

S8-10

S8-10

Macleods Pharmaceuticals Ltd. Andheri, Mumbai	<b>MACLEODS</b> PHARMACEUTICALS LTD.
Analytical Division (Validation Lab), R and D Center	Annexure - 4
Working Standard Certificate of Analysis	Pg. No.: 1 of 1

Product : SALBUTAMOL SULFATE

Mfg. Name	MELODY HEALTHCARE PVT. LTD.	WS No.	JWS160602800
Batch No.	SS / 14018	RS No.	EPCRS 3.0
Effective Date	30 / 06 / 2016	Valid up to	May - 2017
Storage Condition	Store protected from light.		

Sr. No.	TESTS	SPECIFICATION	RESULTS
1	DESCRIPTION	White or almost white, crystalline powder.	White crystalline powder.
2	IDENTIFICATION		
	By NMR	The NMR spectra of the sample should be concordant with the NMR spectra of Salbutamol Sulphate EP Reference standard.	The NMR spectrum of the sample is concordant with the NMR spectra of Salbutamol Sulphate EP Reference standard.
3	Loss on drying (% w/w)	Not more than 0.5	0.26
4	Assay (% w/w as, $C_{26}H_{34}N_2O_{10}S$ )		
	a) As is basis	NA.	99.8
	b) On dried basis	Not less than 98.0 and not more than 101.0	100.0
Remark: The sample complies with specifications for above mentioned tests & qualified as working standard against EP reference standard Lot No. 3.0			



Prepared by <i>[Signature]</i> 30/06/16	Checked by <i>[Signature]</i> 30/06/16	Approved by <i>[Signature]</i> 30/06/16
---	--	---