WRS
M6-6

QUALITY CONTROL DEPARTMENT Glenmark

CERTIFICATE OF ANALYSIS

Product : Montelukast (As Sodium) Tablets 10 mg
Pack Description : 30 tablets packed in a 60 cc HDPE container with 33 mm CRC cap and 1 x 2 g silica gel desiccant.
Generic Name : Montelukast (As Sodium) Tablets
Mfg Date : Sep 2015
Batch Number : 19151915
A. R. Number : 40000028550

Exp Date : Aug 2017
Batch Size : 150,000 Tablets
Market : Africa Region
Date of Report : 06/01/2016

TEST	SPECIFICATION	OBSERVATION
Description	Round, Beige colored, biconvex film coated tablets engraved with 'G' on one side and '392' on other side.	Round, Beige colored, biconvex film coated tablets engraved with 'G' on one side and '392' on other side.
Identification	**A. Montelukast:** **I: By HPLC:** The retention time of the principal peak in the chromatogram of the Sample solution should correspond to that of the Motelukast peak in the chromatogram of the Standard solution in the test for Assay. **II: By UV:** UV absorption spectra of the Sample solution and the Standard solution should exhibit maxima and minima at same wavelengths. **B : For Colour:** **I: For Titanium Dioxide:** Yellow color should develop **II: For ferric oxide:** Red color should develop	Meets the requirement Meets the requirement Meets the requirement Meets the requirement
Uniformity of mass	206.00 mg ± 5 %	202.29 mg
Disintegration time	Not more than 30 minutes	03 minutes 12 seconds
Dissolution (By HPLC)	Not less than 80 % (Q) of the labeled amount of Motelukast is released in 20 minutes. Level: Acceptance criteria **(ph.Eur.2.9.3 as updated)** S1: Each unit is not less than Q + 5 % S2: Average of 12 units (S1 + S2) is equal to or greater than Q and no unit is less than Q – 15 % S3: Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, not more than 2 units are less than Q -15 % and no unit is less than Q – 25 %	1. 97 % 2. 101 % 3. 100 % 4. 100 % 5. 104% 6. 106 % Min: 97 % Max: 106 % Mean: 101 %

COMPILED BY:
NAME: Machindra Kadam
DESIGNATION: Executive
DATE: 06/01/16

CHECKED BY:
NAME: Ganesh Pandit
DESIGNATION: Manager
DATE: 06/01/16

APPROVED BY:
NAME: Smita Belande
DESIGNATION: Asst. manager
DATE: 06/01/16

Glenmark Pharmaceuticals Ltd.
Corporate Office: Glenmark House, HDO-Corporate Building,Wing A, B D Sawant Marg, Chakala, Off Western Express Highway Andheri (E), Mumbai - 400 099. T : 91 22 4018 9999 F: 91 22 4018 9986 www.glenmarkpharma.com
Registered Office: B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026
Manufacturing Site: Plot No S-7, Colvale Industrial Estate, Colvale, Bardez, Goa - 403 513 T: 91 0832 6652 222 F: 91 0832 6652 323

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : Montelukast (As Sodium) Tablets 10 mg
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TEST	SPECIFICATION	OBSERVATION
Uniformity of dosage units (Content uniformity) (By HPLC)	Criteria 1 : Acceptance value NMT 15.0 when determined on 10 dosage units	4.2
	Criteria 2 : Acceptance value NMT 15.0 when determined on 30 dosage units and No dosage units is less than 0.75M and more than 1.25M	
Related substances (By HPLC)	Acid impurity :Not more than 0.15 %w/w	Below LOQ
	Sulphoixde impurity :Not more than 0.5 %w/w	0.11 %w/w
	Keto impurity :Not more than 0.15 %w/w	Below LOQ
	Ester impurity :Not more than 0.15 %w/w	Not Detected
	Dehydrated impurity :Not more than 0.15 %w/w	0.01 %w/w
	Chloro alcohol impurity :Not more than 0.15 %w/w	Not Detected
	Single maximum unknown impurity :Not more than 0.20 %w/w	0.04 %w/w
	Total impurities :Not more than 2.00 %w/w	0.31 %w/w
Assay (By HPLC)	Not less than 9.50 mg and not more than 10.50 mg of Montelukast Sodium equivalent to Montelukast.	10.07 mg
	(95.0 % w/w – 105.0 % w/w of Label claim)	100.7 %w/w
Water content (By KF)	NMT 6.0 % w/w	4.6 %w/w
Test for Microbial Enumeration and Specified Micro organisms	Total aerobic microbial count : NMT 1000 cfu / g	< 10 cfu/g
	Total combined yeast and mold count : NMT 100 cfu / g	< 10 cfu/g
	Absence of specified organisms:	
	Escherichia coli : Absent	Absent

LOQ : Limit Of Quantitation
LOQ for Acid impurity is 0.01 %w/w
LOQ for Keto impurity is 0.01 %w/w
Remark: The referred batch complies as per above referred specification.

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