


WRS  
M6-7

APPENDIX -V

		<b>Healthcare Pharmaceuticals Limited</b> <b>Rajendrapur, Gazipur, Bangladesh</b>	
<b>Certificate of Analysis (Working Standard)</b>			
<b>Material Name :</b> <b>Montelukast Sodium</b>		<b>Material Code:</b> <b>HR 1204</b>	<b>Batch No.:</b> <b>MTN(M)/15059</b>
<b>Manufacturer Information</b>		<b>In-house Information</b>	
Name of the manufacturer: Melody Healthcare Pvt. Ltd		QC Ref. No.: HAP-0304/15	
Country of origin: India		Date of standardization: 13.11.2015	
Mfg. Date : 01.08.2015		Valid upto: 13.05.2017	
Exp. Date : 31.07.2018			

Sl No.	Test Parameters	Specifications	Results
1.0	Description	Off-white to yellowish crystalline hygroscopic powder.	Off-white crystalline hygroscopic powder.
2.0	Identification		
	2.1 Infrared absorption	2.1 Infrared spectrum must similar with that of working standard	2.1 Corresponds
	2.2 HPLC	2.2 Retention time of major peak must similar with standard.	2.2 Corresponds
	2.3 Test for sodium	2.3 Must show positive test.	2.3 positive
3.0	Solubility	Freely soluble in water and methanol.	Corresponds
4.0	Water content	Not more than 2.0 %	1.49 %
5.0	Heavy metals	Not more than 20 ppm	< 20 ppm
6.0	Related substances		
	6.1 Single impurity 6.2 Total impurities	6.1 Not more than 0.5 % 6.2 Not more than 1.0 %	6.1 0.25 % 6.2 0.51%
7.0	Assay	On Anhydrous basis	98.0% to 102.0 %
		As is basis	-----
8.0	Residual Solvents		
	8.1 Methanol	8.1 Not more than 3000 ppm	8.1 279 ppm
	8.2 Acetonitrile	8.2 Not more than 410 ppm	8.2 Not detected
	8.3 Methylene chloride	8.3 Not more than 600 ppm	8.3 Not detected
	8.4 n-Hexane	8.4 Not more than 290 ppm	8.4 Not detected
	8.5 Ethyl Acetate	8.5 Not more than 5000 ppm	8.5 Not detected
	8.6 Tetrahydrofuran	8.6 Not more than 720 ppm	8.6 Not detected
	8.7 Cyclohexane	8.7 Not more than 3880 ppm	8.7 Not detected
	8.8 n-Heptane	8.8 Not more than 5000 ppm	8.8 Not detected
	8.9 Toluene	8.9 Not more than 890 ppm	8.9 Not detected
	8.10 Dimethylformamide	8.10 Not more than 880 ppm	8.10 Not detected

Conclusion: This material conforms to the approved Specifications

Prepared by  
Sr. Officer, QC

Checked by  
Sr. Executive, QC

Approved by  
Asst. Manager, QC

FORM No.: FGEQC/168.01

Ref. SOP: GEQC-016

