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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "204592."

Active Ingredient:	DICLOFENAC
Dosage Form;Route:	CAPSULE;ORAL
Proprietary Name:	ZORVOLEX
Applicant:	IROKO PHARMS LLC
Strength:	18MG
Application Number:	N204592
Product Number:	001
Approval Date:	Oct 18, 2013
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	DICLOFENAC
Dosage Form;Route:	CAPSULE;ORAL
Proprietary Name:	ZORVOLEX
Applicant:	IROKO PHARMS LLC
Strength:	35MG
Application Number:	N204592
Product Number:	002
Approval Date:	Oct 18, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

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Patent and Exclusivity Search Results from query on Appl No 204592 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N204592	001	8679544	Apr 23, 2030		Y		
N204592	001	8999387	Apr 23, 2030			U - 55	
N204592	001	9017721	Apr 23, 2030		Y		

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N204592	001	NP	Oct 18, 2016
N204592	001	I - 692	Aug 22, 2017

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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