



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "078553."

Active Ingredient:	DICLOFENAC SODIUM
Dosage Form;Route:	SOLUTION/DROPS;OPHTHALMIC
Proprietary Name:	DICLOFENAC SODIUM
Applicant:	NEXUS PHARMS
Strength:	0.1%
Application Number:	A078553
Product Number:	001
Approval Date:	Dec 28, 2007
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	AT

Patent and Exclusivity Info for this product: [View](#)

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through September 2015

Patent and Generic Drug Product Data Last Updated November 09, 2015

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U.S. Department of **Health & Human Services**

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