3.2.2.6 Reference Standards or Materials

APPENDIX –V

Healthcare Pharmaceuticals Limited
Rajendrapur, Gazipur, Bangladesh

Certificate of Analysis (Working Standard)

Material Name :	Material Code:	Batch No.:
Salbutamol Sulphate	HR 1841	SALM213

Manufacturer Information	In-house Information
Name of the manufacturer: Lusochimica S.P.A	QC Ref. No.: HAP-0354/14
Country of origin: Italy	Date of standardization: 18.11.14
Mfg. Date : 01.07.13	Valid upto: 18.05.16
Retest Date : 31.07.16	

Sl No.	Test Parameters		Specifications	Results
1.0	Description		White or almost white, crystalline powder.	White crystalline powder
2.0	Solubility		Freely soluble in water, practically insoluble or very slightly soluble in ethanol 96% and in methylene chloride.	Correspons
3.0	Identification: 3.1 IR spectrum 3.2 Reaction of Sulphates		3.1 The IR spectrum of the sample corresponds with the standard. 3.2 Must correspond.	3.1) Corresponds 3.2) Corresponds
4.0	Appearance of solution		Solution S is clear and not more intensely coloured than reference solution BY_6	Corresponds
5.0	Optical rotation		- 0.10 ° to + 0.10 °	0.0 °
6.0	Acidity or alkalinity		Must correspond.	Corresponds
7.0	Loss on drying		Not more than 0.5%	0.19%
8.0	Sulphated ash		Not more than 0.1%	0.06%
9.0	Boron		Not more than 50 ppm	< 50 ppm
10.0	Related substances 10.1 Impurity C 10.2 Impurity D 10.3 Impurity F 10.4 Impurity N 10.5 Impurity O 10.6 Each unknown impurity 10.7 Total impurities		 10.1 Not more than 0.2%% 10.2 Not more than 0.3% 10.3 Not more than 0.3% 10.4 Not more than 0.2% 10.5 Not more than 0.2% 10.6 Not more than 0.1% 10.7 Not more than 0.9%	 10.1) Not detected 10.2) Not detected 10.3) Not detected 10.4) Not detected 10.5) Not detected 10.6) Not detected 10.7) Not detected
11.0	Assay	On dried basis	99.0 % to 101.0 %.	100.12 %
		As is basis	----------	99.93 %

Conclusion: This material conforms to the approved Specifications.

Prepared by	Checked by	Approved by
Sr. Officer, QC	Asst. Manager, QC	Manager, QC