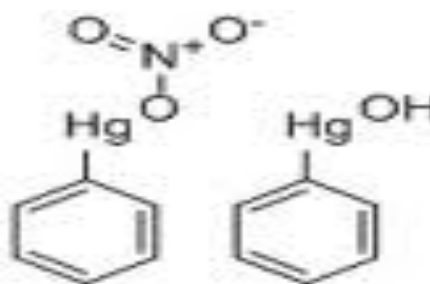
CIRON DRUGS & PHARMACEUTICAL PVT LTD
QUALITY ASSURANCE

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

PREPARED BY	CHECKED BY	APPROVED BY
 MS SHALINA BAGAJI OFFICER-QC	 MRS SHARAU CHAVAN EXECUTIVE-QA	 MRS PAYAL SHETTY MANAGER-QRA



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RAW MATERIAL STANDARD TESTING PROCEDURE

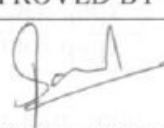
ITEM : PHENYLMERCURIC NITRATE BP

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

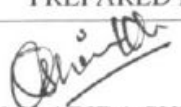
MOLECULAR FORMULA : NaCl

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.

PREPARED BY	CHECKED BY	APPROVED BY
 MS ABIDA SHEIKH OFFICER QC	 MRS VANITA JOSHI EXECUTIVE QA	 MR DEEPAK SOHONI MANAGER QRA



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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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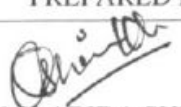
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ITEM : **SODIUM CHLORIDE BP**

SPECIFICATION	AS PER BP	PAGE NO.	3 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

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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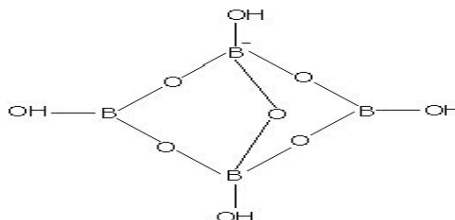
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RAW MATERIAL STANDARD TESTING PROCEDURE

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 : $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$

MOLECULAR WEIGHT : 381.4

STORAGE : Protected from light.

CATEGORY : Excipient

SHELF LIFE : Not less than 4 years

PREPARED BY	CHECKED BY	APPROVED BY
MS ABIDA SHEIKH OFFICER QC	MRS VANITA JOSHI EXECUTIVE QA	MR DEEPAK SOHONI MANAGER QRA



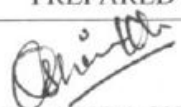
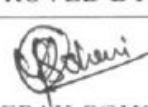
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QUALITY ASSURANCE

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 %

PREPARED BY	CHECKED BY	APPROVED BY
 MS ABIDA SHEIKH OFFICER QC	 MRS VANITA JOSHI EXECUTIVE QA	 MR DEEPAK SOHONI MANAGER QRA



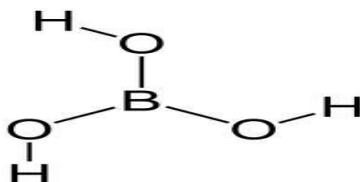
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RAW MATERIAL STANDARD TESTING PROCEDURE

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

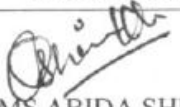
MOLECULAR FORMULA : H₃BO₃

MOLECULAR WEIGHT : 61.8

STORAGE : In an airtight container, protected from light.

CATEGORY : Excipient

SHELF LIFE : Not less than 4 years

PREPARED BY	CHECKED BY	APPROVED BY
 MS ABIDA SHEIKH OFFICER QC	 MRS VANITA JOSHI EXECUTIVE QA	 MR DEEPAK SOHONI MANAGER QRA



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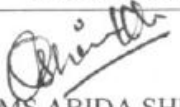
ITEM : **BORIC ACID BP**

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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 MS ABIDA SHEIKH OFFICER QC	 MRS VANITA JOSHI EXECUTIVE QA	 MR DEEPAK SOHONI MANAGER QRA



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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 : H₂O

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 | | |

PREPARED BY	CHECKED BY	APPROVED BY
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