

B 20-2  
Macleods Pharmaceuticals Ltd. Andheri, Mumbai  
Analytical Division (Validation Lab), R and D Center  
Certificate of Analysis for Reference Standard

**MACLEODS**

Annexure - 10

Pg. No.: 1 of 1

Name Of The Reference Standard: BUDESONIDE

RS No. RS16070003 Effective Date 04 / 07 / 2016  
Batch No. BP / 1111 / 006 / 430 Valid up-to Oct. - 2017  
Source AARTI INDUSTRIES LIMITED.  
Storage Store in a well-closed, airtight containers. Protect from light.

Sr. No.	TESTS	SPECIFICATION	RESULTS
1	DESCRIPTION	A white or almost white, crystalline powder.	Almost white powder.
2	SPECTRAL IDENTIFICATION		
	By MASS	The characterization of sample by mass spectrophotometry should indicate the same molecular weight as obtained by empirical formula.	Confirms to the structure
3	Loss on drying (% w/w)	Not more than 0.5	0.13
4	Residue on Ignition (% w/w)	-	0.04
5	Related Substances (By HPLC, % w/w)		
	Any other impurity	Not more than 0.5	0.10
	Total impurities	Not more than 1.5	0.41
6	Potency (% w/w, on as is basis, as $C_{25}H_{34}O_6$ )		99.4

Remark: The above data confirms to the structure and is qualified as Reference standard.

Prepared by	Checked by	Approved by
 21/07/16	 21/07/16 OCT 2016	 21/07/16

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