

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Patent and Exclusivity for: N216196

Product 001

MITAPIVAT SULFATE (PYRUKYND) TABLET EQ 5MG BASE

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	9193701	10/26/2032			U-3319		03/08/2022
001	9682080	05/03/2032			U-3319		03/08/2022
001	9980961	05/03/2032			U-3319		03/08/2022
001	10632114	05/03/2032			U-3320		03/08/2022
001	11234976	10/11/2038			U-3321		03/08/2022
001	11254652	11/21/2038	DS	DP			03/08/2022
001	11793806	04/12/2033			U-3320		10/31/2023
001	11878049	07/31/2041			U-3782		01/26/2024
001	RE49582	04/11/2035	DS	DP			07/27/2023

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NCE	02/17/2027
001	ODE-392	02/17/2029

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