

Laboratory Haffkine Bio-Pharmaceutical Corporation Limited, Quality Control Laboratory, Acharya Donde Marg, Parel, Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6576

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Validity 29.11.2017 to 28.11.2019

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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**BIOLOGICAL TESTING**

I.	DRUGS & PHARMACEUTICALS			
1.	Vaccines			
a.	Bivalent 1 & 3 Oral Poliomyelitis Vaccine IP (bOPV1 &3)	Sterility Testing	IP 2014 Page No. 59-66	Qualitative
		Potency Testing	I.P. 2014 Page No. 3128-3133	Range for testing $10^{-3.0}$ to $10^{-7.5}$ CCID <sub>50</sub> /dose Limit of Detection is 0.0625 CCID <sub>50</sub> /dose

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**CHEMICAL TESTING**

<b>I.</b>	<b>DRUGS &amp; PHARMACEUTICALS</b>			
<b>1.</b>	<b>Pharmaceutical Raw Materials</b>			
<b>a.</b>	<b>Magnesium Chloride</b>	Acidity	As per IP 2014 (Page 2139, 2140) Ref STP No. QC(C) / PV/ 006, Rev No. 06 Effective Date: 4 <sup>th</sup> Feb. 2013	Qualitative Visual observation
		Alkalinity		
		Identification of Magnesium and chloride		Qualitative
		Appearance of solution		Qualitative
		Arsenic		Qualitative
		Heavy metals		Qualitative
		Sulphates		Qualitative
		Iron		Qualitative
		Assay (Complexometry)		80% to 120%
<b>b.</b>	<b>Potassium Chloride</b>	Acidity	As per IP 2014 (page 2520) Ref STP No. QC(C)/PV/003 Rev No. 06 Effective Date: 1 <sup>st</sup> Feb. 2013	Qualitative Visual observation
		Alkalinity		
		Appearance of solution		Qualitative
		Arsenic		Qualitative
		Heavy Metals		Qualitative
		Iron		Qualitative
		Sulphates		Qualitative
		Barium		Qualitative
<b>c.</b>	<b>Calcium Chloride</b>	Acidity	As per IP 2014 (page 1249) Ref STP No. QC(C)/PV/007 Rev No. 05 Effective Date: 2 <sup>nd</sup> May 2013	Qualitative Visual observation
		Alkalinity		
		Appearance of solution		Qualitative
		Arsenic		Qualitative

**Anuja Anand  
Convenor**

**N. Venkateswaran  
Program Director**

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		Heavy Metals		Qualitative
		Iron		Qualitative
		Sulphates		Qualitative
		Barium		Qualitative
d.	<b>Magnesium Sulphate</b>	Acidity	As per IP 2014 (page 2144) Ref STP No. QC(C)/PV/010 Rev No. 06	Qualitative Visual observation
		Alkalinity	Effective Date: 4 <sup>th</sup> Feb. 2013	Qualitative
		Appearance of solution		Qualitative
		Arsenic		Qualitative
		Heavy Metals		Qualitative
		Iron		Qualitative
		Chlorides		Qualitative
		Assay (Complexometry)		80% to 120%
e.	<b>Potassium Dihydrogen Orthophosphate</b>	Iron	In-house, Ref STP No.:- QC(C)/PV/009 Rev. No. 06 Effective Date: 1 <sup>st</sup> Feb. 2013	Qualitative
		Loss on drying		Not more than 0.1% to 30%
f.	<b>Sodium Bicarbonate</b>	Appearance of solution	As per IP 2014 (Page 2738, 2739)	Qualitative
		Arsenic	Ref STP No. QC(C)/PV/005 Rev No. 06	Qualitative
		Heavy metals	Effective Date: 4 <sup>th</sup> Feb. 2013	Qualitative
		Iron		Qualitative
		Sulphates		Qualitative
		Chlorides		Qualitative
g.	<b>Sodium Metabisulphite</b>	Arsenic	As per IP 2014 (page 2760) Ref STP No. QC(C)/PV/049 Rev No. 03	Qualitative
		Heavy metals	Effective Date: 6 <sup>th</sup> May 2013	Qualitative
		Iron		Qualitative
h.	<b>Phenol Red</b>	Arsenic	In-house, Ref STP No. QC(C)/PV/012 Rev No. 06 Effective Date: 1 <sup>st</sup> Feb. 2013	Qualitative

