



[FDA Home](#)<sup>3</sup> [Drug Databases](#)<sup>4</sup> [Orange Book](#)<sup>5</sup>

## 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:	<b>AT</b>

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

[Return to Electronic Orange Book Home Page](#)<sup>6</sup>

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

### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](http://www.fda.gov/oc/default.cfm)
6. [../default.cfm](http://www.fda.gov/oc/default.cfm)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies](#)

U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees Science & Research Regulatory Information Safety  
Emergency Preparedness International Programs News & Events Training and Continuing Education  
Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive](#)



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

---

**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)
6. [../default.cfm](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)