New Suitability Petitions

6th December 2024

November 2024

RESEARCH DELTA

New Suitability Petition (Nov - 2024)

ABOUT

This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn. Information used for analyses is sourced from:

1. Upcoming Suitability Petitions studied from filing documents.
2. Approved product details from GenUS – Research Delta Advisors.
3. Labels of existing drugs approved by regulatory agencies like USFDA

New Suitability Petition (Nov - 2024)

Suitability Petitions Filed

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1	Pharmobedient Consulting LLC	Filed	01-Oct-24	Cyproheptadine Hydrochloride	PERIACTIN (012649)	Tablet	4mg	Strength	2mg	Link
2		Filed	05-Nov-24	Amlodipine; Hydrochlorothiazide; Valsartan	Premium Content					
3		Filed	05-Nov-24	Omeprazole and Sodium Bicarbonate						

New Suitability Petition (Nov - 2024)

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
4		Filed	05-Nov-24	Triamcinolone Acetonide	Premium Content					
5		Filed	05-Nov-24	Cisatracurium Besylate						
6		Filed	14-Nov-24	Midodrine Hydrochloride						
7.		Filed	16-Nov-24	Dapsone						

New Suitability Petition (Nov - 2024)

Suitability Petitions Accepted/Denied

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1		Denied	07-Nov-24	Lidocaine	Premium Content					
2		Denied	04-Nov-24	Levothyroxine Sodium						
3		Accepted	06-Nov-24	Bupivacaine Hydrochloride						

New Suitability Petition (Nov - 2024)

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
					Premium Content					
4		Accepted	06-Nov-24	Levetiracetam in Sodium Chloride						

New Suitability Petition (Nov - 2024)

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
5		Denied	13-Nov-24	Vasopressin	Premium Content					

New Suitability Petition (Nov - 2024)

Suitability Petitions Approved/Withdrawn

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1		Final Approval	29-Oct-24	Metronidazole	Premium Content					
2		Final Approval	30-Oct-24	Hydromorphone Hydrochloride						

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