

(CIN: U24230GJ2012PTC072692)

**Quality Control Department Certificate of Analysis  
(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2203911	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP20004142
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Oct-2020	<b>Exp. Date</b>	Sep-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	30-Oct-2020
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1°C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		
13.1.1	<b>For greater than or equal to</b>	Not More Than 6000 particles per	132.33 Particles per

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Ashish.Patel	Analyzed On	17-Nov-2020 13:06
Reviewed By	Paresh.Gajjar	Reviewed On	17-Nov-2020 13:06
Approved By	Omprakash.Sharma	Approved On	17-Nov-2020 13:07

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**Otsuka Pharmaceutical India Private Limited**  
**Village-Vasana-Chacharwadi, Tal-Sanand,**  
**Ahmedabad-382 213.India.T:+91 2717 667000**  
**F:+91 2717667050 W: www.otsukapharma.in**



(CIN: U24230GJ2012PTC072692)

**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2203911	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP20004142
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Oct-2020	<b>Exp. Date</b>	Sep-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	30-Oct-2020
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

	<b>10 µm</b>	container	container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	10.67 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Ashish.Patel	Analyzed On	17-Nov-2020 13:06
Reviewed By	Paresh.Gajjar	Reviewed On	17-Nov-2020 13:06
Approved By	Omprakash.Sharma	Approved On	17-Nov-2020 13:07

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**Printed on: 11-Feb-2021 12:11**

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210068	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000648
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	21-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	05-Feb-2021 11:50
Reviewed By	Ashish.Patel	Reviewed On	05-Feb-2021 12:14
Approved By	Sanjay.Patel	Approved On	05-Feb-2021 13:08
<b>Printed by: Ashish.Patel</b>		<b>Printed on: 05-Feb-2021 15:40</b>	
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**(CIN: U24230GJ2012PTC072692)**



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**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210068	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000648
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	21-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	32.33 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	3.00 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	05-Feb-2021 11:50
Reviewed By	Ashish.Patel	Reviewed On	05-Feb-2021 12:14
Approved By	Sanjay.Patel	Approved On	05-Feb-2021 13:08

**Printed by: Ashish.Patel**

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210069	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000671
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:28
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:24
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 12:50
<b>Printed by: Ankit.Halari</b>		<b>Printed on: 06-Feb-2021 16:15</b>	
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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210069	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000671
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	27.33 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	3.00 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:28
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:24
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 12:50

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210070	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000681
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:32
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:04
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 13:03

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**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210070	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000681
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	10.67 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	0.33 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:32
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:04
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 13:03

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**Quality Control Department Certificate of Analysis  
(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210071	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000695
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:33
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:18
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 13:04

Printed by: Ankit.Halari

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**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210071	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000695
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	22-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	8.33 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	0.33 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	06-Feb-2021 11:33
Reviewed By	Ankit.Halari	Reviewed On	06-Feb-2021 12:18
Approved By	Sanjay.Patel	Approved On	06-Feb-2021 13:04

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**Quality Control Department Certificate of Analysis  
(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210072	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000716
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	07-Feb-2021 11:45
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 12:40
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 14:29

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Printed on: 07-Feb-2021 16:20

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**Otsuka Pharmaceutical India Private Limited**  
**Village-Vasana-Chacharwadi, Tal-Sanand,**  
**Ahmedabad-382 213.India.T:+91 2717 667000**  
**F:+91 2717667050 W: www.otsukapharma.in**  
**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210072	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000716
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	6.33 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	0.33 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	07-Feb-2021 11:45
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 12:40
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 14:29

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210073	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000710
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	07-Feb-2021 11:49
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 12:46
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 14:38

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**F:+91 2717667050 W: www.otsukapharma.in**  
**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210073	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000710
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	7.00 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	0.67 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	07-Feb-2021 11:49
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 12:46
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 14:38

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210074	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000740
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Sanjay.Gamethi	Analyzed On	07-Feb-2021 15:28
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 15:29
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 15:31
Printed by: Ankit.Halari		Printed on: 07-Feb-2021 16:25	
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**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210074	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000740
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	23-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	271.67 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	21.67 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Sanjay.Gamethi	Analyzed On	07-Feb-2021 15:28
Reviewed By	Ankit.Halari	Reviewed On	07-Feb-2021 15:29
Approved By	Sanjay.Patel	Approved On	07-Feb-2021 15:31

