



WRS
S8-7

28

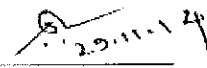
 Healthcare	Healthcare Pharmaceuticals Limited. Rajendrapur, Gazipur, Bangladesh	
	Pulmocare-AF MDI (Salbutamol 100 mcg)	Module 3

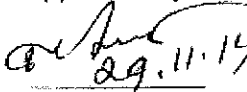
3.2.2.6 Reference Standards or Materials

APPENDIX -V

 Healthcare		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: Lusochemica 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.	Corresponds
3.0	Identification: 3.1 IR spectrum	3.1 The IR spectrum of the sample corresponds with the standard.	3.1) Corresponds
	3.2 Reaction of Sulphates	3.2 Must correspond.	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	10.1 Not more than 0.2% %	10.1) Not detected
	10.2 Impurity D	10.2 Not more than 0.3%	10.2) Not detected
	10.3 Impurity F	10.3 Not more than 0.3%	10.3) Not detected
	10.4 Impurity N	10.4 Not more than 0.2%	10.4) Not detected
	10.5 Impurity O	10.5 Not more than 0.2%	10.5) Not detected
	10.6 Each unknown impurity	10.6 Not more than 0.1%	10.6) Not detected
	10.7 Total impurities	10.7 Not more than 0.9%	10.7) Not detected
11.0	Assay	On dried basis	99.0 % to 101.0 %.
		As is basis	99.93 %

Conclusion: This material conforms to the approved Specifications.


 Prepared by
 Sr. Officer, QC


 Checked by
 Asst. Manager, QC


 Approved by
 Manager, QC