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CERTIFICATE OF ANALYSIS

PREVICOX 227MG

COMMERCIAL LOT: PRT3621AA

PRESENTATION: BL30CP

FILLED PRODUCT LOT NUMBER: PRT3621A

MANUFACTURING DATE: 11-Jul-2019

EXPIRY DATE: 06/2023

TESTS	THRESHOLDS	RESULTS
APPEARANCE	TAN/BROWN, ROUND, CONVEX, SCORED TABLET ENGRAVED WITH "M" ABOVE THE SCORE, AND "227" BELOW THE SCORE ON ONE SIDE.	TAN/BROWN, ROUND, CONVEX, SCORED TABLET ENGRAVED WITH "M" ABOVE THE SCORE, AND "227" BELOW THE SCORE ON ONE SIDE.
IDENTIFICATION OF FIROCOXIB (TLC)	CONFORMS	CONFORMS
IDENTIFICATION OF FIROCOXIB (HPLC)	CONFORMS	CONFORMS
ASSAY OF FIROCOXIB	$95.0 \leq R \leq 105.0$ % of label claim	100.0 % of label claim
FIROCOXIB RELATED SUBSTANCES	CONFORMS	CONFORMS
FIROCOXIB ANY DEGRADATION PRODUCT (EACH)	$R \leq 0.5$ % (w/w)	<0.5 % (w/w)
FIROCOXIB TOTAL DEGRADATION PRODUCTS	$R \leq 2.0$ % (w/w)	0.1 % (w/w)
MEAN WEIGHT	$900 \leq R \leq 994$ mg.	949 mg.
CONTENT UNIFORMITY	CONFORMS TO PH. EUR. 2.9.6	CONFORMS TO PH. EUR. 2.9.6
DISSOLUTION	CONFORMS (30MIN)	CONFORMS (30MIN)
Q	$R = 75$ %	75 %
AVERAGE (N=6)	$R \geq 80$ %	99 %
IDENTIFICATION OF FERRIC OXIDE	CONFORMS TO IDENTIFICATION TEST FOR FERRIC SALTS (USP191)	CONFORMS TO IDENTIFICATION TEST FOR FERRIC SALTS (USP191)

**WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE COMPETENT
AUTHORITIES**

Signature / Function
Isabelle COUDERT / Quality Control Manager