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**Quality Control Department Certificate of Analysis  
(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210075	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000750
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	24-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	08-Feb-2021 11:49
Reviewed By	Ankit.Halari	Reviewed On	08-Feb-2021 12:03
Approved By	Sanjay.Patel	Approved On	08-Feb-2021 12:35
Printed by: Ankit.Halari		Printed on: 09-Feb-2021 15:46	
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**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210075	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000750
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	24-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	249.67 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	10.67 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Khushbu.Gajjar	Analyzed On	08-Feb-2021 11:49
Reviewed By	Ankit.Halari	Reviewed On	08-Feb-2021 12:03
Approved By	Sanjay.Patel	Approved On	08-Feb-2021 12:35

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**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210076	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000766
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	25-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

S. No.	TEST	SPECIFICATION	RESULT
1	<b>Description</b>	Clear and colourless liquid	Clear and colourless liquid
2	<b>Extractable Volume</b>		
2.1	<b>For 10.0 ml</b>	Not Less Than 10.0 ml	10.4 ml
3	<b>Acidity or Alkalinity</b>	If the test solution is yellow, it should become red on the addition of 0.1 ml of 0.01M Sodium hydroxide. If the test solution is red, it should become yellow on the addition of 0.15 ml of 0.01M Hydrochloric acid	The test solution is yellow, it is become red on the addition of 0.1 ml of 0.01M Sodium hydroxide
4	<b>Conductivity</b>		
4.1	<b>For less than or equal to 10 ml</b>	Maximum 25 $\mu\text{S}\cdot\text{cm}^{-1}$ (at 25°C $\pm$ 1 °C)	1.1 $\mu\text{S}\cdot\text{cm}^{-1}$
5	<b>Oxidisable substances</b>	Test solution should remain faintly pink	Test solution is remain faintly pink
6	<b>Chlorides</b>		
6.1	<b>For less than or equal to 100 ml</b>	Maximum 0.5 ppm	Less than 0.5 ppm
7	<b>Nitrates</b>	Maximum 0.2 ppm	Less than 0.2 ppm
8	<b>Sulfates</b>	Test solution should not shows change in appearance for at least 1 hour	Test solution is not shows change in appearance for at least 1 hour
9	<b>Aluminium</b>	Maximum 10 ppb	Less than 10 ppb
10	<b>Ammonium</b>		
10.1	<b>For less than 50 ml</b>	Maximum 0.6 ppm	Less than 0.6 ppm
11	<b>Calcium and magnesium</b>	Test solution should produce pure blue colour	Test solution is produce pure blue colour
12	<b>Residue on evaporation</b>		
12.1	<b>For less than or equal to 10 ml</b>	Maximum 0.004%	0.002 %
13	<b>Particulate Contamination: Sub-visible particles</b>		
13.1	<b>For less than or equal to 100 ml volume</b>		

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Bhanu Pratap.Singh	Analyzed On	09-Feb-2021 11:40
Reviewed By	Ankit.Halari	Reviewed On	09-Feb-2021 11:58
Approved By	Chirag.Mistri	Approved On	09-Feb-2021 12:17
<b>Printed by: Ankit.Halari</b>		<b>Printed on: 09-Feb-2021 15:22</b>	
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**(CIN: U24230GJ2012PTC072692)**



**Quality Control Department Certificate of Analysis**  
**(Finished Product)**

**Product: Sterilised Water for Injections BP**

<b>Batch No.</b>	2210076	<b>Batch Size</b>	2000 lit.	<b>A.R. No.</b>	OPIFP21000766
<b>Brand Name</b>	Not Applicable	<b>Mfg. Date</b>	Jan-2021	<b>Exp. Date</b>	Dec-2023
<b>Fill Volume</b>	10 ml	<b>Quantity Sampled</b>	103 Nos.	<b>Sample received on</b>	25-Jan-2021
<b>Reference Specification No.</b>	FP/QC/019b	<b>Effective Date</b>	28-Feb-2018	<b>Standard Test Procedure No.</b>	FT/QC/019b

13.1.1	<b>For greater than or equal to 10 µm</b>	Not More Than 6000 particles per container	238.00 Particles per container
13.1.2	<b>For greater than or equal to 25 µm</b>	Not More Than 600 particles per container	14.33 Particles per container
14	<b>Sterility</b>	It should be sterile	Sterile
15	<b>Bacterial Endotoxins</b>	Less than 0.25 IU/ml	Less than 0.25 IU/ml

**Remarks: APPROVED (Sample Conforms to above Specification)**

Comment(s): Approved

Analyzed By	Bhanu Pratap.Singh	Analyzed On	09-Feb-2021 11:40
Reviewed By	Ankit.Halari	Reviewed On	09-Feb-2021 11:58
Approved By	Chirag.Mistri	Approved On	09-Feb-2021 12:17

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